WIPO-WTO COLLOQUIUM PAPERS VOLUME 11 (2020) SPECIAL EDITION

WIPO-WTO COLLOQUIUM PAPERS VOLUME 11 (2020)
SPECIAL EDITION

RESEARCH PAPERS FROM THE ALUMNI OF WIPO-WTO COLLOQUIA
FOR TEACHERS OF INTELLECTUAL PROPERTY LAW (2004 – 2019)

Compiled by the WIPO Academy and
the WTO Intellectual Property, Government Procurement and Competition Division
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PREFACE

We are delighted to set before you the 2020 Special Edition of the WIPO-WTO Colloquium Papers, the eleventh in this series.

This peer-reviewed scholarly journal has been published jointly by our two organisations each year since its creation in 2010. It provides a uniquely representative and diverse showcase for emerging IP scholarship from across the globe and the journal aims to stimulate analysis and debate on intellectual property (IP) issues, particularly of interest to developing countries. It offers an avenue for the dissemination of a broader and more geographically diverse and representative range of scholarship than is common in much of the academic literature on IP law and policy. The past ten annual editions, and two regional editions, have included contributions from over 150 scholars from 64 countries around the world.

The past editions of the Colloquium Papers drew together research papers presented for peer review at the WIPO-WTO Colloquium for IP teachers and researchers held annually in Geneva. The onset of the COVID-19 pandemic led to the postponement of the Colloquium scheduled for 2020. However, we were keen to continue to support and recognize scholarship in a year when IP law and policy issues are more topicaly relevant and crucial than ever before.

This led to a call for papers for this 2020 Special Edition of the Colloquium Papers. We invited the colloquium alumni to submit current research papers on three topical themes:

- IP law, policy, and practice in responding to a global health crisis,
- IP, emerging technologies, and the challenges and opportunities of the digital environment, and
- rethinking IP and development: past lessons and new directions for IP law and policy in the framework of the UN Sustainable Development Goals.

We were most impressed by the enthusiastic response to this call for papers and the high-quality research work that the alumni community was able to provide during this challenging period. Our eminent Editorial Board and a diligent editorial team have together ensured the high quality of the papers selected for this edition. Some 22 scholars from five continents have produced wide range of thoughtful and timely analyses of IP policy and legal issues, such as the impact of the digital environment on the IP system, the role and ramifications of IP on access to medicine and public health during the COVID-19 pandemic, sustainable development and the interface between IP and competition policy, the relation of IP to wider policy and governance issues including economic management and the economy, and specific issues relating to enforcement and asset management.

Producing this Special Edition has been a team effort, and we gratefully acknowledge the contributions of all who worked together – in trying circumstances – with dedication and collegiality. We applaud the work of the team of student editors led by Professor Yogesh Pai, and the work of many colleagues within WIPO and the WTO Secretariat – notably, the WIPO Academy and the WTO IPD – who have brought this publication to fruition. We also owe a particular debt of gratitude to the Editorial Board and the editors of the Colloquium Papers. They have been instrumental and indispensable to ensure an engaged, academically sound, and readable source of cutting-edge IP scholarship from an impressive group of emerging scholars from across the developing world.

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ACKNOWLEDGEMENTS

We thank the staff of the WIPO Academy and the WTO Intellectual Property, Government Procurement and Competition Division for their strong support for the project, and in particular to Martha Chikowore and Xiaoping Wu for their work in organizing the Colloquiums annually from 2010 to 2022 and coordinating this publication. Thanks are extended to Yogesh Pai, Jessyca van Weelde, Wardi Zaman, Amit Singhal, Fiona Saju, Garima Mittal and Manika Sharma, for the editorial work conducted. Gao Hang and Jayashree Watal played a key role in the conception and development of the Colloquium initiative. We extend strong appreciation to all for their contributions, and to the many other colleagues not mentioned here, who have done so much to make the Colloquium initiative a success.
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1. COVID-19, TEXT AND DATA MINING AND COPYRIGHT: THE BRAZILIAN CASE *

Allan Rocha de Souza**

ABSTRACT

The COVID-19 pandemic has intensified the importance of text and data mining (TDM) techniques and tools, which are behind several key applications in the fight against SARS-CoV-2. As such, this paper discusses the importance of TDM tools in scientific and technological innovation, as well as how such technologies, which depend heavily on open access and circulation of information, are affected by current copyright protection on databases, especially in developing countries, taking Brazil as an example. To this end, the paper uses bibliographic and documental sources where TDM played a crucial role in research on the pandemic and in combatting disinformation. The work begins with an introduction on TDM, databases, and machine learning technologies, their applications, and their importance for innovation and for scientific and technological innovation. Next, it discusses the nature of database protection via copyright and its implications for the development of data-intensive research and technologies, as well as the role of limitations and exceptions in this process, as illustrated by recent initiatives taken by several countries. The authors conclude that, as it stands, copyright protection of databases creates extraordinary obstacles to the access and use of data for research. In addition, we suggest that the promotion of limitations and exceptions in this area is central to the scientific development and innovation, for reducing the technological gap between countries and, specifically, for the success of the fight against this and other pandemics.

Keywords: copyright, text and data mining, databases, limitations and exceptions, COVID-19.

1. INTRODUCTION

The use of systematic techniques of data collection and analysis as an important element in the construction of scientific knowledge is not a recent phenomenon. In the 18th century, philosopher and theologian Joseph Priestley was already making extensive use of qualitative and quantitative constellations of data and data sets to substantiate his research.1 Similarly, a century later, Ellen Garvey presented the book 'American Slavery As It Is: Testimony of a Thousand Witnesses' as an example of a product resulting from a systematic and meticulous process of collecting, organizing, correlating, and presenting data, following a specific purpose and narrative.2 Likewise, while data has always been seen as an important resource, it was already produced in too large a scale and pace to be used to its full potential, often

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* This paper is part of a large research project on Copyright, Right of Access and Innovation, which has been partially funded by the Brazilian Copyright Institute (IBDautoral), the Arcadia Right to Research in International Copyright Project, and the National Institute of Science and Technology (INCT) Proprietors, together with CAPES, CNPq, and FAPERJ.

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1 Rosenberg D, ‘Data before the Fact’ in Lisa Gitelman, Raw Data is an Oxymoron (The MIT Press 2013) 15-40.

2 Garvey EG, ‘facts and FACTS: Abolitionists’ Database Innovations’ in Lisa Gitelman, Raw Data is an Oxymoron (The MIT Press 2013) 89-102.
requiring the employment of special analysis techniques to obtain results ‘by approximation’ (e.g., filtering, selection, and sampling). The main difference is that today, with the improvement of information and communication technologies, it has become possible to analyze vast amounts of data in real-time and obtain results at previously unseen levels of completeness and granularity.\(^3\)

This scenario presents unique challenges for all countries, especially for developing ones, which tend to lack the necessary regulatory and institutional structures to thoroughly undertake the opportunities for research and innovation at present. In this context, the present study highlights the circumstances in Brazil in the hope of offering insight on the way developing countries might respond and avoid deepening the existing technological and knowledge gap. To this end, the work focuses on three main topics. Firstly, it looks into use and importance of text and data mining (TDM) tools for research and innovation. Secondly, it explores how current copyright-database protection impacts innovation and the struggle against the pandemic. Finally, it discusses the importance of copyright limitations and exceptions in this aspect.

To that end, the present paper begins by bringing forth selected cases from Brazil to illustrate the scientific and social importance of data-intensive technologies in the struggles against the COVID-19 pandemic and the spread of disinformation. It then provides a brief analysis of TDM technologies, their role in developing and operating AI systems, and how access to databases and other source materials are crucial in data analysis. We go on to observe the multi-layered protection afforded by the current copyright law structure over databases and the obstacles it presents to data-intensive innovation. Finally, before concluding, the work stresses the role of copyright limitations and exceptions in TDM and their implementation in developed countries, as well as Brazil’s current position regarding the matter, highlighting the need for developing countries to respond to current technological demands and bridge the divide in worldwide technological innovation.

2. SOCIAL VALUE AND INNOVATION IN DATA USE: EXAMPLES FROM BRAZIL

The possession and use of large amounts of data is currently seen by governments, businesses, and non-commercial entities as a valuable tool in innovation. These resources have been playing an increasingly vital role in several fields such as helping improve decision-making in the development of new technologies and providing support for faster, better, and novel scientific research. In the field of health, data resources have helped introduce improved medical diagnostics and genetic sequencing techniques to better understand various diseases.\(^5\)

In the latter case, Brazil presents a recent example of how data-driven genetic research has been of valuable assistance during the COVID-19 pandemic. As the first cases of the disease were found in the country, a team of researchers from the Adolfo Lutz Institute and the University of São Paulo managed, in just 24 hours, to conduct a sequencing of the samples collected and discern the regions of origin of the virus, by analyzing the history of mutations seen in the organisms found in the samples and combining it with the observation of patient travel records, with the help of genetic data globally shared via the GISAID Platform.\(^5\) The said platform provides royalty-free access to its genetic database while

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creating simple rules for acknowledging the original creators of the data and restricting its usage by third parties.6

Such findings had several practical implications. Firstly, they suggested that the genomes analyzed presented variations in relation to the Chinese strain meaning that, at the time, the virus was already being internally transmitted in Europe, which pointed out possible locations for the implementation of travel restriction measures.7 More importantly, however, was the second implication: according to two of the main researchers of the study, successfully performing these sequencing methods constituted a crucial step towards understanding the main characteristics of the pathogen and how much it mutated – which was essential for developing effective treatments and vaccines.8

Another area where intensive data analysis proves itself increasingly useful is journalism, especially when it comes to fact-checking and combating disinformation. In Brazil, multiple fact-checking and news agencies have made consistent efforts to verify content produced in social media and other outlets. In Brazil, the G1 Portal, owned by Globo – one of the largest media conglomerates in the country – has an entire section dedicated to this activity, called ‘Fato ou Fake’ (‘Fact or Fake’, in Portuguese). There, teams from different forms of media (e.g., radio, television, magazines, and the internet) collaborate in a joint effort to quickly obtain confirmation on content veracity.9

Another Brazilian example is Aos Fatos (‘To the Facts’, in Portuguese), which has a Radar based on algorithms constantly curated by linguists. The software collects publications and posts on several media such as WhatsApp, Facebook, YouTube, and others, looking for keywords that match content which is typically associated with false information on several topics, including those related to the COVID-19 pandemic.10 The agency then verifies the information and grades it from 1 (most unreliable) to 10 (most accurate or reliable).11 The agency also has a bot on Twitter, called Fátima, dedicated to debunking false information on the platform that the agency has already checked.12

Despite all the clear advances, the mere possession of data is insufficient to make such projects viable. This is because raw data when considered in isolation, has no intrinsic meaning or utility in itself since the information that is sought is only revealed when data is adequately contextualized and interpreted.13 In other words, the great value currently attributed to data depends on its being processed by sophisticated collection and analysis tools capable of sifting through all that content and making sense of it.14

3. TEXT AND DATA MINING, AI, AND DATABASES

A crucial part of the above-mentioned process involves the use of text and data mining (TDM), which is defined as the set of techniques dedicated to finding patterns of interest from large amounts of data in a complex process of information collection. The analysis begins by the selection, cleaning, and integration of the relevant data

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14 Dean J (n 3) 4-5.
into a single location and converted into an intelligible format. Then TDM is applied to find correlations and patterns from which a variety of information can be extracted and evaluated by the analyst or by the machine, and then presented to the user.\textsuperscript{15}

With the increase in computing power and the ever-growing production of data seen today, it follows that the amount of data one has to work with usually demands processing power that far exceeds what human beings can achieve, making it unfeasible to operate a large database or mine its contents without proper assistance. The use of artificial intelligence (AI) systems is to assist in these tasks – instead of letting the AI systems perform entirely on their own – is therefore on the increase, through a so-called machine learning process. Machine learning refers to the use of procedures and techniques that enable a machine to process information and, as the name suggests, learn from it, extracting information that will serve as a basis for task-solving and pursuing assigned objectives in a flexible way.\textsuperscript{16}

The use of machine learning has been advocated to address several issues, including the COVID-19 pandemic. Recent publications propose using AI systems in the formulation of predictive models of case growth\textsuperscript{17} as well as for developing new medication\textsuperscript{18} and diagnosing methods for COVID-19, be it through information analysis\textsuperscript{19} or imaging.\textsuperscript{20} In Brazil, Aos Fatos demonstrates that, when vast quantities of data are produced and replicated every second, sorting through what is true or false as well as signaling incorrect content that re-appears regularly, can be quite a challenge for a human team of experts to do consistently. The use of AI algorithms, e.g., the ones operating the Radar has become increasingly important in fact-checking.

On the other hand, while AI and algorithms are generally capable of rapidly processing unimaginable amounts of data, they do not have the same sophistication of thought that humans possess. Machine-learning tools usually require millions of inputs in order to apprehend simple information that an ordinary person would be able to gather in no more than a glance.\textsuperscript{21} The selection and classification of large amounts of data are, therefore, crucial for an algorithm to learn and achieve the intended results of its operation.\textsuperscript{22} Drawing on the work of Russel and Norvig,\textsuperscript{23} it is possible to assert that data is a central element today in the operation and training of AI systems, assuming its position as a key player in data analysis which was once exclusively attributed to the algorithm.

It should be noted, therefore, that the AI itself is but one part of the architecture that makes text and data mining possible. One must also consider several other components such as the servers responsible for searching for relevant data, the knowledge base that informs the parameters to be used in the processing, search and evaluation of patterns, the user interface, and, most importantly, the sources of the data that is collected which is usually stored in databases.\textsuperscript{24}


\textsuperscript{21} Martens B (n 3) 3.


\textsuperscript{23} Russel S, Norvig P, Artificial Intelligence (Regina Célia Simile tr, 3rd ed, Elsevier 2013) 25.

\textsuperscript{24} Han J, Pei J, Kamber M (n 15) 7-9.
In a digital format, databases can be defined as structures created out of information collected from various sources. In practical terms, their purpose is to allow the collected data to be preserved and accessed in a more organized fashion, enabling various pieces of information to be effectively cross-referenced. Such organization includes the creation and storage of metadata and indexes, as well as descriptions of the applications used. These groupings or collections of data and metadata are part of a large system that includes computer software dedicated to creating, processing, and administering these databases – which comprise the database management system (DBMS): the applications that work as an interface between users and the DBMS, and the users themselves.25

Databases play a key role in the architecture of data collection and analysis, serving two primary purposes: first, as points of origin for extraction, query, and operational activities, and secondly, as data warehouses i.e. points of destination where all the data collected from multiple sources are reunited, so that its contents can be adequately modeled and prepared for the upcoming analysis, and the results of data mining can be stored for future cross-referencing.26 The assembly, acquisition, and maintenance of large databases are, therefore, vital components within the framework that is built to make data mining possible.

4. MULTIPLE LAYERS OF PROTECTION: REGULATORY OBSTACLES TO DATA USE

While several organizations largely see the collection and possession of large quantities of data as a crucial asset for improving their activities, it is also true that the process of building and maintaining databases is often “messy”, demanding considerable investment of time, technical resources, and, more importantly, financial and human capital.27 It should, therefore, come as no surprise that certain rights holders regard this as an incentive to seek the limiting or constraint of access to their databases, so as to prevent third parties from using the contents of such databases without authorization.28

This usually stems from the understanding that data, as a set of abstract representations, is non-rival (their consumption does not prevent subsequent use by third parties) and, in theory, ‘non-excludable’ (controlling and restricting their acquisition would be very difficult or impossible).29 This peculiar nature of data would in turn mean that simply copying a database from elsewhere would cost much less than creating a new one, leading to possible underinvestment. Such a concern would lead to the adoption of institutional measures, at national and global levels, aimed at mitigating the issue.30 One such measure was the insertion of databases and their content into an institutional-technical system of intellectual-property rights protection that operates, according to Estelle Derclaye, in three main ‘layers’: copyright, technological protection measures, and anti-circumvention measures.31

At the first layer, since the introduction of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in 1994, collections of data have been globally granted, alongside computer programs, the status of protected works under copyright law, and any protected works contained inside these repositories retain their protection as well. Even before that, Brazil already had a similar provision for databases at the time under the Brazilian Copyright Act of 1998 (Article 7, XIII

25 Kroenke DM, et al. (n 15) 3-32.
26 Han J, Pei J, Kamber M (n 15); Kroenke et al. (n 15) 492-494; Kelleher J, Tierney B (n 15) 8-9.
27 Dean J (n 3) 12.
31 Derclaye E (n 30) 196.
Here, one specific consideration must be made: in all cases mentioned above, copyright law only applies to databases when their content is selected or arranged in a manner that constitutes intellectual work. In other words, they must be sufficiently new or ‘distinguishable’, bringing something so original that they could not be mistaken for other works of the same genre. This is not the case with most digital databases, which usually serve to store content automatically, following standardized methods of collection and organization of content. There are three reasons for this: first, because the value of that data comes from the inferences drawn from it, not from its arrangement (as seen earlier); second, because the selection criteria for data collection is often purely quantitative ('the more, the better'), and lastly, because it is natural that such databases prefer to adopt specific storage and organization standards for reasons of accessibility and compatibility.

Regardless, the protection afforded by copyright law to databases has two implications: first, while many databases will not satisfy the legal criteria for protection, some will – and that means accessing and using their content will require previous and express authorization from the rights holders, even if the said content is comprised entirely of unprotected material (such as public information or just raw data). Secondly, as stated above, protected works inside a database retain their respective rights independently which means that using them still requires permission from the owner of each piece. If Lawrence Lessig had indicated the inherent difficulty of locating and negotiating with every rights holder in a simple collection of films featuring one artist, this would elevate to impossibly high levels once we consider that data analysis usually covers an enormous quantity of data – and, quite possibly, of protected works and owners as well. Last but not the least, substantial amounts of the data, including metadata, are either public, of public interest or outside the purview of intellectual property (IP). That being said, the reality of information technology has led to efforts in creating systems dedicated to controlling and restricting, by technical means, unauthorized access, and usage of protected works. In other words, we have, at the second layer of protection, the implementation of technological protection measures (TPM), dedicated to preventing copyright infringement rather than relying on the law to penalize it. In databases, the DBMS, being responsible for managing the database and its access, could technically serve this role.

While the above can be effective in avoiding infringement, one must be critical of the abusive use of such tools. From the imposition of abusive clauses or the restriction on access and use of non-protected data or works in the public domain to the installation of spyware, it has already been pointed out that such mechanisms often use the architecture of databases to control access and use of protected content beyond the scope that would normally be afforded by copyright law, restricting legitimate uses of lawfully acquired material.

Regardless, technical barriers are not invulnerable as anyone with sufficient knowledge and resources can surpass them. And this is where the third layer of

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24 Lessig L, Free Culture: How Big media uses technology and the law to lock down culture and control creativity (The Penguin Press 2004) 103.
protection, according to Derclaye, operates in the form of anti-circumvention measures. These measures are established by copyright law to bar the suppression, modification, or destruction of technological protection devices that seek to prevent infringement, as well as the production, sale, and distribution of devices that may be used for such purposes.\(^\text{37}\) An example can be found in Article 107 of the Brazilian Copyright Act, which outlaws the alteration, suppression, modification, or destruction of technical devices put in place to avoid unlawful copying of a work.

Despite being put in place by copyright law, anti-circumvention measures belong to a third layer because the protection they offer is not aimed at databases or software themselves but at the technological devices that prevent unauthorized access or copying of protected works. Therefore, they would constitute a kind of ‘paracopyright’, which operates outside the core object of copyright, but still within the system.\(^\text{38}\) Moreover, in countries such as Brazil, there is no provision specifying that copyright limitations and exceptions override this clause, thus creating the possibility for these measures to override user rights effectively granted by law.

5. LIMITATIONS AND EXCEPTIONS FOR RESEARCH AND INNOVATION: BRIDGING (OR DEEPENING) THE DIVIDE

When considered together, these layers of protection become especially problematic once we consider that TDM typically require the copying, extraction, and modification of existing content in third-party databases, implying that such acts would require prior authorization from the owners. Consequently, there is a potential danger of violation of reproduction rights, especially if a substantial part of the collection is copied which is quite common since many TDM processes aim to obtain as much relevant information as possible. On the other hand, if we are dealing with an original database, both the reproduction of relevant material and the discarding of content irrelevant to the analysis may also constitute copyright infringement, as they may replicate or alter the selection or arrangement of the database from which the material was extracted, implying infringement of both the right to reproduce and adapt the work.\(^\text{39}\)

According to José de Oliveira Ascensão, all these are intensified by the reduction of copyright limitations, which exist precisely to balance the exclusivity resulting from the copyright system due to public interest \(^\text{40}\) and to reconcile it with other equally important fundamental rights.\(^\text{41}\) This is evinced by the fact that the extension of copyright to databases, at least in Brazil, was not followed by a limitation stipulating the conditions under which the access and use of databases and their contents would be allowed, even if only for scientific research purposes. This becomes particularly egregious if one considers that TDM generally does not interfere with the normal economic exploitation of a copyrighted work as it mainly involves using archives as a source for data analysis. There is no use of the expression of these works – which is the actual object of copyright protection, as the idea/expression distinction dictates.\(^\text{42}\)

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\(^{37}\) Derclaye E (n 30).


\(^{40}\) de Oliveira Ascensão J, Direito da Internet e da sociedade da informação: estudos (Forense 2002) 33, 136.


It is also important to note that, while some projects can rely on relatively open databases widely adopted by fellow researchers (such as in the COVID-19 genetic sequencing case) or do possess human and financial resources to carry out fast and intensive data-gathering work on their own (such as ‘Fato ou Fake’ and ‘Aos Fatos’), not all research projects fall under these two possibilities. In fact, in the academic field, it is common to find journals or other means of scientific communication that sometimes impose prohibitive fees for access to the texts they disseminate, often leading to the necessity to be affiliated to some institution capable of licensing multiple publishers.

In such a scenario, researchers whose investigation work may require the use of copyrighted material are faced with three options: (1) to avoid using protected material altogether, thus limiting the available material for analysis and possibly compromising the effectiveness, quality, or even the viability of the research; (2) to seek authorization from the rights holders—which is becoming increasingly unfeasible, as previously noted; or (3) to use protected material without authorization and subject to eventual litigation, bringing potentially prohibitive financial and temporal costs.

The result is an institutional framework that generates insecurity for users and imposes bureaucratic barriers to legitimate access to databases and the use of their content, undermining data collection and analysis, now so rooted in the process of scientific research and of innovation in general. Considering such burden, the final decision may well be not to engage in the research at all.

With that in mind, proposals for creating copyright limitations and exceptions for TDM, or at least regulatory measures dedicated to enabling their use in some capacity, have been tabled and implemented in several industrialized countries over the last two decades. In the United States, for instance, reproduction and use of copyrighted material for text and data mining and data analysis have already been considered fair use, as seen in *Kelly v. Arriba Soft Corp, Authors Guild, Inc. v. Hathi Trust* and in *Authors Guild, Inc. v. Google, Inc. (Google Books)*.

Meanwhile, in Europe, there have been discussions regarding the creation of a regulation applied to the European Union as a whole. In the steps leading to the creation of a new Copyright Directive, academic institutions such as the European Copyright Society and the Max Planck Institute have tabled proposals of their own regarding the use of copyrighted materials for TDM, including situations in which lawful access to the data is not possible or for commercial purposes. Daniel Gervais went so far as to take limitations and exceptions already in place for TDM in the United Kingdom, France, and Germany as examples for special topics to be considered when crafting a regulation of that sort, such as the rights involved, the nature of use, the ability to forfeit the law via contract and position regarding anti-circumvention measures, among others.

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44 Kelly v. Arriba Soft Corp., 336 F.3d 811, 822 (9th Cir. 2003); Authors Guild, Inc. v. HathiTrust, 755 F.3d 87, 90 (2d Cir. 2014); Authors Guild, Inc. v. Google, Inc. (Google Books), 804 F.3d 202 (2d. Cir. 2015); Carroll MW, ‘Copyright and the Progress of Science: Why Text and Data Mining is Lawful’ (2020) Washington College of Law Research Paper No. 2020-15.
In the end, the Directive 2019/790 for the Digital Single Market brought about two new TDM limitations and exceptions to be implemented by their Members: Article 3 is specific for the use of lawfully accessed materials for scientific research and preservation, while Article 4 is a blanket regulation allowing text and data mining for any purpose, provided that such right was not already reserved by the rightsholders. Meanwhile, the Japanese Copyright Act, which, in 2009, had previously included a TDM provision in the form of Article 47-7, has incorporated, in 2018, several articles concerning the possibility of reproducing protected works for any non-expressive purpose, including computational data analysis – more specifically, in Articles 30-4, 47-4 and 47-5.

6. BRIDGING (OR DEEPENING) THE DIVIDE

In Brazil, as very likely in many other developing countries, the situation is different from what we observe in developed countries. Although Brazil’s National Plan for the Internet of Things in 2019 establishes the free flow of data as one of its main foundations (Article 1), no regulation aiming at promoting such a principle has been implemented so far. That same year, while the government opens a public consultation for Copyright reform with special mention to the need to adapt to AI and data-intensive technologies, the call remarkably focuses on raising user awareness about online copyright infringement, but brings nothing regarding the subject.

It was only in 2021 that the Brazilian Strategy of AI recognized the need for discussing the implementation of a TDM exception in an official capacity. While there are still no effective regulations in this regard, Bill No. 21/2020, which seeks to regulate AI operation in Brazil and is currently under discussion at the Brazilian Senate, features one particular provision in this direction: its Article 5, VIII states that the usage of data, databases or protected texts in order to train AI systems shall not constitute copyright infringement, as long as it does not interfere with normal exploitation of the work.

Discussions of this nature are becoming increasingly imperative not only in Brazil, but in low and middle-income countries in general, especially considering the regulatory divide in copyright balance pointed out by Sean Flynn and Michael Palmedo: while all countries seem to have more open and user-friendly copyright regulations over time, developing nations seem to be stuck in a 30-year gap in comparison to more developed countries. As regards TDM for research purposes or innovation, the pattern seems to be reinforced, as most countries with TDM limitations and exceptions (or with a broad research clause that is open to such techniques) are either located in the Global North or largely industrialized. Most developing nations do not have such openness: in South America, for instance, Ecuador stands out as the only country in the region with a clear TDM

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68 Act No. 48 of 6 May 1970 (Copyright Act) Amendment of Law No. 73 of 2009 (Japan)
69 Act No. 48 of 6 May 1970 (Copyright Act) Amendment of Act No. 30 of 2018 (Japan)

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52 Portaria GM, No. 4.617, of 6 de abril de 2021. Instituto a Estratégia Brasileira de Inteligência Artificial e seus eixos temáticos (Diário Oficial do União 2021) (Brazil).
exception in the form of Article 212, No. 9, VIII of the 'Código Orgánico de la Economía Social de los Conocimientos, Creatividad e Innovación', which allows libraries and archives to perform text mining in some circumstances. A few other countries in the region do have limitations that are at least conducive to text and data mining, such as Article 71(O) of the Chilean Copyright Law and Article 16(a) of Colombia’s Law No. 1915/2018 – both of which allow transitory reproductions of works. Other countries in the region, such as Brazil, Argentina, and Uruguay, keep very restrictive limitation regimes, especially when it comes to scientific and technological research.

Therefore, it is imperative to reconsider the current state of many copyright regimes, especially in the Global South. While many countries have taken decisive steps in recent years to ensure that national IP regulations can better act as enablers of innovation, most of the reforms seen up to this point seem to be concentrated in developed nations. If the Brazilian cases observed in this study are of any indication, however, not only do developing countries struggle with the same issues but they can also bring important contributions to the resolution of such problems. Bridging the institutional divide in openness between North and South is, thus, of the utmost importance if one seeks to truly obtain satisfactory results in the combat against several global crises – whether they be a pandemic of the body or of the mind.

7. CONCLUSIONS

This paper focused on the use and importance of TDM tools for research and innovation and how current copyright database protection and corresponding limitations and exceptions impact on innovation and the struggle against the pandemic. The paper looked at the Brazilian experience, namely its early research efforts against COVID-19 and national initiatives against disinformation so as to stress the importance of said technologies for developing countries and the necessity to address TDM regulations beyond the context of developed nations.

From the outset, the paper presented some key applications of data-intensive technologies and their social value, particularly in Brazil, where data-driven genetic research has provided valuable assistance during the COVID-19 pandemic, having also been employed in fact-checking and in combatting disinformation. The second part addressed the content of Text and Data Mining and the role of AI in supporting the processing of vast amounts of data to find patterns of interest and to extract knowledge out of relational or non-relational resource pools, as well as the effective embeddedness of AI technologies in TDM. We went on to focus on the insertion of databases and their content into an institutional-technical system of IP rights protection that operates, according to Estelle Derclaye, in three main 'layers': copyright, technological protection measures, and anti-circumvention measures. The copyright protection granted to databases, the risk of facing infringement claims in countries where there are no suitable L&Es in copyright law, and the importance of enabling access to data to conduct scientific research was then examined. We stress that it is imperative to reconsider the current state of many copyright regimes, especially in the Global South, considering that most of the reforms seen up to this point seem to be concentrated in developed nations.

The analysis concludes that, in a context where scientific and journalistic activity increasingly depends on access to data to flourish and provide better results, the Brazilian cases have provided strong evidence not only of the role of data-intensive activities in the resolution of globalized problems, but also of the importance of an institutional and regulatory environment that works as an enabler and promoter of research and innovation. Allowing such a gap to continue means more than just imposing renewed obstacles to development; it also means prolonging health crises and creating difficulties for the maintenance
of healthy political discourse and the improvement of social welfare throughout the world.

As a final suggestion, we take the opportunity to advise developing countries to incorporate, as soon as possible, friendlier and more expansive limitations and exceptions to copyright that could ensure the proper balance under current circumstances as well as promote one’s ability to innovate, such as permitted uses for research purposes and TDM activities. Furthermore, as has become clear, this is not simply a local and national problem, but an international one, as such activities are increasingly carried under cross-border cooperation. This issue may call for international agencies such as World Intellectual Property Organization to take a fresh look into the need to promote worldwide research and text and data mining limitations and exceptions, including by means of discussion and adoption of legal instruments, model legislation and guidance documents.

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2. TRADEMARK INFRINGEMENTS: CRIMINAL PROCEEDINGS IN BULGARIA

Plamena Popova*

**ABSTRACT**

Article 61 of the TRIPS Agreement requires the Members to provide for criminal procedures at least in cases of wilful trademark counterfeiting. The Bulgarian legislative framework establishes criminal procedures that exceed the above-required minimum under Article 61 of the TRIPS Agreement.

Initiation of criminal proceedings is a frequently chosen and applied as civil or administrative legal remedy for the protection of trademark rights in comparison to the other available procedures, especially in relation to significant infringement cases. Criminal procedures have proven to be a reliable and effective way for the protection of trademark in Bulgaria. Why?

This paper aims to provide an overview of the main elements and specifics of the legal framework regarding criminal proceedings in the area of trademark protection in the Republic of Bulgaria. A general overview of the legal framework and practice/case law of the competent authorities is a key point of the analysis of IP protection and enforcement in Bulgaria.

The paper further discusses specific issues that criminal proceedings in Bulgaria present, as well as the current trends and issues which may be observed in Bulgaria. The analysis of the application of criminal procedures in the paper follows the structure and elements of Article 61 of the TRIPS Agreement.

Finally, the paper attempts to outline a model (based on the current state analysis of the criminal procedures in the Republic of Bulgaria) for a high standard for the protection of trademark rights.

*Keywords: criminal proceedings, IP enforcement, trademark counterfeiting, Republic of Bulgaria.*

1. INTRODUCTION

Trademark owners are entitled to act against unauthorised uses of their protected trademarks. States or at least the World Trade Organization (WTO) Members, are bound to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)\(^1\) to establish criminal procedures along with other legal remedies for enforcement of intellectual property (IP) rights against unauthorised use of trademarks to various extents.

The negotiations round that brought the WTO into existence, namely the Uruguay Round of 1986-1994, has provided a forum for the tensions to be observed from perspectives of IP, among others.\(^2\) The TRIPS negotiations and the agreement that followed are an expression of the international agenda for stronger protection of IP rights.\(^3\) The TRIPS Agreement came into effect along with the WTO establishment itself as a part of the Uruguay treaties

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\(^2\) Clift C, ’Why IPR issues were brought to GATT: a historical perspective on the origins of TRIPS’ in Research Handbook on the Protection of Intellectual Property under WTO Rules, Correa CM (eds), Edward Elgar Publishing Inc. (UK 2010). Among others, the author argues that during the 19th century less advanced countries spent many efforts to achieve access to technological advancements and indeed the hope for easier access was one of the reasons to enter TRIPS.

As is already well-known, the starting point (and one of the primary goals) of the TRIPS Agreement is to fight against counterfeit products, i.e., anticounterfeiting issues. Among others, the TRIPS Agreement sets the baseline and minimum standard to be covered by WTO Members in relation to criminal prosecution and criminal procedures for protection and enforcement of IP rights.

The Republic of Bulgaria has introduced a criminal regime for the prosecution of trademark infringements that surpasses the minimum standard set by the TRIPS Agreement. Criminal proceedings can be considered reliable ways for effective protection of the exclusive rights of Trademark Owners. The paper aims to review the current developments of criminal prosecution on trademark infringements in the Republic of Bulgaria to outline some of the specific issues observed, and to analyse/compare its (of criminal procedures as a legal remedy) role to other legal remedies provided for the protection of IP rights from the perspective of the TRIPS legal framework.

2. ON CRIMINALISATION OF IP INFRINGEMENTS – INTERNATIONAL OBLIGATION AND NATIONAL APPLICATION

The criminalisation of IP infringements is a concept recognised at international level through the TRIPS Agreement, setting minimum requirements regarding criminal liability. The criminalisation of trademark counterfeiting and copyright piracy was originally recognised in common law countries (the US and UK) – already at the end of the nineteenth and beginning of the twentieth century. Though IP rights are private rights, criminal prosecution of its infringements implies the presence of negative effects on public interest, such as the wider legal systems, the interests of consumers, public safety, and health etc. Accordingly, the criminal enforcement of IP rights becomes a matter of criminal and public law.

The TRIPS Agreement, in particular, provides an obligation for all its Members to introduce criminal liability in relation to certain IP infringements. Article 61 of the TRIPS Agreement provides that: Members shall provide for criminal procedures and penalties to be applied at least in cases of wilful trademark counterfeiting or copyright piracy on a commercial scale. Members may provide for criminal procedures and penalties to be applied in other cases of infringement of intellectual property rights, in particular, where they are committed wilfully and on a commercial scale.

As it may be noted, the minimum standard set by Article 61 of the TRIPS Agreement requires the introduction of criminal liability in cases of:

i) Wilful – in other words, where the intent is present by the infringer;

ii) Trademark counterfeiting or copyright piracy;

4 Watal J, ‘Developing Countries and the Protection of Intellectual Property Rights, Columbia Studies in WTO Law and Policy’ (2007) Cambridge University Press. Watal raises the question “Why Did Developing Countries Accept the TRIPS Agreement in the Uruguay Round?” and finds that one of the main reasons was the drive for a successful outcome of the Uruguay Round as a whole and the achievement of the treaties package.


6 Ibid. A justification of providing criminal measures to act against certain types of IP infringements is as follow: Civil remedies make sense if the infringer can be identified readily, will comply with injunctions or interdicts, and is able to pay damages and (where applicable) legal costs. Honest trade competitors may infringe IP rights but they do not counterfeit. Counterfeiters tend to fall in a different class. They are not ‘honest’ competitors and civil remedies are, in their case, in the ordinary course of events ineffective.

7 Ibid. The TRIPS Agreement includes a definition regarding the content of ‘trademark infringement’ in its footnote 14 (a): ‘For the purposes of this Agreement: counterfeit trademark goods shall mean any goods, including packaging, bearing without authorization a trademark which is identical to the trademark validly registered in respect of such goods, or which cannot be distinguished in its essential aspects from such a trademark, and which thereby infringes the rights of the owner of the trademark in question under the law of the country of importation’.

8 The TRIPS Agreement includes a definition regarding the content of ‘copyright piracy’ in its footnote 14 (b): ‘For the purposes of this Agreement: (b) “pirated copyright goods” shall mean any goods which are copies made without the consent of the right holder or person duly authorized by the right holder in the country of production and which are made directly or indirectly from an article where the making of that copy
iii) On a commercial scale\textsuperscript{10}.

Because the Republic of Bulgaria is a signatory to the TRIPS Agreement, criminal sanctions for IP infringements have been introduced in its national legislation. Notably, the ‘copyright piracy’ is criminalised via a specific provision, i.e., Article 172a\textsuperscript{11} of the Criminal Code of Republic of Bulgaria as of 1995. The ‘trademark counterfeiting’ (along with other infringements on industrial property rights such as industrial designs, geographical indications etc.) is criminalised via specific provision, i.e., Article 172b\textsuperscript{12} of the Criminal Code of Republic of Bulgaria as of 2006.

3. ARTICLE 172b OF CRIMINAL CODE – TRADEMARK COUNTERFEITING

The aim of this paper is to review and analyse the application of criminal measures in cases of trademark infringement and counterfeiting. Trademark infringement as a crime under Article 172b is defined as:

Anyone who, without consent from the owner of the exclusive right thereupon, makes use of the commercial activity of a trademark, industrial design, a variety of plant or race of animal, making the object of said exclusive right, or makes use of a geographical indication or a counterfeit thereof without a legal justification, shall be punished by deprivation of liberty of up to five years and a fine of up to BGN 5,000.

On intent/wilfulness – The Bulgarian Criminal Code and the Bulgarian criminal law, in general, recognises two types of guilt (i.e., the subjective element by the perpetrator towards the act of crime) – intent and negligence\textsuperscript{13}. The Criminal Code further (Article 11, para. 4) specifies the acts which are committed by negligence and punished only when specifically mentioned in the law. This means (as no specification regarding negligence as a form of guilt is given in Article 172b of the Criminal Code) that trademark counterfeiting is punishable when committed intentionally. The latter is in line and corresponds fully with the TRIPS’ requirement, as stipulated in Article 61, on trademark counterfeiting – to be criminally prosecuted when performed wilfully.

\textsuperscript{10}In this regard, the Panel in the WTO DS 362 (China-IPR) found that the term ‘commercial scale’ in Article 61 meant ‘the magnitude or extent of typical or usual commercial activity with respect to a given product in a given market’.

\textsuperscript{11}Article 172a (New, SG No. 50/1995).

\textsuperscript{12}Article 172b (New, SG No. 75/2006).

\textsuperscript{13}Article 11, para. 1 of the Criminal Code provides that ‘An act dangerous to society shall be considered culpably committed where it is intentional or committed through negligence.’

\textsuperscript{14}Acts committed through negligence shall be punishable only in the cases provided by law.
The objective elements that should be established (proved) under the above text of Article 172b cover:

1. affixing of the mark on the goods or on their packaging;
2. offering of the goods with this mark for sale or putting them on the market, or storing or holding them for these purposes, as well as offering or providing services with this sign;
3. the import or export of the goods with this sign;
4. the use of the mark as a trade or company name or as part of trade or company name;
5. the use of the mark in commercial papers and in advertisements;
6. the use of the sign in comparative advertising in a way, which is in violation of Article 34 of the Competition Protection Act.

On Lack of Consent/Authorisation – Referral and interpretation of the first element – lack of consent – is not necessary as long as there is no ambiguity. Lack of consent by the trademark owner means exactly that – lack of consent. Counterfeit, non-original goods are those on which the mark is placed without the consent of the Trademark Owner – i.e., the right has been violated in the first and main form of use – the affixing of the mark and the production of the goods in question. The Trademark Owner (or his representative) is the sole person/entity that may make a statement regarding this element of the factual composition of Article 172b of the Criminal Code – whether there is consent or not for a certain mark to be used. The ’lack of consent’ element as stipulated in Article 172b of the Criminal Code corresponds fully with the specification given in the TRIPS Agreement in this regard ’without authorisation’.15

On Use in Commercial Activity – ’Use in commercial activity’ is a concept interpreted in light of the Law on Trademarks and Geographical Indications, where it is provided with its legal definition, namely Article 13, para. 2 of the LMGI defines the use in the course of trade as follows:

15 Footnote 14, TRIPS Agreement – definition of ‘counterfeit trademark goods’.

16 Therefore, a hypothesis is possible in which the goods are original (i.e., produced with the consent of the right holder), but their subsequent use (placing on the market, offering for sale, etc.) is done without his consent.
[...] a sign that is capable of distinguishing the goods or services of a person from those of other persons.\textsuperscript{17}

Furthermore, the LMGI defines the scope of the exclusive rights conferred by a trademark in Article 13, para. 1, which states that:

Trademark rights include the right of the trademark proprietor to use it, to dispose of it and to forbid third parties from using in commercial activity without his consent any sign that:

1. is identical to the mark, for goods or services identical to those that the mark is registered for;
2. due to its identity or similarity with the mark and the identity or similarity of the goods and services designated by the mark and the sign, there exists a likelihood of confusion among consumers, including the risk of association between the sign and the mark.

Thus, the criminal prosecution in the Republic of Bulgaria follows two hypotheses under the meaning of the LMGI. The hypothesis of Article 13, para. 1, item 1 of the LMGI explicitly prohibits third parties from using identical signs with respect to identical goods/services without the consent of the trademark owner. In this case, the presence of an identical (to a trademark) sign on identical goods is sufficient for application of the provision (it is not necessary to prove the ‘likelihood of confusion of consumers’, which represent a legal question that is part of the next hypothesis – of Article 13, para. 2, LMGI). The presence of a sign that is not identical does not in itself mean that there is no infringement on a trademark – as it may concern the hypothesis of similar signs used regarding similar/identical goods/services, where the likelihood of confusion is presented (hypothesis of Article 13, para. 2, LMGI).

As it may be noted, the scope of criminal prosecution (sanctions) under Bulgarian legislation is wider than that specified in the TRIPS Agreement, which points that:

\textbf{counterfeit trademark goods’ shall mean any goods, including packaging bearing without authorisation a trademark, which is \textit{identical} to the trademark validly registered in respect of such goods, or which cannot be distinguished in its essential aspects from such a trademark [...]}.\textsuperscript{18}

The Bulgarian criminal provisions on trademark infringements cover trademarks registered for goods as well as for services. Furthermore, it covers the use not only of identical but also of similar signs, whereas the extent of similarity with the registered trademarks may vary.

To summarise – criminal liability regarding trademark infringement under Bulgarian legislation surpasses the minimum standard set in the TRIPS Agreement.

4. APPLICATION OF ARTICLE 172B OF CRIMINAL CODE – SPECIFIC ISSUES

The development of criminal proceedings in relation to trademark counterfeiting and infringements demonstrates specific issues, part of which will be subject of review and analysis in the current paragraph.

A. REGARDING TRADEMARKS

As not only unauthorised use of identical but also of similar registered trademark signs are criminalised under

\textsuperscript{17} LMGI Article 9, para. 1.
\textsuperscript{18} The TRIPS Agreement includes a definition regarding the content of ‘trademark infringement’ in its footnote 14(a).
Bulgarian legislation, some specific issues may arise in this regard.

a) On Expert Opinions

It is a common practice for competent authorities (in pre-court criminal proceedings as well as in the court stage) to rely on expert opinions in the frames of criminal proceedings.

The performance of expert examination and the presentation of an expert opinion in cases (whether civil, criminal, or administrative) requires the need to apply special knowledge to clarify certain issues in the case. Prof. Stalev points out very precisely that the need for the appointment of experts as it 'follows from the impossibility of the court to be omniscient'. Special knowledge can relate to the field of science, technology, arts, crafts, various professions, etc. In criminal proceedings (as well as in civil and administrative proceedings), the need for special knowledge not possessed by the competent authority to resolve the case leads to the appointment of experts. Experts have precisely that special knowledge which the competent authority lacks. The expert's conclusion on the task assigned is referred to as an expert opinion, and the same should assist the competent authority in revealing the truth in a specific case. Expert examinations are, in essence, the establishment of facts and factual issues of essential importance for the case, for which special knowledge is needed, which the competent authority lacks. Undoubtedly, expert examination and opinions are not necessary to establish legal issues for which the competent authority (depending on the stage of the criminal proceedings) has all the necessary legal knowledge. However, in cases of trademark counterfeiting, the limits to which an appointed expert may provide (bound the competent authority) to its conclusions that are blurred (see also p. 4.3. below regarding establishing the fact of 'lack of consent' by the Trademark owner). It is clear that the issues on similarity/identity between the compared signs and trademarks, respectively between the goods/services, are factual questions – and, as such, may be subject to expert opinions. On the other hand, the question of the 'likelihood of confusion' of the public is a legal question. For establishing its presence is necessary legal, rather than special, knowledge, so no expert opinion is required as long as the competent authority (in the pre-court phase of criminal proceedings – the prosecutor, in the court phase – the competent criminal court) is presumed to possess legal knowledge. Given the above, expert opinions that also provide replies on legal issues (as the presence or lack of likelihood of confusion) though common, is not correct from a legal point of view. As a whole, expert opinions may be useful in criminal proceedings when special knowledge is necessary with regard to factual questions, but not when legal issues are reviewed and should not represent a mandatory element of a criminal investigation and prosecution.

b) Defences by the Infringers

An interesting approach may be noticed in the past years by some infringers to defend themselves from the unauthorised use of trademarks. This approach may be generalised as an objection based on their own trademarks or industrial designs.

In some cases, the infringer attempts to rely on the use of own trademark (design) and such cases have created a distorted concept of 'co-branding' (distorted as the use of at least one of the applied trademarks is not authorised).

The 'co-branding' hypothesis refers to placing two (or more) trademarks on one product. Numerous cases are known in which two trademarks are affixed on one product at the same time, which are respectively valid and registered, with the consent of the respective

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19 Сталев, Ж. 'Българско гражданско процедурно право' (2008) стр. 312 и сл.
trademark owners. Hyllier and Tikoo define co-branding as follows:

the practice of double branding products in which the product receives more than one brand name.

Leuthesser defines co-branding as the combination of two or more well-known brands (brands) in one product and as a strategy that is an alternative to the development of new products. Co-branding can also be used for an already developed product by achieving an association with a person/company other than the main manufacturer. It is possible for a new product to be branded and therefore associated with more than one trademark and manufacturer, respectively. In all cases, the consumers and the public would associate the product on which their trademarks are affixed with the two companies holding the relevant exclusive rights, and not just with one of them. Co-branding, the sharing of trademarks owned by different entities, does not prevent the performance of the main functions of the trademarks when the consent of the trademark owners is present.

Bouten defines co-branding as a marketing strategy that allows a brand to innovate and establish itself in the market with the support of another partner brand. This strategy is used by a number of trademark owners in modern markets and is known to the public and consumers.

Thus, affixing of an infringing sign may not be validated/justified by placing a trademark owned by the infringer on the product in question. Yet, such a defensive strategy is used often by infringers, including in the course of criminal proceedings. The prohibition on using trademarks without the consent of their owner is valid, even when the infringing goods are placed with another trademark. Co-branding is a commonly used trading strategy and thus, to assume that in the case of co-branding, there is no need to receive consent from one of the trademark owners is legally absurd. It would mean that any infringer could apply for and register ‘own trademarks and use them on a product together with well-known brands to claim that such use is lawful – without the need for the consent of the other trademark owner for such use.

However, Bulgarian courts maintain the firm view that co-branding does not constitute a valid ground for the use of another trademark(s) without consent for such use by its owner. As stated in Definition No. 493784 of 25 September 2018 under criminal case No 15259/2018 of the Sofia District Court: The conclusions made by the prosecutor are incorrect due to the fact that the presence of a product on its own trademark does not allow the use of other non-proprietary brands, if the consent of the right holder lacks, whose object are these trademarks, neither legalise the use of such trademarks, as accepted by the state prosecution. Therefore, the 'logical conclusion' of the public prosecutor that the owner of the mark 'C. V.' may (as long as he has placed this mark on a pair of shoes) place (without the request or with the permission and consent of the respective trademark holders) another mark. (e.g., ‘H. P.’), and to 'exonerate' him or make his products ‘original’ is deeply untrue and not based on proper knowledge of trademark law.

Another approach used by infringers is to seek to file an application for the infringing trademarks and or industrial designs and to claim that these applications may validate the infringing activity as a legitimate activity. It is well-known that there is a certain period between the application and the registration of a trademark, in which other trademark owners may oppose the registration, based on its earlier IP rights. In some cases, infringers attempt to justify the use of the sign for which they filed

an application, even when the trademark owner has filed an opposition against such application. Furthermore, some infringers attempt to justify that even when the application of such trademark is fully refused (based on the opposition filed by a trademark owner) the use of the sign is still lawful for the period between the application and the refusal of registration. In practice, however, this position would mean that any infringer could apply to register a sign identical or similar to a well-known trademark and claim that, in the period between the date of the application and the subsequent refusal of registration, the sign was used lawfully.

The above problem is even more pressing with respect to industrial designs, where the protection is granted under the so-called 'registration regime', i.e., industrial designs are registered by the IP office if the respective application meets the formal requirements, without checking the existence of a previous identical/similar designs or other industrial property. However, even in the case of registration, the protection of industrial designs is dependent on the owners of prior rights for similar designs not filing a cancellation action against the newly registering, and infringing, designs. Still, also in these instances, infringers attempt to get away from IP liability with largely fraudulent design applications, which they file exclusively with the intention to copy existing design and infringe on their rights of their owners.

**B. USE IN COMMERCIAL ACTIVITY**

Commercial activity is not a legal concept. In essence, it covers commodity and monetary relations in society, with the legal form of these relations being transactions. The concept of "commercial activity" within the meaning of Article 172b of the Criminal Code specifies the way in which the Trademark owner’s right may be violated. It is subject to interpretation only in the context of Article 13, paras. 1 and 2 of the LMGI (please see above p. 3 regarding the content of the provision).

In Interpretative Decision23 No. 1 of 31 May 2013, on Interpretative Case No. 1/2013, the General Assembly of the Criminal College of Supreme Court of Cassation of Republic of Bulgaria clearly pointed out that the understanding of the objective content of Article 172b of the Criminal Code to be viewed as supplemented by the Commercial Act is not shared: First of all, the Commercial Act does not introduce a legal definition of commercial activity but builds it through the concept of trader, indicating which persons are traders / Article 1 of the Commercial Act / and who are not / Article 2 of Commercial Act. The rulemaking-approach places emphasis on the quality of individuals and not on activities carried out. In contrast, Article 13, para. 2 of the LMGI has created a comprehensive list of activities in which it is possible to violate the trademark law. Obviously, the legislator did not mean the Commercial Act, but he was distinguished from him, avoiding inclusion in the signs of the criminal composition of the special quality of trader, unlike other Criminal Code texts.

Therefore, the activities expressly and exhaustively included in the list of Article 13, para. 2 of the LMGI, are the forms of the act of 'use in commercial activity', which carry out the composition of the crime under Article 172b of the Criminal Code. In order to implement 'use in commercial activity' within the meaning of Article 13 of the LMGI, it is sufficient to have any of those actions representing the individual, independent forms of the act.

As outlined above, the concept of 'commercial activity' in the light of Article 172b of the Criminal Code should not be considered within the meaning of the Commercial Act, but under the LMGI. Therefore, the collection of evidence from a commercial register etc. is irrelevant to the case, obligatory for all national courts, administrative and local self-governmental bodies when applying the interpreted provisions and thus practically they become source of law.

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23 In case of contradictory or wrong practice of the Supreme Court of Cassation and the Supreme Administrative Court the general assembly of the judges of the relevant colleges of both courts shall jointly adopt an interpretative decision. Further, as the interpretative decisions are
for proof of such activity (under the meaning of the Commercial Act) carried out by a particular person. The fact of carrying out any of the forms of “use in the commercial activity” provided in Article 13, para. 2 of the LMGI (and not the implementation of commercial activity within the meaning of Commercial Act) is the fact that it is subject to proof in the course of investigating under Article 172b of the Criminal Code.

The Interpretative Decision No. 1 of 31 May 2013, on Interpretative Case No. 1/2013, of the Supreme Court of Cassation of Republic of Bulgaria provides the following reading on the concept of ‘commercial activity’ in the frames of trademark law: The element ‘commercial activity’ of the crime under Article 172b of the Criminal Code is present in the hypotheses of Article 13, para. 2 of the LMGI, when the activities are carried out for the realization of economic benefits; it does not depend on the subject’s activity of trade under the Commercial Act.

The above interpretation represents a continuation of the understanding of ‘commercial scale’ used in Article 61 of the TRIPS Agreement (and defined by the Panel in the WTO DS 362 (China- IPR)) and provides an opportunity to evaluate the particularities of each criminal case. However, the practice (in both, pre-court and court, stages of criminal cases) is currently diverse, given the wide range for factors to be assessed by the competent authority.

One of the important forms of ‘use in commercial activity’, especially in view of the Republic of Bulgaria24 developments on criminal proceedings, is the import of counterfeit goods/products. The legal definition of the term ‘import or export of goods’ is given in § 1 item 12 of the Additional Provisions of the LMGI, according to which – ‘import or export of goods’ is the actual movement across the border of the Republic of Bulgaria of goods bearing a sign identical or similar to a registered trademark or registered geographical indication, or an imitation thereof, whether or not a customs procedure has been applied to those goods.

In order for the goods to be imported or exported, the actual crossing of the border of the Republic of Bulgaria is sufficient, which leads to the commission of the crime under Article 172b of the Criminal Code. The prerequisites provided for the LMGI are essential. Namely – there is a transfer of goods across the border of the Republic of Bulgaria. The very transfer of the goods through the territory of the Republic of Bulgaria already constitutes their use in commercial activity and, as such, implements an element of the objective side of Article 172b of the Criminal Code. For goods to be imported or exported, it is not necessary for them to be placed under any customs regime, as the actual crossing of the border of the Republic of Bulgaria leads to the implementation of this element of the crime under Article 172b of the Criminal Code25.

According to the Interpretative Decision No. 1 of 31 May 2013, on Interpretative Case No. 1/2013, of the Supreme Court of Cassation of the Republic of Bulgaria, if, however, the goods/products are transited through the territory of the Republic of Bulgaria, these should be targeted at EU consumers (with a view to realising criminal liability) and adds the following:

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24 This is due to the fact that Bulgaria is outer border of EU and thus, a large number of counterfeit goods/products, intended not only to Bulgarian market, but to the markets of European countries, are attempted to be imported exactly through the borders of Republic of Bulgaria.

25 The definition of ‘import’ and ‘export’ in the LMGI is not accidental. It is designed precisely to distinguish these concepts from the concepts of ‘import’ and ‘export’ within the meaning of customs legislation. It is explicitly stated in the definition of the LMGI that there will be import or export even without the customs regime being activated. The legislator has explicitly emphasized the actual crossing of the country’s border, without being bound by the activation of customs regimes within the meaning of Council Regulation No. 2913/93 and Council Regulation (No. 2454/93, which are applicable according to Article 5, para. 4 of the Constitution of the Republic of Bulgaria, as well as of the Customs Act and the Regulations for its implementation.
This understanding of the law requires in each case to clarify whether goods in transit to a third country are destined for the European market. When there is no data in this direction, there are no grounds for criminal liability for violation of the right to industrial property under Article 172b of the Criminal Code.

Moreover, according to the said Interpretative Decision No. 1 of 31 May 2013, on Interpretative Case No. 1/2013, of the Supreme Court of Cassation of Republic of Bulgaria, under the customs transit regime, the actual transportation of goods across the border of the country through their introduction into its customs space is assumed, due to which it is possible to commit a crime under Article 172b of the Criminal Code. However, this hypothesis is conceivable when transiting only non-original goods destined for the European consumer.

Finally, it should be underlined that the Interpretative Decision No. 1 of 31 May 2013, on Interpretative Case No. 1/2013, of the Supreme Court of Cassation of the Republic of Bulgaria excludes cases involving original goods from the application of criminal liability under Article 172b of the Criminal Code.

C. LACK OF CONSENT

The identification of goods, their determination as counterfeit or original, is of key and leading importance for the criminal investigation of crimes under Article 172b of the Criminal Code.

The original and non-original (or ‘counterfeit’) goods are distinguished by one leading and main feature – the consent of the owner of the respective exclusive right to affix the respective mark (mark) on the specific product (garment, perfume, or other items). Original goods are the ones on which the mark is affixed with the consent of the Trademark owner. A non-original (counterfeit) is a commodity on which the mark (mark) is affixed without the consent of the right holder.

Identification of a specific good as genuine or counterfeit is indeed a key point to the criminal proceedings. If the consent of the trademark owner is not given in the first and main form of use in commercial activity (the affixing of the mark, i.e., the production of the specific product), then the product is fake, and it is pointless to check whether the consent of the trademark owner is given for subsequent uses. It is not possible for a counterfeit product, i.e., produced without the consent of the right holder, to be distributed, placed on the market, offered for sale, etc., without the consent of the right holder.

The only possible way to establish the fact whether goods are counterfeit is through a statement of the trademark owners (or through a proxy). The only legally valid statement as to whether or not consent must be given by the trademark owner because they are the person in whose legal sphere, (due to the existence of an exclusive right to the respective trademark) the legal opportunity to provide or not provide his consent arises. No person other than the trademark owner (or a representative expressly authorised) may provide such a statement.

In order to establish the above and to enable a trademark owner to give a statement on the products/goods, it is necessary to carry out product identification. For this aim, the trademark owner needs access to the specific product to be able to indicate whether the product in question is counterfeit or original. This access is (should be) provided by taking pictures of the specific product (or even samples if necessary). Providing pictures of the goods (each individual item) to the right holder (or his representative) and giving an opinion on whether the goods are original or counterfeit by the right holder (or his representative) is a procedure that is applied and established in practice, in particular – cases of customs detentions under Regulation (EU) No. 608/2013 on the protection of IP rights by the customs authorities. Regulation 608/2013 regulates at European and national level, the activities of customs authorities in the import / export of goods which are alleged to infringe IP rights. Therefore, the Regulation is aimed at one of the forms of use included in Article 13, para. 2 of the LMGI – and in this case it is crucial to establish whether the goods are counterfeit or original (i.e., whether they were produced with the consent of the trademark owner). Therefore, when goods are detained, the customs authorities provide the trademark owner (or his representative) with pictures/photos of the seized goods (or
expert departments that, when sending photos, give an opinion on whether the goods are original or counterfeit. And this is because, apart from the trademark owner (or a representative authorised), there is no other person who can provide a valid statement whether the trademark owner has given his consent for the respective goods to be produced, i.e., the mark of the mark to be affixed on the goods. The expert examination (and expert opinion) in the pre-court phase criminal proceedings may confirm whether the marks affixed to the goods are identical or similar to the registered trademarks of the trademark owners but cannot conclude whether the goods are counterfeit or original. As stated above, whether a product is counterfeit or original is determined solely by whether the trademark owner has given his consent to affix the mark to the particular item – therefore, only a statement by the trademark owner (or his authorised representative) is valid to establish whether the goods are counterfeit or not.

In summary, to establish the origin of the goods, i.e., whether they are original or counterfeit, it is necessary to perform product identification by the trademark owner.

The performance of product identification by a trademark owner was in the last years accepted to be performed to a certain extent in the frames of criminal proceedings in Bulgaria. The product identification, though a key point for the criminal investigation, was not widely performed and is still not accepted by some of the competent authorities, which prefer to point the question on originality (and lack of consent) to the appointed experts. As mentioned above, the experts may address different factual questions and issues. However, no expert may provide a valid statement whether the consent of the trademark owner is provided (such statement may be given solely by the trademark owner upon examination of the goods in question).

D. WILFUL ACTIVITY

The case law and court practices in the Republic of Bulgaria have already defined the parameters to be applied in the determination of wilfulness regarding acts that may represent criminal activities under the meaning of Article 172b of the Criminal Code.

According to a Decision of the District Court – Plovdiv of 29 July 2010: The obligation to inspect the mark affixed to the goods is applicable to any subject of the crime under Article 172b of the Criminal Code. The right of the proprietor to the rights of the trademarks is therefore exclusive because it has an effect on everyone from the moment of publication of the registration. Anyone who offers goods with a mark registered as a trademark, respectively identical or similar to it, is obliged to comply with the general prohibition to use it without the consent of the right holder.


Finally, the Guidelines for the Work of the Prosecutor’s Office on Intellectual Property Crimes confirms that the presence of previous acts with the same subject, committed by the same perpetrator, is extremely essential and should be reviewed by the competent authorities as a fact. The Guidelines confirm that the existence of earlier crimes against IP is a clear indication of intent.
E. OTHER SPECIFICS OF THE CRIMINAL PROCEEDINGS IN THE REPUBLIC OF BULGARIA

Additional provisions regarding specific criminal proceedings in the Republic of Bulgaria, include damages in criminal proceedings. In particular, Article 119 of the LMGI introduces a presumption on the amount of damages as follow:

- When the claim is established on grounds, but there are no data for known amount, the claimant may claim as compensation:
  - from BGN 500 to BGN 100,000, as the specific amount shall be determined at the discretion of the court at the conditions of Article 118, paras. 2 and 3, or
  - the equivalence at retail prices of legally produced goods, identical or similar to the goods – subject of the infringement.

In the past years, the presumption set above in Article 119, para. 1 (2) of the LMGI, i.e., evaluation of damages via the retail prices of original goods, represents the usual practice in criminal proceedings to establish the amount of damages. The above provision and the set practice is being challenged now via a request for a preliminary ruling, made by Regional Court Nessebar and representing C-655/21 of CJEU.27

F. CIVIL CLAIMS FOR DAMAGES

Pursuant to the Criminal Proceedings Code, the criminal court has the right to not allow the civil claim for joint consideration in the frame of a criminal court case, and actually, it is the common practice. Nevertheless, if there is a guilty conviction pronounced by the criminal court, the trademark owner has the right, based on the conviction, to submit a civil claim for damages. In the civil case, the civil court is obliged to accept the conclusions of the criminal court regarding the guilt of the infringer and for the infringement. Therefore, the infringement and the guilt are not subject to proof in the civil case. The trademarks owner is obliged to prove the amount of the damages. The civil claim is based on the expert opinion for the amount of the damages prepared in the criminal proceeding, but the civil court is not obliged to accept the conclusion of the expert opinion from the criminal proceedings. In view of that, the amount of the damages is subject to proof in the civil proceedings.

G. DESTRUCTION OF COUNTERFEIT GOODS

Criminal proceedings are often initiated with regard to customs seizures, where an objection is filed. Some prosecutor offices had the practice to initiate ex officio criminal proceedings in relation to customs seizures, even after the entry into force of Regulation 608/2013. In cases of criminal proceedings, the state charges for storage of the seized goods until their actual destruction is due by the competent authority (Prosecutor’ Office). The destruction of the goods after the finalisation of the criminal proceedings is organised and performed/controlled by the competent authority – the Prosecutor’ office or Criminal court (depending on the stage, pre-court or court, where the respective criminal case is finalised).

27 Questions of the referral are as follow: “1. Are the legislation and case-law in accordance with which the harm suffered by the trademark proprietor forms part of the constituent elements of the offences referred to in Articles 172b(1) and (2) of the Criminal Code consistent with the standards introduced by Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 in relation to harm caused by the unlawful exercise of IP rights? 2. If the first question is answered in the affirmative, is the automatic presumption, introduced by case-law in the Republic of Bulgaria, for determining the harm – in the amount of the value of the goods offered for sale, calculated on the basis of the retail prices of lawfully manufactured goods – consistent with the standards of Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004?”
5. CONCLUSIONS: CRIMINAL PROCEEDING IN REPUBLIC OF BULGARIA

The criminal proceeding is a principal option for establishing the fact of the infringement, along with the possibility to initiate civil or administrative proceedings. Criminal proceedings may be initiated by the trademark owner or any natural or legal person, as well as by the police authority ex officio. The proceedings are regulated by the Criminal Proceedings Code. The competent investigations body is the body in which area of competence the crime has been committed.

The practical problems are faced because of not understanding (by part of the competent authorities) the seriousness, as well as the essence, of IP infringements and, in particular, the trademark counterfeiting. Further efforts on widening the knowledge and understanding, through specialised materials and expert educational initiatives, pointed to the competent authorities (investigators, prosecutors, courts) are necessary in the Republic of Bulgaria.

Pursuant to the Bulgarian legislation, there is no criminal liability for legal entities. In view of that, the criminal proceedings are initiated against the managers of the companies, but there is a possibility, simultaneously, to initiate administrative proceedings against the company. There are examples of successful criminal proceedings regarding activities in warehouses, production sites and other significant cases in Bulgaria. As a whole, criminal proceedings are initiated for significant cases of trademark infringements and have proved to be an effective way for the protection of trademark rights in the last years.

The Republic of Bulgaria’s level of criminal liability regarding IP infringements is higher than that set by the TRIPS minimum standard. The TRIPS Agreement requires criminal liability in some cases of infringements on IP rights, while Bulgarian legislative regime allows for criminal liability to be sought in an extended (in comparison to TRIPS requirements) format. Insofar, the criminal cases on IP infringements proved to represent a significant part of the legal frame for IP protection in the Republic of Bulgaria.

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3. THE INABILITY OF COMPULSORY LICENSES TO ADDRESS THE PROBLEM OF MEDICINES AND VACCINES ACCESS IN LDCs IN THE CONTEXT OF THE COVID-19 PANDEMIC

Philibert Baranyanka

ABSTRACT

With the outbreak of the pandemic caused by the Coronavirus SARS-COV 2, COVID-19, research has been undertaken to find vaccines or drugs against this global scourge. This research led to the development of vaccines that were quickly made available to the populations of rich countries, the latter having undertaken to vaccinate all their populations. For developing countries, a global mechanism, COVAX, has been set up to help these countries immunize at least, the most vulnerable people. However, these efforts remain insufficient to immunize a large part of the world population.

Therefore, some have proposed, in order to provide access to these vaccines to populations in developing countries, to suppress or suspend the patents on the COVID-19 vaccines. This is neither an equitable nor a sustainable solution for the sake of research or innovation. Others argue that compulsory licensing mechanisms should be mobilized to allow low-income countries to get access to those new vaccines for their populations.

In fact, the compulsory licenses are presented as a step forward in solving the problem of access to medicines for the populations of the LDCs. Both the ancient and the new system of compulsory licensing impose, however, many administrative, legal, and policy barriers to the export of generics and involves a series of barriers to the flow of new medicines and vaccines. This unique framework provided for by the WTO Agreements makes it more complicated and complex to import or export new drugs than any other product manufactured under compulsory licenses.

Keywords: patent, compulsory license, drugs (medicines), LDCs, TRIPS Agreement, amendment, Doha Declaration.

1. INTRODUCTION

Known as a non-voluntary license, the compulsory license is an authorization granted by the public authorities to a third person, other than the patentee, allowing him to use or exploit an invention without the consent of the patentee. It is compulsory because it is issued by the authority when certain conditions justify it (public interest, competition objectives, health emergency, failure of the agreement of the patentee, etc.), unlike the voluntary license granted by the patentee, after a contractual assignment of rights, to a third party, the licensee. The granting of a compulsory license to exploit an invention without the authorization of the patentee may be used in all fields, including that of health. The term compulsory license is not expressly included in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement). It is drawn from the doctrine on Article 31 of the TRIPS Agreement, which frames the use of other use without authorization of the right holder.

In its original version, to mean before its amendment on 30 August 2003 in the Doha Round negotiations, the TRIPS Agreement prohibited the possibility of exporting or importing products produced under the compulsory minimums. For example, Article 33 of the TRIPS Agreement states that the term of protection is at least 20 years. This implies that Members may grant more, but not less than this minimum term.


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1 Verschave FX, [dir.], La santé mondiale, entre racket et bien public (Mayer 2004) 236.

2 The TRIPS Agreement sets the minimum rules for the protection of IP rights that Members must incorporate into their national laws. They cannot provide for protective measures that are below than these minimums. For example, Article 33 of the TRIPS Agreement states that the term of protection is at least 20 years. This implies that Members may grant more, but not less than this minimum term.
licenses. Indeed, under Article 31(f), compulsory licenses are issued mainly for the supply of the market of the Member who has granted them. They were, therefore, intended to solve only the internal problems of the country that issued them. Therefore, original compulsory licenses provided in the TRIPS Agreement could not address the health concerns of countries that do not have the capacity or infrastructure to locally produce the drugs and vaccines, which is the case for the least developed countries (LDCs) and many other developing countries. This significantly reduces the scope and effectiveness of compulsory licensing as an instrument to address the problem of access to medicines when the country is unable to provide its own production or when it needs to respond quickly to an emergency. That is why additional measures have been adopted at the WTO, in the margins of the Doha Round negotiations⁴, to correct this situation, by adopting the authorization for the export and import of medicines produced under compulsory licenses. But this must follow a very strict procedure and conditions, as will be seen in the paragraph devoted to this new version of compulsory licenses. But before we get to that point, we must start with the mechanism of the general version of compulsory licenses, the new version being an exception provided for medicines only.

2. COMPULSORY LICENSES IN THE TRIPS AGREEMENT

Article 31 (other use without authorization of the right holder)³ provide that the Member may authorize the use of the patented object without the authorization of the right holder, particularly in cases of national emergency⁶. Thus, compulsory licenses were presented as an answer to the problem caused by patents in access to medicines in the South countries and in the LDCs in particular⁷. In theory, the use of compulsory licenses could make medicines affordable and accessible while ensuring that the patent owner receives remuneration for the exploitation of his invention. In most developed countries, compulsory licensing is one of the mechanisms that WTO Members use to promote competition and access to medicines. However, the fact that products manufactured under compulsory licenses cannot be exported deprives them of their usefulness as an instrument for promoting access to medicines. What is the guiding principle of compulsory licenses, and what is the procedure for their use to address an emergency need?

A. THE PRINCIPLE OF COMPULSORY LICENSES AND THEIR APPLICATION

In principle, compulsory licenses are granted in the event of a national emergency in order to permit the local exploitation of a patented invention in order to solve a conjectural problem that the country is facing. The TRIPS Agreement expressly authorizes Members to grant compulsory licenses on the basis of their particular circumstances. It is the Member himself who determines the circumstances that justify the granting of these compulsory licenses, but this use must cease when the circumstances justifying them no longer exist⁸.

Article 31 of the TRIPS Agreement, which allows compulsory licenses, does not specify the grounds on which such licenses may be granted⁹. It lists only, for information, some situations justifying their granting. It is referred to that a Member may derogate from the normal

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³ The Doha Round of negotiations (Qatar) began with the WTO Ministerial Conference, which was held from 9 to 13 November 2001. The Doha Round is the current round of trade negotiations between WTO Members. This round of negotiations began on 1 January 2002, initially for a maximum of three years, and continues until today! Also known as the development round, its goal is to fundamentally reform the international trade system through the reduction of trade barriers and the adoption of revised trade rules. The work program includes some 20 areas, including agriculture, services and IP that have already been negotiated. Negotiations between developed and developing Members, however, have yet to reach a compromise in areas such as agriculture and non-agricultural market access (WTO, The Doha Round, https://www.wto.org/english/tratop_e/dda_e/dda_e.htm accessed 16 January 2018).

⁴ According to footnote 7 of the TRIPS Agreement, other uses mean uses other than those permitted under Article 30 of this Agreement, namely exceptions to patentee.

⁵ TRIPS Agreement, Article 31(b).


⁷ TRIPS Agreement, Article 31(g).

rules of patent protection in situations of ‘national emergency or other circumstances of extreme urgency or in the case of public use’\textsuperscript{10}. These situations may include reasons of public health (for example, following a natural disaster, war or epidemic)\textsuperscript{11}. Thus, a compulsory license may include medicine, an instrument, or any other product whose use relates to health (hospital equipment and materials, diagnostic equipment, etc.)\textsuperscript{12}.

Thus, the protection of the public interest, like public health, is sufficient to justify the granting of compulsory licenses. For those reasons, epidemic or pandemic diseases, like COVID-19, can be considered as a national emergency to justify the granting of such licenses and thus meet the needs of developing countries in terms of access to medicines or vaccines\textsuperscript{13}. It is therefore accepted that the WTO Member can exploit any patented invention for public health reasons and use compulsory licenses to produce drugs or vaccines and provide them at the cost of production, or even free of charge, to the poorest patients who need them urgently\textsuperscript{14}.

While Article 31 of the TRIPS Agreement leaves Members free to determine the grounds for granting compulsory licenses, it is very explicit in terms of the conditions that must be fulfilled for a compulsory license to be granted. In addition to the obligation to apply for the voluntary license before it can be granted \textit{ex officio} by the public authorities, the owner of the patent must, in the event of compulsory use of his invention, receive ‘adequate remuneration, taking into account of the economic value of the authorization’\textsuperscript{15} and this condition is applied to all types of compulsory licenses.

Although a system of compulsory licensing is provided for in many national laws, the number of such licenses granted in practice remains relatively low in developing countries. However, even if their use is relatively limited, they are an effective mechanism for stimulating competition and a credible weapon that can lead the patentee to grant price reductions or a voluntary license\textsuperscript{16}. According to Ladas, ‘the advantage of the existence of provisions concerning the granting of compulsory licenses in national legislation is that the threat created by these provisions incites patent owners to grant contractual licenses on reasonable terms’\textsuperscript{17}. Beier has developed a similar reasoning by noting that ‘compulsory licensing, because of the fear that it gives rise to forced licensing procedures, makes patentees more inclined to grant voluntary licenses’\textsuperscript{18}. In Brazil, for example, Decree No. 3201/99 provides that in cases of national emergency or for reasons of public interest recognized by the authorities, a compulsory license may be granted \textit{ex officio} on a temporary basis if necessary\textsuperscript{19}. In 1999, Brazil has threatened to produce generic drugs for HIV/AIDS and to grant a compulsory license to obtain from pharmaceutical companies’ discounts on their patented medicines. For many years, this strategy has been successful\textsuperscript{20}. However, one compulsory license was granted in 2007 for non-commercial public use of efavirenz for a period of five years and a rate of remuneration of the patentee of 1.5%. While the patentee was offering a 30% discount on its prices, the first batch of generic efavirenz products under compulsory license from July 2007 had a discount of 65-70%\textsuperscript{21}. This example is presented as evidence of the effectiveness of compulsory licensing in solving the problem of access to medicines in poor countries. But if this has been possible in Brazil, this cannot be valid in

\textsuperscript{10}TRIPS Agreement (n 5).

\textsuperscript{11}Correa C, Velasquez G, \textit{L’accès aux médicaments: entre le droit à la santé et les nouvelles règles du commerce international} (Harmattan 2009) 44-45.

\textsuperscript{12}Ibid 73.

\textsuperscript{13}This allowed, for example, Zimbabwe to declare in May 2002 a “six-month emergency”, allowing the manufacture of generic drugs used in the treatment of HIV / AIDS or its opportunistic diseases (Guesmi A, (n 8)268-269).

\textsuperscript{14}Guesmi A (n 7) 267-268.

\textsuperscript{15}TRIPS Agreement, Article 31(h).


\textsuperscript{17}Petities Ladas S, \textit{Patents, trademarks and related rights national and international protection} (Vol. 1, HUP 1975) 427.

\textsuperscript{18}Karl Beier, ‘Exclusive rights, statutory licenses and compulsory licenses in patent and utility model law’ (1999) 30 International Review of Industrial Property and Copyright Law 260.

\textsuperscript{19}Correa C, Velasquez G (n 11) 77.

\textsuperscript{20}Ibid 77.

\textsuperscript{21}Correa C, Velasquez G (n 11) 78.
most poor countries, since besides these countries do not have the same industrial capabilities as Brazil, these drugs produced in Brazil or other emerging countries cannot be exported to other southern countries.

B. THE LIMITS OF COMPULSORY LICENSES TO ALLOW ACCESS TO MEDICINES IN THE LDCs

The text of Article 31 of the TRIPS Agreement contains an important provision regarding the scope of the use of compulsory licenses in solving the problem of accessibility of patented medicines by the populations of LDCs. Indeed, any use of compulsory license must be authorized ‘mainly for the supply of the internal market of the Member who authorized this use’\(^{22}\). Thus, the TRIPS Agreement prohibits the use of compulsory licenses that are not intended to supply the domestic market of the country that issued them. However, importation is the only option that LDCs can use to buy drugs since they do not have the capacity to produce them locally. This significantly reduces the effectiveness of compulsory licensing as a tool to facilitate access to medicines, as local production may not be feasible in several LDCs and other developing countries, given that the size of their local markets does not justify such production or investment for the private sector\(^{23}\). Indeed, the problem for many LDCs is the lack of means to manufacture their own medicines, especially in case of emergency situations. They must therefore refer to imports. However, a developed Member could not, under Article 31 of the TRIPS Agreement, allow the use of a patent for the purpose of exporting a patented medicine that would be necessary for a country other than him, even in case of emergency. The latter, rich or poor, could not authorize the importation of drugs manufactured under a compulsory license in another country that authorized their production\(^{24}\).

As a result, countries that do not have sufficient infrastructure, technical and financial capacity in the pharmaceutical sector to locally produce the medicines they need are not able to take advantage of the compulsory licensing system. However, they may allow the importation of medicines from countries where they are not patented, which is random in the case of more interesting drugs, inventors hastening to patent them wherever they are likely to be easily reproduced\(^{25}\). For this, seen in this aspect, the TRIPS Agreement opposes compulsory licensing to satisfy international markets through export and import. However, it should be noted that, even though the WTO Dispute Settlement Body (DSB) has not yet been seized for the interpretation of Article 31 of the TRIPS Agreement, the presence of the word ‘mainly’ implies, according to us, that the export of the products manufactured under compulsory licenses remains possible. In our point of view, the usual meaning of this provision is erroneous because its right interpretation is that exports are possible, even though they are not the principal activity of the licensee of the patented product. This provision simply means that the use of a compulsory license for export may be an exception\(^{26}\), the rule being internal use. Something which is an exception is not illegal. It is only circumscribed or subject to conditions. The beneficiary of the compulsory license may export his products, but only in exceptional circumstances, which can be the case in an emergency. The only problem is that the TRIPS Agreement did not provide for the conditions for this eventuality.

Moreover, it is difficult to determine the criteria that would make it possible to judge the ‘main’ or ‘subsidiary’ nature of these exports (in particular with regard to amounts, volumes, frequencies, destinations, etc.). The consequence of this confusing situation is that it is the countries without technological capabilities that are in difficulty and who are most affected by the problem of

\(^{22}\) TRIPS Agreement, Article 31(f).

\(^{23}\) Remiche B, Kors J (n 9) 189.


\(^{25}\) Correa C, Intégration des considérations de santé publique dans la législation en matière de brevet des pays en développement (South center 2001) 162.

\(^{26}\) This is an exception to the use of compulsory licenses, which is itself an exception to the normal patent system.
access to medicines\textsuperscript{27}. This prompted LDCs, particularly African countries, to request a revision of this mechanism to allow the export and import of medicines produced under compulsory licenses and a new version of compulsory licenses was adopted in response to the concerns of those countries that "do not have the local capacity to produce themselves the generic drugs they need"\textsuperscript{28}.

3. THE AMENDMENT OF ARTICLE 31(f) AND PARAGRAPH 6 OF THE DOHA DECLARATION AND THEIR LIMITS

In 2001, during the Doha WTO Ministerial Conference, a declaration was adopted concerning the links between the TRIPS Agreement and public health problems. While some people attach importance to this statement, reiterating the idea that intellectual property (IP) protection remains an incentive for the development of new medicines, it explicitly mentions, in a clear manner, the harm to public health that patents represent, given their impact on the prices of medicines\textsuperscript{29}. Following this more political than legal signal\textsuperscript{30}, the most important measure taken in the WTO framework to solve patent problems in the field of public health has been the Decision of the WTO General Council of 30 August 2003, which allows the export or import of drugs produced under compulsory licenses for countries that do not have the infrastructure or the capacity to produce them locally. This Decision, which was provisional, was made permanent by the ratification of the Protocol amending the TRIPS Agreement, open to signatures by WTO Members, in accordance with Article X of the Marrakech Agreement establishing the WTO, since 6 December 2005. Although this 2003 Decision was presented as a step forward in solving the problem of access to medicines for the populations of LDCs, it did not produce the expected effects because of several failures (paragraph b), which handicapped its effectiveness. Indeed, this new procedure for exporting medicines produced under compulsory licenses (paragraph a) is long, cumbersome, and restrictive. This means that Members, which are not directly concerned, are not ready to engage in these ‘new’ compulsory licenses.

C. THE ‘NEW’ OR ‘SPECIAL’ COMPULSORY LICENSING PROCEDURE FOR MEDICINAL PRODUCTS

The Doha Declaration is a compromise resulting from negotiations between WTO Members to reassure international public opinion\textsuperscript{31} and to demonstrate the willingness of Members to settle the question of access to new drugs and vaccines. This political commitment to solve the patent problem in access to medicines (point i) has been reflected by the adoption of the 2003 Decision, which has become binding since then, pending the ratification and entry into force of the Protocol to amend Article 31 of the TRIPS Agreement (point ii).

4. THE 2001 DOHA POLITICAL CONSENSUS ON THE INEFFECTIVENESS OF ‘ORIGINAL’ COMPULSORY LICENSES

The Doha Declaration, which embodies this consensus, states in paragraph 6 that Members with insufficient manufacturing capacity or low technological capabilities in the pharmaceutical sector find it difficult to make effective use of compulsory licenses under the TRIPS Agreement. The Declaration recommends to the TRIPS Council to find a quick solution to this problem. This Declaration is the first relaxation of the constraints on the

\textsuperscript{27} Remiche B, Kors J (n 9) 190.
\textsuperscript{30} It is only a declaration and not a treaty or agreement, in the sense of international, and does not reflect, as such, commitments of Members. Remiche B, Kors J (n 9) 235.
\textsuperscript{31} Bototytutu E, Propriété intellectuelle et droits de l’homme : l’impact des brevets pharmaceutiques sur le droit à la santé dans le contexte du VIH/SIDA en Afrique (Bruylant 2007) 387.
LDCs on the issue of access to medicines\textsuperscript{32}. Even if a Declaration does not constitute a binding legal instrument in international law, the Doha Declaration is considered as an interpretative framework of the TRIPS Agreement, which must be interpreted in the light of this Declaration, which ‘allows making righteous decisions with respect to conflicting interests’\textsuperscript{33} under the TRIPS Agreement\textsuperscript{34}. In recognizing the importance of the problem of access to medicines in the developing countries and the urgent need to find solutions quickly, the Doha Declaration recognizes that there is a problem regarding the use of compulsory licenses in developing countries that do not have local manufacturing capabilities for medicines. The Doha Declaration thus had important political and legal implications. Although it is not binding, it has a certain value in that even if Members cannot require the application of the provisions it contains, they must at least observe what has been agreed upon, and their partners cannot blame them, even if this behaviour was contrary to pre-existing rules\textsuperscript{35}. With the adoption of this Declaration, the consensus on the patent issue and public health was formed and served as proof of the existence of the opinio juris\textsuperscript{36} that has formed around this issue\textsuperscript{37}. The Doha Declaration recognized the need to fill the gap found after the entry into force of the TRIPS Agreement and set guidelines that members have to follow. Indeed, Article 4 of the Doha Declaration states that the TRIPS Agreement does not prevent Members from taking measures to protect public health. Accordingly, the Agreement must be interpreted and implemented in a manner that supports the right of Members to promote the health of their populations and promote the access to medicines for all\textsuperscript{38}. It, therefore, represents new provisions that can no longer be validly opposed in the DSB and affirms the right of Members to interpret and apply the TRIPS Agreement in a manner that protects health. Subsequently, the influence of the Declaration on the formation of the 2003 Decision and the 2005 Amendment was decisive.


The 2001 Declaration was clarified and made enforceable by the Decision taken on 30 August 2003, of the General Council. This Decision has the scope of a provisional derogation from Article 31(f) of the TRIPS Agreement, pending its proper revision. By this Decision, the WTO General Council intended to prescribe the abandonment of the provision of the TRIPS Agreement, which limited the import or export of pharmaceutical products produced under compulsory licenses. By this Decision, Members are now allowed to derogate, under certain conditions, from the obligations established by Article 31(f) of the TRIPS Agreement and to proceed with the export of generic drugs manufactured under compulsory licenses to ‘eligible importing Members’\textsuperscript{39}. By clarifying the content and conditions of implementation of paragraph 6 of the Doha Declaration\textsuperscript{40} in order to promote the import and export of generic medicines, it enshrines the legality of the importation of generic drugs from countries in which they are also patented but which are not able to produce them themselves, or that they do not have the technical capabilities, or that local production would be complex or expensive to implement\textsuperscript{41}.

\textsuperscript{32} Remiche B, Kors J (n 9) 235.
\textsuperscript{33} This is to balance the interests of patent holders and those of patients who need to use drugs covered by these patents.
\textsuperscript{34} Gervais D, L’Accord sur les ADPIC: propriété intellectuelle à l’OMC (Larcier 2010) 77-78.
\textsuperscript{36} This may be considered that this is a new source of international law, not provided for in Article 38 of the ICJ Statute, or at least a new technique for the creation of international legal rules, all the more so an international body is bound by the resolutions it adopts, even if they are not binding on Member States. This way of developing international law is particularly effective in new areas: economic law, environmental law, etc.
\textsuperscript{37} Ibid 69.
\textsuperscript{38} ‘Eligible importing Member’ means any LDC Member, and any other Member that has made a notification to the TRIPS Council of its intention to use the system set out in Article 31bis and his Annex as an importer, it being understood that a Member may notify at any time that it will use the system in whole or in a limited way, for example, only in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use (Article 1(b) of the Annex of the TRIPS Agreement).
\textsuperscript{41} Correa C, Intégration des considérations de santé publique, 90.
At the WTO Ministerial Conference in Hong Kong in December 2005, Members approved the changes that were transforming this temporary abandonment of Article 31(f), in the case of medicines, into a definitive amendment to the TRIPS Agreement only and exceptionally in the case of medicines. Indeed, Article 31bis incorporates in the TRIPS Agreement the provisions of the Decision of 30 August 2003, thus making it final. Article 31bis states that the obligations of an exporting Member under Article 31(f) shall not apply regarding granting that Member of a compulsory license to the extent necessary for the production of a pharmaceutical product and its export to an eligible importing Member. This is the first amendment of the WTO Agreement. Despite this, the importation and exportation of medicines produced under compulsory licenses are subject to prior modification of national laws in relation to Article 31(f) of the TRIPS Agreement. However, the law modification is not always an easy procedure, whether in the importing or exporting countries, given the states that characterize the pharmaceutical field. Since 30 August 2003, only three exporting countries have amended their laws to adapt Article 31(f), namely Canada, Norway and India. As for the importing countries, apart from Rwanda, no other Member has yet changed its national law to comply with the 2003 Decision or the 2005 Protocol. From the foregoing, it would not be wrong to conclude that the decision of 30 August 2003 did not achieve its objectives.

THE FAILURES OF THE REVISED VERSION OF THE COMPULSORY LICENSES FOR MEDICINAL PRODUCTS

The new procedure of compulsory licenses for medicinal products has many obstacles that hinder its effectiveness in solving the problem posed by patents in the field of medicines access. Apart from the fact that the Protocol on the amendment of Article 31 of the TRIPS Agreement was not greeted with enthusiasm by the LDCs and has not yet been incorporated into the national legislation of potential exporters, it provides for a cumbersome procedure that imposes many constraints. In addition, the drug-producing countries continue to use their political and economic influence to obtain from Southern countries the abandonment of the use of these new compulsory licenses, notably by entering into bilateral or regional agreements on IP: TRIPS plus. The result is that about 15 years after its adoption, the new procedure of compulsory licenses has been used only once and with less efficiency since the medicines requested by Rwanda were produced and delivered only four years after the start of the procedure. This single example to date of the export of generic drugs from Canada to Rwanda provides evidence of the inefficiency and non-operationality of this new solution contained in the 2005 Protocol amending Article 31(f) of the TRIPS Agreement.

France, while the latter is not an "eligible importing Member" (Esmail L, Elliott R, Accès aux médicaments et la propriété intellectuelle: un réunionsd’experts internationaux sur le Régime canadien d’accès aux médicaments, les développements dans le monde et les nouvelles stratégies pour améliorer l’accès, 19-21 avril 2007: rapport sur la réunion <http://www.aidslaw.ca/publications/interfaces/downloadFile.php?ref=1253> accessed 23 December 2017. In addition, recipient countries were not well specified, which is normal for an NGO operating in more than one country. After several negotiations, Rwanda, with the support of MSF, has notified the WTO of the issuance of a compulsory license and its intention to import a triple therapy (zidovudine/lamivudine/nevirapine) from Canada. On 19 September 2007, Canada granted a compulsory license to a Canadian firm, Apotex, to produce 260,000 tablets of Apo-Triavir at cost and ship them to Rwanda. On 23 September 2008, Apotex announced that it was ready to deliver the product to Rwanda. A total of 15.6 million tablets of Apo-Triavir were exported to Rwanda at a price of CAD 0.195 per tablet. Correa C (n 41) 95-96.
6. **LDCs LACK OF ENTHUSIASM FOR THE 2005 PROTOCOL AMENDING THE ARTICLE 31(F) OF THE TRIPS AGREEMENT**

The Marrakesh Agreement Establishing the WTO makes the modification or clarification of WTO agreements conditional on a Decision of the Ministerial Conference ratified by a two-thirds majority of the members. Article X of the Agreement Establishing the WTO provides, in its third paragraph, that amendment takes effect once it has been ratified by two-thirds of the Members, in accordance with the internal procedures of each Member. In application of this Article, the Hong Kong Ministerial Conference of December 2005 gave Members until 1 December 2007 to ‘accept’48 this Protocol. This deadline has been postponed several times, and the required number of signatories has not been reached at the end of 2011. Thus, the WTO General Council has decided to postpone the entry into force of the Protocol indefinitely until the required ratifications are reached.

Finally, on 23 January 2017, the WTO announced the entry into force of the 2005 Protocol ‘after its ratification by two-thirds of the Members’49, as provided by Article X of the Marrakesh Agreement establishing the WTO, and replaced, from that moment, the August 2003 Decision that remained in force until that date. However, by that date indicated by the WTO as the date of entry into force of the Protocol, only 16 LDCs out of 48 have ratified.50 A surprising number for an amendment that was supposed to solve the problem of access to medicines, a problem that affects them more than other countries. The reason for the lack of interest of most of these LDCs for this amendment is that they are aware that the provisions contained in this Protocol will not allow them to solve the problem of access to medicines, given the cumbersome nature of the mechanism it plans. Moreover, if the amendment were to improve the situation, the change would already have been noted since. Although the Protocol has not yet entered into force, the Decision of 30 August 2003, which provides for the same mechanism, was provisionally in force51.

Nevertheless, the problem of access to medicines has remained intact, despite almost two decades that have passed since its adoption. The obstacles of the application of the 2005 Protocol remain even after its entry into force. The difficulties are to look elsewhere, especially in the cumbersome of this mechanism.

7. **THE CUMBERSOME NEW PROCEDURE OF COMPULSORY LICENSES**

The complexity of the new compulsory licensing mechanism has generated some scepticism about its functionality. While the Doha Declaration called for a quick and easy solution to be implemented, it is a cumbersome, lengthy, and costly mechanism provided for in the decision of 30 August 2003. Before importing medicines produced under compulsory licenses, the ‘Eligible importing Member’ that wishes to issue the compulsory license must demonstrate the failure of its attempt to negotiate with the patent holder52. This was not required in the general TRIPS flexibility regime if the license is issued in a national emergency. Thus, this new mechanism complicates the ‘normal or general’53 procedure of compulsory licenses, a system that was already particularly difficult to implement.

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48 In this context, this verb ‘accept’ means ‘ratify’.  
50 See the list of countries that have ratified the Protocol of the amendment of the TRIPS Agreement <https://www.wto.org/english/tratop_e/trips_e/amendment_e.htm> accessed 15 January 2018.  
51 It should be noted that even the non-ratification of the 2005 Protocol, which would make the August 2003 Decision permanent, does not prevent it from being applied in accordance with the provisions of the Agreement Establishing the WTO (Article 10 of the 2003 Decision and Article XXIII of the GATT 1994 paras. 1(b) and (c)).  
53 It should be recalled that the compulsory licensing system provided for in the 2003 Decision and the 2005 Amendment applies only to medicinal products. Other products remaining under the general compulsory licensing regime as provided for in Article 31 of the TRIPS Agreement.
The process of using these new compulsory licenses is extremely laborious. To obtain supplies of drugs produced under compulsory licenses, the Member in need of these drugs makes the request to another Member who has the capacity to produce them. The latter makes the order and is a guarantor to the pharmaceutical firm that agrees to produce them. The obligation to issue compulsory licenses simultaneously in the producing country and the importing country, the multitude of notifications and information to be transmitted to the WTO, the proof of the needs of the importing country and its inability to produce locally, are factors that would make the process more cumbersome and slower. These administrative procedures complicate the mechanism to the point of rendering the decision of 30 August 2003 and 2005 Protocol ineffective. Thus, importing countries, which until then only had to declare a compulsory license to be able to obtain generic supplies of a patented medicine, are, by this device, obliged to carry out information and notification procedures to the TRIPS Council.

In addition, the exporting Member has to manufacture only the product in a quantity that it has notified to the WTO. In fact, the compulsory license must specify the name and quantity of the products that the country wants to export in this context. All drugs produced under compulsory licenses must be identified by means of specific labelling or marking (colour, shape, or packaging) to distinguish them from the patented products for which they are equivalent. This implies that if a company wants to produce for several different countries, it must proceed to a different marking for each country of destination. It must export all the products manufactured in each eligible importing Member, which in turn must take reasonable measures to ensure that the exemption does not result in the diversion of the exported pharmaceutical products and to prevent their re-export or use by ineligible Members. This is likely to discourage developed country firms from becoming involved in the process of exporting drugs produced under compulsory licenses, as this requirement of multiple marking constitutes an additional constraint or burden in money and time. For example, Appotex did not wish to receive a new order from Rwanda, claiming that it had lost money in the first order of antiretroviral it has delivered to Rwanda.

The exporting country must finally vouch for remuneration and payment to the patent holder. Thus, in the event the importing country fails to honour its commitments, it is the exporting country that should pay this remuneration. In addition, the conditions under which the amount of such remuneration is determined remains imprecise, as mentioned above. As far as this remuneration is concerned, the importing country is relieved of all liability to the patentee, who may directly seize the exporting country. Thus, instead of encouraging the export of drugs produced under compulsory licenses, the mechanism provides a kind of sanction to companies

54 The country wishing to use the mechanism must establish that it does not have manufacturing capacity in the pharmaceutical sector or that it is insufficient and that it is not in a position to acquire such capabilities in the short term, unless it is a LDC in which case this does not apply, as the LDCs are presumed not to be in possession of it.  
56 ‘Exporting Member’ means a member using the system to produce pharmaceutical products for, and export them to, an eligible importing member. See the Annex of the TRIPS Agreement, paragraph 1(c), <https://www.wto.org/english/tratop_e/trips_e/wtd641_e.htm> accessed 14 December 2017.  
57 Gervais D (n 34) 76.  
58 Gervais D (n 34) 79.  
59 Re-export is not even allowed for developing or LDC Members with similar health problems who have signed a regional trade agreement within the meaning of Article XXIV of the GATT 1994. Diversion (export to a third country instead of the country for which the product was manufactured) remains the main concern of rich countries. The circumstances which justify the manufacture of a medicinal product under a compulsory license for export to a country A and notifications requirements do not apply to a country B, and the latter must make the orders and notifications provided if it also wants to benefit from the system. Gervais D (n 34) 387.  
60 Appotex is the Canadian pharmaceutical firm that produced and exported the compulsory licensed antiretrovirals in Rwanda.  
62 Correa C, Velasquez G (n 16) 92.
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and developed countries that would be engaged in the procedure.

The most worrying is that generic manufacturers are allowed to produce only piecemeal and in quantities previously specified. It is hard to imagine how they could engage in investment by making adequate production facilities without the guarantee of a sustainable market or a sufficient volume to amortize its investment costs. This situation alone constitutes a major discouragement. Except in exceptional circumstances (many orders, production process easy to copy, etc.), it is hard to see how the mechanism would motivate firms to become involved in such a process, without forgetting, as we have seen, the pressures that these firms and their country exercise over other countries that intend to use them.

In addition, requiring a manufacturer to obtain a compulsory export license for each offer and for each recipient country is a significant obstacle. This requirement implies that the manufacturer establishes a production line to execute an order and dismantle everything after and to build or refurbish other new infrastructure for another. It is simply surreal, as long as the needs of the countries are often identical and often concomitant, especially in case of epidemics, diseases, or disasters. There is, therefore, a clear desire on the part of developed countries to defeat the mechanisms provided for by the new compulsory licensing procedure provided for in the 2003 Decision.

8. THE WEAK INVOLVEMENT OF DEVELOPED COUNTRIES

Already, several developed countries (such as Australia, Canada, United States, Japan, and the European Union) have indicated that they will not use the new system of compulsory licenses as importers63. This is logical because they have sufficient capacity to produce locally the drugs they need. Others (such as China, South Korea, Mexico, and Turkey) said they would only use it in emergencies64. Even worse, despite the lawful nature of these compulsory licenses, their use remains residual, also because, the pressure exerted by the rich countries and their firms on the governments of the developing countries which are using or planning to use them.

Some countries that have indicated their intention to use it have been threatened by some developed countries with commercial retaliation. These threats are sufficiently dissuasive for these countries of the South to give up the use of compulsory licenses65. Indeed, the United States brought a complaint before the WTO challenging the fact that it was possible to acquire a compulsory license in Brazil even if the patent was not of Brazilian origin66. In addition, Thailand was also granted a compulsory license for efavirenz in 2006 to import it from India at a price corresponding to half of its marketing price in Thailand. In retaliation, one of the pharmaceutical companies withdrew the pending applications for approval of new drugs in Thailand. Meanwhile, the United States has threatened Thailand with commercial retaliation on jewellery, wood and microprocessors and has placed it on the ‘priority watch list’, that of countries whose IP protection is judged inadequate67. Thus, political, and economic pressures remain a recurring problem even in the case of the new compulsory licensing procedure, despite the fact that these pressures have been formally denounced in the Doha Declaration and in the 2005 Protocol itself68. In paragraph 4, the 2001 Declaration states that the pressure to impede the use of available flexibility in the TRIPS Agreement runs counter to the spirit and purpose of the Agreement. This provision has no longer been

64 ibid.
65 See the US Trade Representative’s 30 April 1999, press release which lists countries that may be subject to economic trade sanctions under Special Section 301 of the US Trade Act. Correa C, Velasquez G (n 11) 47.
66 Remiche B, Cassiers V (n 24) 144.
67 Correa C, Velasquez G (n 11) 77.
68 Protocol amending the TRIPS Agreement, Article 31bis, paragraph 4.
respected; a Declaration remains a simple declaration without any binding legal force. The answer to the problem of patents and access to medicines in the LDCs is, therefore, neither in the old version of the compulsory licenses, nor in the new one designed specifically to solve this problem, nor in any other exception provided for through the WTO Agreements.

In the context of the SARS-COV-19 pandemic, it already seems that the provision of the 2005 Protocol cannot operate, that why many countries, United States, France, the BRICS, European Union, among these, are in favour of the suspension of patents on new vaccines against COVID-19 to allow poor countries to acquire the doses necessary to vaccinate their populations at a lower cost.

If the countries are traditionally hostile to any measures aimed at calling into question the current system of patents, with regard to drugs and patents, and even want to suspend them, it is because they have observed the failure of the mechanism established by the 2005 Protocol. In addition to the suspension of patents on vaccines against COVID-19, other mechanisms have been introduced to allow the vaccination of a large part of the world population, especially in the COVAX mechanism.

Even if these measures, including that of suspending patents, do not constitute adequate answers, in my opinion, to the problem of patents and access to drugs in developing countries, they at least have the merit of showing that the system put in place within the framework of the WTO is not likely to resolve it and that we must still get to work to adopt mechanisms likely to resolve it. Proposals exist. It only remains to analyse and adopt them.

9. CONCLUSIONS

Despite the flexibility of the TRIPS Agreement and other WTO Agreements that are favourable to the LDCs and that they can be exploited to take action in favour of health, the reality is that these countries are still unable to have access to new medicines for their populations. Indeed, in addition to the fact that these flexibilities are inoperative because of technical incapacity and the fear of trade and economic retaliation by rich countries, developing countries cannot use compulsory licenses. The latter, which are the most interesting of these flexibilities and which could enable the LDCs to obtain generic medicines, has proved ineffective in most of these countries. Article 31 of the TRIPS Agreement authorizing such compulsory licenses provides in paragraph (f) that they may be granted only for the supply of the domestic market of the Member who authorized them. Thus, as this provision is interpreted as a formal ban on the export of drugs produced under compulsory licenses, the LDCs cannot exploit it to obtain the medicines they need at reasonable and affordable prices for their populations. Their pharmaceutical industries lack the technical capacity and human resource skills in drug production. The implementation of local production in the LDCs is therefore not technically or economically viable in these countries.

It is in this perspective that the 2001 Doha Ministerial Conference allowed the relaxation of the compulsory licensing rules by inviting Members to take measures favourable to health. In 2003, the TRIPS Council adopted a Decision amending Article 31(f) and making it enforceable until the entry into force of the 2005 Protocol amending the TRIPS Agreement, which made this derogation from Article 31(f) permanent. The novelty of this 2003 Decision is that for countries without technical capacity, the importation of drugs manufactured elsewhere under compulsory licenses became legally possible, thus repealing the provision that prevented their export. But the conditions to be fulfilled as well as the formalities to be done are all constraints and limits to the use of this new system of compulsory licenses. Indeed, this new system imposes many administrative, legal, and political obstacles to the export of generics. While the problem of affordable prices for patients in the LDCs may theoretically be limited by this
new system of compulsory licenses, the implementation of this new system is more restrictive than the general rules of the TRIPS, and it has become more complicated and complex to import or export drugs than any other product manufactured under compulsory licenses. Because it has multiple requirements and multiple notifications, and because it is based on country-by-country, drug-by-drug action, it creates a lot of paperwork and stretching delays that do not take into account the urgent drug needs that the countries and patients often face.

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ABSTRACT

Traditional input factors such as land, equipment, real estate, and other tangible resources are often used to create income. Thus, in secured financing, tangibles are readily accepted by financing institutions based on their materiality and hence practicability and certainty. Today, the world has noticed a shift to the knowledge economy where the creation of wealth is based on intangible assets such as information, creativity, and intellectual property (IP). Intangibles have developed to become an asset class. Meanwhile, IP is a creation of the mind with traditional financial tools such as assignment. The effective management of knowledge assets like IP rights, for instance, enables the delivery of financial and economic benefits. With the cash flow associated with, for example licensing and assignment, the rights flowing from copyright as an IP category could be traded and commercialised. This paper critically examines the use of IP rights deriving from copyright as an asset-backed security in Africa. Taking South Africa and the OHADA States as case studies, it discusses the feasibility, under law, of securitising copyright assets to enable right holders’ access to credit, even before start-up. The paper concludes with recommendations for proper financing of the creative industries, which are determinant factors of the African knowledge economy.

Keywords: intangibles, copyright, securities, collateral, exclusive rights, assignment, South Africa, OHADA.

1. INTRODUCTION

In today’s knowledge economy, information products play an essential role in the economic growth of developing countries. Examples are numerous: films, musical works, computer programs, etc. Copyright regulates authorship and the rights associated with products qualifying as creative works. Copyright is a category of intellectual property (IP). Other categories refer to industrial property and include patents, trademarks, trade secrets, industrial designs, etc. IP falls within the concept of property as used in Section 25 of the South African Constitution. Often, tangible (corporeal) property (things) is encountered as objects of security agreements. Things can be movable or immovable. Human senses easily apprehend this kind of property. Property is, therefore, a thing, easily perceptible. These attributes reinforce its appropriateness as security. The opposite stands true. The fact that a certain property is not tangible can restrict its suitability as an object for security purposes. Wille et al. describes such property as ‘an abstract conception with an intrinsic pecuniary value’.

The lack of financial means has been a major obstacle for owners of intangible property in creative industries in developing countries. Generally, funds scarcity for the creation of works of authorship prevents economic uplifting. Because adequate financing enables the successful commercialisation of creative ideas, copyright owners have been led to use their rights as security for bank lending. South African courts, in the case of Louis Pasteur v. Bonitas Medical, have qualified ‘good


[5] [2018] ZASCA 82.
Copyright as Collateral in Securities Lending Transactions: A Comparative Analysis between South Africa and OHADA Countries

security’ as easily realisable assets such as debtors’ property or investments. Meanwhile, several authors describe the cession of share’s personal rights/guarantees as less good security.

In OHADA, copyright backed collateral as a form of financing is not common as a majority of the corporations are not willing to invest in an industry that has just started growing. Also, as is the case in many other countries, using IP to gain access to credit is eagerly accepted when main patents or brands are involved. OHADA financing institutions are afraid of losing their money due to uncertainty, adverse selection, or moral hazard surrounding those rights in the region. Generally, financial institutions hesitate to lend money to copyright owners. The re-deploy ability of copyright and related challenges in the advent of default and the borrower’s reputation may explain the fears of the financial institutions.

The Supreme Court of South Africa has rectified this derogatory approach in, Laugh It Off Promotions CC v South African Breweries International (Finance) BV t/a Sabmark International and Another. The Court, in this case, reiterated that:

The fact that property is intangible does not make it of a lower order. Our law has always recognised incorporeal as a class of things in spite theoretical objections thereto.

The local market of OHADA nations grasps remarkable trade businesses, individuals and companies making a living in the creative sector. This sector includes a range of activities from fashion design, cultural theatres, music, performing and visual arts, the movie industry, traditional architecture, the craft industry, etc. With the rise of technological advancement, modernisation, and global awareness, the OHADA creative sector has witnessed an explosive expansion to ICT related businesses, including electronic commerce, software and computer services, video games production, etc.

Most of these creative industries in OHADA’s emerging creative sector are constantly exploring strategies to encourage their rise and economic readiness. Creations of the mind, such as inventions, literary and artistic works, designs, symbols, names, and images, used in commerce, are regulated by copyright. Copyright is generated through creative activity. Through copyright, the owner can secure economic benefits in the marketplace. Copyright as an incentive tool rewards authors with exclusive remuneration rights as a counterpart for their creativity and investment. Like all property, the owner can lease it, license it, give it away or sell it.

Local entrepreneurs in OHADA Central African countries, for example, are restricted in terms of access to funding. For small and medium creative industries operating in these various creative sectors, access to credit is necessary for start-up or survival. Financing becomes an accelerator for economic empowerment in these developing economies. It equips SMEs with funding, therefore boosting economic growth.

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7 Ibid.


To achieve economic development in the creative sector, African film producers, for example, need access to financing. The only backed-up tool at hand is the copyright work which could include the cinematograph film embedded on a disc, fashion design, or film production. It becomes important to question to what extent copyright owners realise the market value of their works through their exploitation as a financing instrument. And especially the response of the OHADA banking legal system to the issuance of loans to copyright owners with creative work as collateral.

In the face of negative apprehensions of intangible property, it could seem that they are legally inappropriate for security purposes.

This article sheds light on the securitisation of copyright as assets for financing business operations. The paper firstly concentrates on the acceptability of security over intangible assets, specifically in the case of the rights flowing from copyright. The legal regulating theories relating to incorporeal, and property are highlighted in the South African Roman-Dutch perspective and the OHADA Napoleonic Civil Code approach. The paper further underlines to what extent the legal traditions of these countries have affected their legal capacity to grant securities over intangibles. The paper analyses issues arising in the course of adopting IP assets as security. Discussions follow on subsequent legal changes adopted in South Africa and OHADA and aiming recognition and accommodation of copyrights as collateral in the lending market. The paper concludes with an address to the need for appropriate security objects to overcome the small economic growth noticed in those sub-African regions.

2. COPYRIGHT AS PROPERTY

With the growing integration of IP as a valuable asset in the industry sector, IP has become a driver of global development. Today, intellectual capital is often the key objective in mergers and acquisitions. A proper understanding of the role of IP in a corporation and its subsequent valuation is the cornerstone of the rightful exploitation of intellectual assets.

Property is a wide concept, including rights and things. Generally, one can divide things into two categories: immovable and movable. Land and every right or interest in land or minerals qualify as corporeal immovable property, while rights constitute incorporeal movable property. In South Africa, the right to property is constitutionally protected and is not limited to land. The right to property extends to intangible assets: IP, state debts, licenses and permits, and commercial interests, for example. In the instance where such intangible assets have interests vested in, the creation of state monopolies will affect their management. An IP asset is classified as movable property. South African law provides for the transfer of copyright as movable property by assignment, testamentary disposition or operation of law. Although qualified as movable property, IP rights are not tangible. Henceforth, an IP right is an incorporeal movable property. The courts have affirmed that an intangible asset, despite its immaterial nature and incorporeal aspect, falls within the meaning of property and movable property and can constitute the subject matter of security.

17 s. 2 Insolvency Act 1936.
18 Constitution (n 3), s. 25.
21 Insolvency Act 1936, s. 2.
22 Copyright Act of 1978.
23 Bank of Lisbon and South Africa Ltd. v Master of the Supreme Court (1986) ZASCA 121.
A. INTANGIBLE MOVABLE PROPERTY AND SECURITY

Sломовитц А. Ј. in Video Parktown North (Pty) Ltd v Century Associates and others25 purposely qualified copyright as species of ownership. Copyright comprehends a set of exclusive transferrable rights to the copyright owner. Copyright over a piece of work is tied with a plethora of economic and moral rights:

- Economic rights: the right to exploit the work in material form26 and the right to publicly communicate the work in the non-material form.27
- Moral rights: the right to claim authorship of the work, the right to object to any distortion, mutilation, or derogatory action in relation to the work.28

In OHADA, the author of the work enjoys the exclusive right to exploit his work in any form whatsoever and obtain monetary advantage therefrom.29

In BSDA v Groupe Walf30 the local court affirmed the exclusive right of the copyright owner to exploit the work and perceive the fruits of its exploitation.31

Transfer of IP rights to a financial institution as security for a credit facility is a form of exploitation of personal rights in it. Even though an incorporeal property cannot be transferred physically, some personal rights flowing from the IP rights can be transferred. The rights flowing from copyright as an IP category operate as a monopoly granted to creators over their intellectual creations. In practice, it is a combination of incorporeal rights entitling the copyright owner to exclusive entitlements. The bundle of rights in copyright could apply to literary works such as books or computer programs. They could equally apply to artistic works. Examples are music, paintings, films, and sculptures. The moral rights flowing from copyright relate to the personality of the author. Whereas the economic rights enable the lawful owner to extract financial benefits each time the work is used by third parties.

Copyright holders such as artists, filmmakers, writers, or musicians, like other individuals in the marketplace, have a need to provide security for credit facilities made available to them. The same also occurs for a loan or overdraft facility. However, a credit provider requires security from a debtor before it is prepared to grant a credit facility. The amount of capital that a creditor is willing to advance to a business depends on the reliability of the business and the value of the assets given as security.32 The question, therefore, arises to what extent IP rights in copyright can be utilised as valid security for a credit facility.

B. THEORETICAL BACKGROUND

According to Brits,33 real security law can be defined as the use of institutions of property law, such as rights acquired in or burdens imposed on proprietary objects/things, to help ensure the fulfilment of personal obligations.

26 National Soccer League t/a Premier Soccer League v Gidani (Pty) Ltd [2014] 2 All SA 461 (GI).
27 Moneyweb (Pty) Ltd v Media 24 Ltd and another [2016] 3 All SA 193 (GI).
28 ‘Intellectual Property Handbook: Policy, Law and Use’ (21st, WIPO Publication, 2004) 46; See also Nel and another v Ladismith Co-Operative Wine Makers and Distillers Limited [2000] 3 All SA 367 (C) where the court emphasised that the ownership of any copyright conferred by s 3 or 4 of the Copyright Act on any work shall vest in the author or, in the case of a work of joint authorship, in the co-authors of the work. In this case related to the adaptation of an artistic work, the court mentioned that the substantial features of the original label remain recognisable in the disputed version. That version was accordingly found to be an adaptation of the original, and therefore enjoyed copyright protection.
29 Bangui Agreement on the Creation of an African Intellectual Property Organisation 1999, Article 9(1), Annex VII.
31 Article 33 of Loi relative a la Protection du Droit d’auteur No. 73-52 du 25 Janvier 2008 Republic of Senegal: « L’auteur jouit du droit exclusif d’exploiter son oeuvre sous quelque forme que ce soit et d’en tirer un profit pécuniaire ».
The banking sector has come to recognise intangibles as a type of assets over which one can establish real security rights. The copyright owner with the bundles of rights in his patrimony can also use it as an object of security in the same way as a movable asset or a piece of land.

a) Classification of Copyright as Property in South African and OHADA Contexts

In South Africa, there is no express statutory provision concerning the creation of a right of real security for copyright. Therefore, the need to determine the nature of IP prior to identification of the mean by which they could be offered as real security (mortgage, bond, hypothecation, etc.). It has been noted that, in the absence of legislation on the securitisation of IP, classification type determines the type of real security.

Property rights include all kinds of property, i.e., immoveable, movable, immaterial, and incorporeal property. It is trite law in South Africa that securitisation of movable corporeal property can be attained through a pledge or by registering a notarial bond over the asset.

Incorporeal moveable property may be securitised by means of a security cession, otherwise called cession in securitatum debiti. Real security provides the creditor with a limited real right in the property of the debtor as security for the repayment of the principal debt. Real securities are of two types: legal securities and securities by agreement. For the purpose of this paper, we will only consider security by agreement. They are of three types: Pledge, mortgage, and cession in securitatum debiti. Those are real securities born out of an agreement between the debtor and the creditor. Their definition is of essence to this study.

Pledge is a right over the movable or incorporeal property of another which serves to secure an obligation. The debtor provides his assets to the creditor in pledge until full payment of the debt. In the restrictive sense, a mortgage refers to the real security right over an immovable property for which a mortgage bond is registered in the Deeds Office. Cession in securitatum debiti is real security related to incorporeal property whereby the debtor pledges his creditor’s rights against third parties to the creditor of the principal/extant debt.

OHADA countries, in their capacities of former French colonies, have adopted the classification of property under the French Civil Code. In line with Article 516 of the Code, there are two kinds of property: movables and immovables. Immovables refer to property immovable either by their nature (example of lands) or by destination (example of animals attached to farming). The traditional definition of property under the French Civil Code did not accommodate intangibles as a category. It was the subsequent analysis of the Doctrine that came to establish financial intangibles such as shares and industrial intangibles such as IP. Prior to the reform in 2011, OHADA security law did not specifically accommodate the particularities of IP. IP securitisation was only acknowledged as an element comprising the fonds de commerce. Article 53 of the former law referred to the OHADA regional IP law – The Bangui Agreement of the African Organisation of Intellectual Property – for the

36 Ibid.
legal regime applicable to the pledge of IP rights. The latter was indisputably silent on the matter.\textsuperscript{45}

However, on 15 December 2010, to palliate the restrictions noticed at the regional level and related to the securitisation of intangibles, OHADA Member States revised the regional security law to beautify local jurisdictions into a more attractive business environment, especially in the context of secured transactions.\textsuperscript{46} The OHADA Revised Act (The new law) offers more security options to borrowers and financing institutions, especially in the field of IP, including the assignment of receivables by way of security, cash collateral, and the pledge of IP rights. In OHADA, IP rights such as trademarks, trade names, and designs can be pledged. The term pledge, such as used in the OHADA Uniform Act organising securities, refers to the allocation by the settlor of any part of his IP rights as security for a debt.\textsuperscript{47} OHADA lawmaker has nevertheless subjected the pledge of IP rights to new perfection formalities. The pledged IP right must be registered in one of the special registries in order to perfect the pledge.\textsuperscript{48} It is worth noting that besides the pledge, IP rights can still be included in a pledge of fonds de commerce.

This reform certainly enables the use of copyright to bolster creative industries’ financing efforts in OHADA. Lenders have been clothed with the capacity to protect themselves by requiring copyright as collateral that the financial institution can use in case the borrower defaults.

Analysing copyright securitisation implies a necessary understanding of the dual nature of copyright as property under real security law and right under commercial law.

\textbf{b) Theoretical Foundations of Copyright Recognition as Real Security}

An understanding of copyright as a legal entity and right presupposes a review of the philosophical bases for the protection of private property. The mentioned theories are well rooted in intellectual property.

Firstly, the Natural Rights perspective:

Natural law grants property rights to everyone over the work of his hands.\textsuperscript{49} The fact that labour is the unquestionable property of the labourer. Such works could be creations, books, music, paintings and sculptures, films, or technology-based works (such as computer programs and electronic databases). Those works are the fruit of the copyright owner’s sweat of the brow.\textsuperscript{50} Works are fruits, providing copyright over the work to the copyright owner, as to a labourer.\textsuperscript{51} Hettinger\textsuperscript{52} notes that:

The author’s natural property right gives him the right to use his work. Transfer of copyright is one component of the right to use the property right in the thing produced by the author.

Secondly, the utilitarian/economic incentive perspective: Utilitarian theorists promote the rewards of copyright authors with enforceable rights. The South African Copyright Act of 1978 thereof provides that the owner has exclusive rights to do or to authorise the acts of:

- Reproducing the work in any manner or form;
- Performing the work in public;
- Broadcasting the work;

\begin{footnotes}
\item\textsuperscript{47} The OHADA Uniform Act organising securities, 2011 (Rev.), Article 156, defines Pledge of IP as: an agreement whereby the settlor allocates as security for a debt all or any part of his existing or future IP rights such as letters, patent, trademark and trade name, design and registered pattern.
\item\textsuperscript{48} The OHADA Uniform Act organising securities, 2011 (Rev.), Article 160.
\item\textsuperscript{49} Locke J, Two Treatises of Government (Awnsham Churchill, 1689); Merges RP, (n 39).
\item\textsuperscript{50} Walter v Lane [1900] AC 539.
\item\textsuperscript{52} Ibid.
\end{footnotes}
No one has the right to perform those acts without his or her prior consent or license. Only the owner has the exclusive rights to do or to authorise. Otherwise, unauthorised acts shall amount to an infringement. Copyright is, therefore, a right serving the purpose of stimulating artistic creativity for the general public good. The economic perspective theory values copyright as a commercial right. Copyright, in this vein, protects commercially valuable products of the human intellect.

From these two theories flow the legal and commercial aspects of copyright as real security.

C. DUAL NATURE OF COPYRIGHT SECURITISATION IN SOUTH AFRICA AND OHADA: DOCTRINAL APPROACHES RELATED TO THE INCOMPATIBILITY OF PLEDGE WITH DISPOSSESSION AND IMMATERIAL PROPERTY

Generally, real security involves an overlap between the law of property and the law of obligations. Copyright as real security comes into operation through a consensual transaction, i.e., the copyright owner using his/her rights over a work to secure a loan facility from a financial institution. The loan is served in line with the terms of the credit agreement. The use of copyright as security for a loan prompts the IP owner to repay the loan in terms of the loan agreement.

a) The South African Perspective and Traditional Roman-Dutch Law

Creating legal security over copyright involves legal and commercial aspects.

Firstly, it is trite law that IP is an intangible property that lacks a physical existence. In line with the traditional Roman-Dutch school of thought, private property is an incorporeal thing. Roman-Dutch law regards actions real and personal as incorporeal things. As such, personal actions could be dealt with in the same way as corporeal things; they could be sold, mortgaged and pledged. However, because they are intangible, it is not possible to possess an incorporeal thing and, therefore, to transfer ownership by means of delivery. This is supported by Boshoff J. in Oertel NO v Brink, who specifically underlined that:

but in the case of an incorporeal right, such right is not capable of possession in any physical sense, and there cannot also be a real delivery of such right.

In the traditional Roman perspective, there can only be delivery by means of quasi-delivery, otherwise called cession. Delivery is by way of a cession of the right, and the cession which the cessionary has is a quasi-possession.

The contemporary approach to the transfer of incorporeal has nevertheless witnessed a shift from the traditional position. Transfer of immaterial encompasses personal rights. A personal right is a property and can be transferred from the estate of the copyright owner to the estate of a financial institution. Consideration is given here to the legal relationship between a legal subject and the object of the right, for example, the copyright owner and his/her works of creativity. Copyright under the contemporary approach can be transferred from one estate to another. This transfer is regulated by the Copyright Act dealing with intellectual creations.

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54 The Copyright Act of 1978, s. 23.
55 The US Copyright Act of 1909, Article 1, s. 8, Clause 8.
57 Brits R (n 33) 3.
59 Lubbe G (n 37) 409-420.
60 Oertel NO v Brink [1972] (3) SA 669 (W) 674D.
The South African Copyright Act, 1978 (Copyright Act) organises the transfer of copyright in section 22 of the Copyright Act. In line with these dispositions, copyright is transferable by assignment. Karijiker\(^62\) notes that:

The equivalent South African concept to an assignment under English law is the cession [...]

thus, the concept of the assignment of copyright appears to have been simply transposed into South African law.

This transposition is nevertheless with a different meaning. Cession under English law is limited to rights, while assignment under South African law involves both rights and obligations.\(^63\) Copyright as a legal right relates exclusively to the law of property. In this context, it can be transferred in South Africa, as underlined above, via a cession, which regulates the transfer of assets in the context of property law.\(^64\) The object of the copyright being intangible, a bundle of rights related to copyright is incorporeal by nature. Van der Merwe and De Waal underline the difficulty to recognise incorporeal as property from a doctrine perspective.\(^65\) Nevertheless, South African Courts recognise a personal right (example of copyright) is incorporeal. In addition, copyright is classified as a movable property under the Copyright Act.\(^66\) As moveable incorporeal property, in which way can real security rights be created over copyright? Once the copyright work is created and the exclusive right granted to the author subsists in work, those rights, statutory provided, constitute property. The author of the work has real rights over those legal objects in spite of the fact that those are incorporeal rights.\(^67\)

In the absence of a statutory provision on security over IP, except the hypothecation of registered IP rights (for example a trademark, where the deed of security is duly endorsed in the trademarks register\(^68\)), Courts in South Africa have resorted to legal mechanisms to obtain rights of real security over copyright. South African Courts and scholars have admitted that incorporeal movable property may be pledged by means of a security cession\(^69\). This seems to be an acceptable solution after years of debates and philosophical arguments.

In Louis Pasteur Hospital Holdings (Pty) Ltd v Bonitas Medical Fund\(^70\), the Supreme Court of Appeal recalled the legal principles regulating the cession of rights in South Africa:

Since the object of a personal right is as yet unrealised performance due by another, delivery by the cedent or possession by the cessionary is not, in a physical sense, possible. A transfer is accordingly achieved not by reference to the object of the right (the performance) or the concurrence of the debtor who is to render it, but by the interactive meeting of minds of the transferor and the transferee. By their mere agreement, the transfer is affected, irrespective of the prior knowledge or consent or the subsequent notification of the debtor.

The South African solution offers the advantage to accommodate the dual nature of copyright: copyright is a movable property, and pledge is security over moveables, and the commercial aspects of copyright are taken into account by the contractual legal aspects of cession.

\textit{A fortiori}, this appears as a legal incompatibility of terms. Firstly, a pledge is a security over corporeal movable property, while copyright is movable incorporeal.

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\(^62\) Karijiker S (n 35).
\(^63\) \textit{id.}
\(^64\) Consolidated Finance Co Ltd v Reuvid [1912] TPD 1019:1024.
\(^65\) Karijiker S (n 35).
\(^66\) The Copyright Act of 1978, s. 22(5).
\(^67\) Karijiker S (n 35).
\(^68\) See section 41(3) of the Trademarks Act 1993.
\(^69\) There has been a remarkable transformative approach in the recognition of “cession of rights” in South Africa. In 1965, the older approach to the nature of cession was admitted in Gunman v Latib 1965 (4) SA 715 (A) 722A. For the first time, the transfer of personal rights was considered by South African courts in the case Trust Bank of Africa Ltd v Standard Bank of South Africa Ltd 1968 (3) SA 166 (A) 172H. The problems flowing from this approach were underlined by Van den Heever JA in the judgment of First National Bank of SA Ltd v Lynn 1996 (2) SA 339 (A) 350A.
\(^70\) Louis Pasteur Hospital Holdings (Pty) Ltd v Bonitas Medical Fund (2018) ZASCA 82 (31 May 2018).
Secondly, a pledge presumes dispossession of corporeal movable property; meanwhile, the incorporeal nature of copyright precludes dispossession. Courts have nevertheless recognised the pledge of incorporeal characterising security cessions.

Considering copyright as a personal right refers to patrimonial rights regulated by the law of obligations. Courts in South Africa emphasise that the only way in which personal rights can be employed as security is by means of an outright cession coupled with a fiduciary agreement. This type of cession will be analysed in the section discussing the practicability of using copyright as collateral in the lending market in South Africa.

b) The Practicability of Using Copyright as Collateral in the Lending Market in South Africa

South Africa considers rights as an asset in a person’s estate, which can be transferred at will. Securitisation has become a common form of credit security, ensuring access to credit in the country. Security cession is one of the tools of securitisation which allows one to monetise copyright assets. The author of a work can agree with a bank for the cession of his/her copyright for the purpose of backing a loan request.

Any right entitlement in copyright vested in the copyright owner can be construed as such. Copyright security cession occurs with the copyright owner transferring his bundle of rights (or part of it) to the cessionary to back up his loan. This position is voiced by South African academic authors such as Du Bois in Wille’s Principles of South African Law. Pledges have been specifically tailored for movable corporeal property, while copyright is movable incorporeal property in the nature of a bundle of personal rights. In other words, it is not the copyright itself that serves as security, but the personal rights as represented in the bundle of rights. The cedent/copyright owner is deprived of his rights, which subsequently vest solely in the assignee. A deed of cession is the sole document evidencing the transfer of the copyright owner’s personal rights to the financial institution offering the credit facility.

c) Distinguishing between Assignment and Cession

In the case of cession, there is a transfer of a personal incorporeal emanating from an obligation by means of a real agreement made between the cedent and cessionary and arising out of a justa causa. The cessionary can cede his right to someone else if they choose to do so. Under the regime of cession, for any right that the cedent has ceded to the cessionary, the latter will become the owner of the right. The cedent would no longer have any claim to that right.

On the contrary, under the law of insolvency, an assignment amounts to a transfer of right and not a proper form of real security. The bundles of rights (or a part of it) pass to the assignee, but not the ownership. If the assignee becomes insolvent, the copyright forms part of the assignee’s estate. In terms of s. 1(1) of the Security by Means of Movable Property Act 53, the registration of a non-possessory pledge over movable property requires the asset to be ‘specially described and enumerated’, and the possibility of obtaining actual possession of the property serving as the object of security. The strict peculiarity under the Act limits – the integration of open-end assets such as personal rights as security objects.
This is not the same under Copyright law where an assignment extent to the complete transfer of rights.78

d) Distinguishing between out-and-out Cessions and Cessions in Securitatem debiti in South Africa

A cession deals with the transfer of an incorporeal thing (personal right or claim) by agreement. In South Africa, the law regulating real security in lending transactions is remarkable for its pragmatism. The law of financing offers several ways of securitisation of the economic interests in the copyright. In terms of real security law, security over incorporeal moveable property, South Africa operates in practice two types of cession of right: an out-and-out cession and a cession of incorporeal rights commonly identified as in securitatem debiti.

The first type of security cession is an out-and-out cession, otherwise called outright cession. Lubbe defines outright cession as a cession effecting an alienation of rights, a complete transfer of the right to the cessionary.79 An outright security cession vests in the cessionary the right in all its aspects. The cession entitles the cessionary to do whatever he wishes to do with the rights. An illustrative example is the case of Louis Pasteur Hospital Holdings (Pty) Ltd v Bonitas Medical Fund,80 where the cedent testified that the policies which were subsequently ceded to replace the initial policies were an outright cession which resulted in ownership of the policies by the defendant and that this entitled the defendant to do whatever they wished to do with the policies.

The second type of security cession is a cession in securitatem debiti. In this case, the cedent is not wholly divested of interest in the asset he provided as security to the cessionary.81 He retains a reversionary interest. The cessionary will re-cede the rights to the cedent upon satisfaction of the secured debt. The right related to the bundle of rights does not transfer and remains in the copyright owner’s estate.

A cession in securitatem debiti is in effect an outright cession in which an undertaking or pactum fiduciae that the cessionary will re-cede the right to the cedent on the satisfaction of the secured debt. This was underlined by the court in the case of Lief, NO v Dettmann.82

e) OHADA: Departing from the Napoleonic Possessory Ownership

In OHADA, security laws are derived from the Napoleonic Code or the French Civil Code, inherited from the French colonial master. The Napoleonic Civil Code regulating security and property matters is based on possessory ownership, which facilitates the pledge of physical assets only, and therefore creates fundamental limitations regarding the securitisation of intangibles.84 French rules governing the validation of collateral in credit transactions, such as adopted under OHADA laws, did not favour the Member States’ knowledge economies. This prompted the following critique against economic elites’ thought to exert pressure over the design of legal contracting frameworks, seeking arrangements that benefit their interests.85

The non-recognition of intangibles as property and flagrant incompatibility between the immateriality of intangibles, and the dispossession requirement under pledge as recognised security, have fuelled abundant doctrinal literature like in the South African context. In

78 See Sec. 3.1.2. in this paper.
80 [2018] ZASC 82.
81 National Bank of South Africa Ltd v Cohen’s Trustee [1911] AD 235.
82 [1964] SA 252 (A) at 271H.
83 Aretz K, Campello M, Marchica M, 'Access to Collateral and The Democratization of Credit: France’s Reform of The Napoleonic Security

84 Code Civil Napoleon 1804, Article 2075.
response to the Doctrinal debate, French lawmakers have alternated throughout the 20th century securities with or without dispossession in the case of intangibles. Pothier, for example, affirmed that an incorporeal could not be pledged in the absence of dispossession, which is the essence of a pledge.86

Finally, on 23 March 2006, the French law governing security interests was reformed.87 The country officially derogated from the notions of possessory asset ownership applicable since the birth of the Napoleonic Civil Code in 1804. The scope of assets capable of being collateralised has been extended as a fundamental benefit for the betterment of securities offered to credit lenders.

This reform echoed in the OHADA region a few years later. The 2011 OHADA Revised Uniform Act (Revised Act) organising securities has introduced the specific pledge of intellectual property assets in the region coupled with a double range of precautionary measures for financing institutions.

Firstly, the act of pledge must be in writing. The written agreement formalises the existence of the loan.88 It serves as evidence in case of default and redeployment. OHADA security law sanctions the inobservance of the writing exigency by the nullification of the agreement.89

Secondly, the exigency of a range of specific information. The act of pledge must specifically underline the names of the creditor, debtor, and settlor of the pledge.90 Elements permitting the determination of rights allocated as security shall be provided.91 The Revised Act equally requires the designation of elements permitting the identification of the secured debt with information related to valuation, duration, and settlement date.92

The reform in OHADA was a two-ways benefit: Firstly, IP owners had to be protected as borrowers from negative conceptions related to intangibles. Pledge over IP rights was officially organised. Secondly, new requirements for creating and perfecting securities came to protect creditors from difficulties related to the surrender of collateral in case of borrower’s default.

i) Creating and Perfecting IP Securities: Reform in OHADA: Conditions Related to the Nature of the Pledged IP in OHADA

The OHADA law reform made several exigencies in respect to the characteristics of the IP asset to be pledged. It could be assets currently in existence or assets to be acquired in the future.93 Pledged assets should be allocated for certain or ascertainable debts. Mentioned debts could be existing or future.94

ii) Pledge Registration and Realisation in OHADA

The resided security law offers more flexibility and a varied option to creditors in terms of security options. The said pledge may be conventional or judicial.95 Consequently, the law has provided a dual institutional regime both conventionally and judicially. Under the conventional pledge, three specific rights have been granted to the creditor who realises the pledge in case of default:

a. A right to pursue the pledged property96,
b. A right to liquidate the pledged property97, and
c. A right of preference over the pledged property.98

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87 Staffel-Munck Premier bilan de la réforme des sûretés en droit français 2012 Dr. et patr. 56.
89 The Revised OHADA Uniform Act organising Securities, Article 127.
90 The Revised OHADA Uniform Act organising securities, Article 157(1).
91 The Revised OHADA Uniform Act organising securities, Article 157(2).
92 The Revised OHADA Uniform Act organising securities, Article 157(3).
93 The Revised OHADA Uniform Act organising securities, Article 156.
94 Ibid.
95 The Revised OHADA Uniform Act organising securities, Article 92(2).
96 The Revised OHADA Uniform Act organising securities, Articles 104 and 105.
97 The Revised OHADA Uniform Act organising securities, Article 226.
On the judicial pledge option, the creditor may be authorised by a court of competent jurisdiction to register the pledge on IP rights. OHADA provisions relating to sequestration of company stocks apply in this case.

iii) Securitisation of IP Rights

Under the South African Exchange Control Regulations as amended in 2012, the concept of capital extends to any IP right, whether registered or unregistered. The Exchange Control Regulations Act moves on by extending the term ‘export’ to cession or assignment or transfer of any IP right to a person who is not resident in South Africa. Security can be obtained over immovable property by special mortgage of such property and over movable things by means of pledge or notarial bond. Under South African law, rights can also serve as security. The South African Copyright Act regulates the assignment of copyright in section 22. It provides that copyright is transmissible as movable property by assignment. The possibility to treat the bundle of rights existing in copyright as moveable property is of utmost importance for the growth of the credit market. This legal recognition enables the copyright owner to use the exclusive rights attached to his created work to secure a loan to finance his business. Enlarging loan securities beyond tangible assets is crucial for economic development in the 21st century knowledge economy. Admitting the transfer of tangible rights gives knowledge holders the ability to partake in business and trade on equal footing with real right owners. The creator of a work desirous of developing his business can seek a loan facility from a financial institution. The recognition of rights’ transaction gives creators the possibility to transfer their rights over the created work as a backup in case of default in payment.

The transfer of the literary and artistic works on the packaging of audio recording tapes is an illustrative example of the transfer of copyright. This was illustrated in the case of Frank & Hirsch (Pty) Ltd v A Roopan and Brothers (Pty) Ltd, where the manufacturer of audio recording tapes successfully transferred the get-up of the audio recording tapes, the design of the packaging for the tapes and the wording found on the wrapper used as packaging.

The author of a copyright work can cede his rights in the copyright to a financial institution as security for a loan. The transfer operates through a copyright assignment agreement. It operates as a transfer of personal rights with the substitution of contractual creditors.

In OHADA, the Revised OHADA Uniform Act organising securities does not, unfortunately, bring clarifications on the mechanisms regulating the pledge of copyright. In the OHADA region, rights relating to the field of copyright are independent national rights subject to the legislation of each of the Member States in which they have an effect. Though the pledge has been recognised by the Act, the organisation and procedure taking into account the specificities of IP rights categories have not been legislated upon by national copyright laws. To fill this vacuum, an examination of the dispositions of the regional copyright law applicable to OHADA Member States seems necessary.

If the Bangui Agreement grants exclusive rights to the authors over their creativities, the regional Intellectual Property Code of Francophone African nations will have

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99 The Revised OHADA Uniform Act organising securities, Article 158.
100 Exchange Control Regulation Act of 2012, regulation 10(4).
102 Deed Registries Act of 1938, s. 50.
103 Appellate Division, Per Corbett CJ, Botha JA, Goldstone JA, Nicholas AJA, Hamas AJA, 2 June 1993.
104 Lubbe G (n 37) 409-420.
failed to organise the management of copyright in the area of securitisation. Copyright nevertheless grants authors exclusive rights over created works. They have the right to grant authorisation or proscribe the use of those works such as communication to the public, reproduction, broadcasting, adaptation, etc. Same as in South Africa, the OHADA regional IP Code acknowledges the assignment of rights in the management of copyright exclusive rights:

Economic rights shall be assignable by transfer 

Intra vivos.

The World Intellectual Property Organisation (WIPO) defines an assignment as:

A transfer of a property right. Under an assignment, the owner transfers the right to authorise or prohibit certain acts covered by one, several or all rights under copyright.

The Berne Convention (1971) grants the copyright owner the right to assign his work. The owner of a copyright may freely assign any or all his rights to a third party. The copyright assignment can apply only to the acts which the owner of the copyright has the exclusive right to control.

As stated above, in South Africa, the transfer of copyright as security can only be done by cession. South African practice of assignment is a security cession which is a transfer of incorporeal rights deriving from a real agreement. In this case, the property passes to the cessionary, who loses the right to claim that right. This is not the same in the case of assignment where the copyright forms part of the assignee’s estate. Only the right passes to the lender in case of assignment.

Copyright assignment refers to the transfer of the owner’s property rights in the created work. The person to whom the rights are assigned becomes the new copyright owner or right holder. By assignment, the author completely divests him/herself of one or more of their rights under the copyright so that the assignor no longer has any claim to these rights, nor can he/she perform any of the acts covered by the particular rights without the authority of the assignee.

The assignment, such as conveyed to a lender, grants the borrower all economic rights. All ownership interests existing in the work pass to the lender mutatis mutandis. Nevertheless, if the assignee becomes insolvent, the copyright forms part of the assignee’s estate. A copyright assignment could be total or partial. Dean and Dyer emphasise that copyright as a bundle of rights is divisible. Thus, an assignment of copyright can be restricted through any of the following:

- in terms of the acts which the owner of the copyright has the exclusive right to control;
- in relation to the term of the copyright;
- according to a specified country or other geographical areas.

The copyright owner who owns a created literary, artistic, or scientific work is clothed with an ownership interest in that property. He may borrow money from a financing institution and use his copyright as security, subject to the principle ‘nemo dat quod non habet’ implying that at the time of the Agreement, the work must be owned by the copyright owner, as one cannot give what he does not own.

110 Timgou, op cit.
111 Bangui Agreement of 1999, Article 34.
114 Lief NO v Dettmann [1964] (2) SA 252 (A) 271 E-G. Where Vessels JA underlined that: ‘The only manner in which a right of action (either secured or unsecured) can be furnished as security for a debt is by way of cession.’
116 David Feldman No and Emi Music Publishing SA (Pty) Limited (unreported) Case No. 06/23129.
118 The Copyright Act, 1978, s. 22(2).
have. The assignment of the copyright in the secured transaction can be prescribed for a particular period, after which the copyright owner’s proprietary interests are restored – subsequent to the repayment of the loan. In the case of David Feldman, No and Emi Music Publishing SA (Pty) Limited,\textsuperscript{119} Jajbhay, J. sitting in the High Court of South Africa, Witwatersrand local division, emphasised in his judgment that the assignor loses all his entitlements in respect of the specific rights transferred by virtue of the assignment.

An example could be the assignment of software exploitation right for the financing of the exploitation of this software. When the copyright owner applies for a loan using his copyright as backup, it is the duty of the creditor to carefully check the borrower’s right over the copyright. This should be done prior to granting the loan. The security interest in the software copyright precludes anyone else, including the previous or original copyright owner (borrower in the secured transaction), from using the creation.\textsuperscript{120} The financier as assignee is entitled to sue for infringement of the copyright. This unveils another limitation of IP securitisation. The lender might not have the knowledge of IP management, which could alter the interests and entitlements of the copyright under his control.

South Africa permits the transferability of personal rights created by obligations through a cession of rights or cession in securitatem debiti. The cession in securitatem debiti resembles pledge and that the cedent is not wholly divested of interest in the asset he provided as security to the cessionary. Notwithstanding the cession, the cedent retains what has been described as a reversionary interest.\textsuperscript{121}

Transmission operates by means of the pledge without dispossession. The bundle of rights in copyright are legal entities with monetary value. They are therefore transmissible by means of cession. It is trite law in South Africa that an agreement through which the cedent consents for the transfer of his personal rights to the cessionary amounts to a cession.\textsuperscript{122} It affects the passing of personal rights from the cedent to the cessionary;\textsuperscript{123} however, the title of the right remains with the cedent. This solution enables pragmatic financing by allowing securitisation of copyright.

The cession here operates through the concurrence of the wills of the copyright owner and the financial institution.\textsuperscript{124} The copyright owner, as cedent, offers his right as security, and the financial institution/creditor as cessionary accepts to provide a loan based on the personal right(s) offered as security to back up the loan. The mutual intention to transfer is sealed in an agreement.

The requirement of delivery related to all movable property is taken into account by the transmission by mere agreement.\textsuperscript{125} This is what prompted Brits\textsuperscript{126} when he observed that ‘A security cession is legally characterised as being in the nature of a pledge, even though the object of cession is incorporeal’.

3. VALUATION

Copyright can be used for commercial lending. However, the copyright industries can only borrow up to the value of their creativities. Financing in this context requires relative probability.\textsuperscript{127}

\textsuperscript{119} (unreported) Case No. 06/23129.
\textsuperscript{120} See Dean 1993 ELR, Case Comment South Africa – copyright: parallel importation of artistic works: ‘…Having acquired ownership of the South African copyright in the relevant works, F&H got their attorneys to write a sequence of letters to Roopan and informing them of F&H’s ownership of the South African copyright in the works in question and advising them that if they continued to trade in grey TDK tapes embodying the reproductions of the relevant works, they would infringe F&H’s copyright…’.
\textsuperscript{121} Karijiker S (n 35).
\textsuperscript{122} Preformed Line Products V Hardware Assemblies 210 Kumleben J 202 Joc (N).
\textsuperscript{123} Brits R (n 33) 142-182.
\textsuperscript{124} Lubbe G (n 37) 26-27.
\textsuperscript{125} 121 Louis Pasteur Hospital Holdings (Pty) Ltd v Bonitas Medical Fund, [2018] ZASC 82 (31 May 2018).
\textsuperscript{126} DL 450 ‘IP as Collateral’, WIPO/OMPI, 2018, 26.
It is crucial for the financing institution to know the exact value of the collateral which should be sold in case of default. Copyright valuation becomes, therefore, an important prior financing transaction to enable lenders to determine the value and, therefore, the credibility of the collateral in the market.

The successful appropriation and exploitation of IP rights is a source of huge economic impact. Consequently, corporate valuation relies greatly on intellectual assets such as copyright based on IP potential in creating economic growth, enhancing productivity and profitability, and increasing enterprise value. Ellis and Jarboe purposely wrote:

As intangibles emerge as an asset class, large investment banks and boutique private equity firms alike have begun raising and investing funds targeted at IP and other intangible assets... these firms are targeting the traditional venture capital space, looking for promising early-stage innovation and inventions.

If innovation can boost economic growth, it must nevertheless be accompanied by the securing of the associated knowledge as IP. IP cannot engineer economic development in the absence of a successful valuation.

Valuation of the collateral is important not just for the borrower in quest of collateral but also for the financial institution lending the money. Anson notes that two types of questions must be answered when valuing and envisaging the sales of IP assets: firstly, the value and ownership of IP, and secondly, the practicality of the valuation process. Knowledge of the accurate value of the copyright asset offered as collateral is crucial. The practicability of the valuation method is essential.

Nevertheless, copyright as incorporeal property poses specific problems in utilising them as security objects due to their intangibility. Copyright lacks physical substance and, as such, is difficult to value, especially in the absence of a clear situs. Examples are customer lists, databases, novels, etc. Copyright is an IP right and intangible by nature. Contrary to other tangibles (such as assets), IP assets are created by statute, protected by statute, and enforceable in terms of the statute. Unlike tangible assets, copyright does not exist in physical locations. Copyright constitutes resources controlled by individuals or companies or as a result of assignment or self-creation. From copyright, only future economic benefits are generally expected in terms of inflows of cash or assets.

This is not the case in practice with traditional forms of security such as mortgages, pledges, or notarial bonds over corporeals. Those securities over tangible property are frequently encountered and are unproblematic. Taking security over copyright gives rise to various concerns. Except in the case of copyright of a thing over the material creation of the copyright author, it could be difficult to determine the value copyright considered in this case as personal of the right. A creditor relies entirely on its security for the satisfaction of his claim and needs to be assured of its financial reliability.

Despite the above challenges, several jurisdictions have witnessed creative businesses overcoming challenges associated with access to finance buying their IP assets as collateral. The asset-backed music securitisation of Davie Bowie is an illustrative example. The artist made USD 55 million by issuing 10-year bonds out of future revenues from the 25 albums in his back catalogue.

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131 Anson 2008 The Licensing Journal, 3.
133 133 Bank of Lisbon and South Africa Ltd. v Master of the Supreme Court [1986] ZASCA 121; [1987] 1 All SA 286 (A) (30 September 1986).
134 (n 6) 9.
WIPO mentions that the practice of IP as collateral in lending transactions is a recent phenomenon in developed countries.\textsuperscript{136} It becomes important to analyse how to determine the value of copyright in secured transactions?

According to Financial analyst CONSOR in the United States, the first step in the valuation of the IP asset consists in determining the portfolio of copyright assets. In this vein, groups of intangible assets under copyright should be gathered and bundled.\textsuperscript{137} Art-related intangible assets falling under copyright in a company could include, for example, (i) literary works, (ii) musical compositions, (iii) photography, (iv) maps, and (v) engravings.\textsuperscript{138} While, IT and database intangibles would include, for example, operating systems, mailing lists, proprietary software, databases, logo drawings, manuals source code. After the determination of the portfolio of the copyright assets, the financing institution and borrower can start placing value on those assets. That is the valuation process. A financial institution providing a loan on the basis of copyright assets must necessarily access its value. Several methods can be used to determine the fair market value of the IP collateral. Valuation methodologies generally depend on the information available and the specific circumstances.\textsuperscript{139}

The cost approach values the IP according to its current or historical costs. This value could sometimes encompass the difference between the cost for the creation of the work and replacement cost or assessment of the expenses necessary to replace the IP given as collateral.\textsuperscript{140}

In view of the specificities of the African creative industries, and in a context where OHADA has been regarded by some economists as a neoliberal institution with market-oriented reform policies, this paper argues that the valuation of such assets shall be determined by the value of labour, or the costs of labour put in the production of the copyright collateral. Copyright collateral could equally be determined on the basis of the usefulness of the copyright collateral to African society.

A. DIFFICULTIES PERTAINING TO THE SECURITIZATION OF IP RIGHTS

This section critically examines the challenges of the use of copyright as bank lending backup in secured transactions in both South Africa and OHADA countries. What are the risks related to the securitization of bundles of rights in copyright as means to raise funds?

Creditors face numerous impediments when taking security in copyright. Existing hindrances relate, among others, to conflicts between IP law and security law, valuation, risks related to the personal nature of the assets backing the security, and absence of registration which prevents securities from being perfected.

a) Difficulties Related to the Absence of Registration

In the OHADA region, the fact that copyright as property is not subjected to registration requirements and issuance of a certificate of registration by public authorities as part of registration mechanisms, advertising, and other formalities aiming its opposability to third parties is an important restricting factor.\textsuperscript{141} This makes it difficult for copyright to be used as collateral in loan transactions.\textsuperscript{142}

Both regional security and IP law of OHADA Member States did not figure out securitisation mechanisms applicable to copyright assets. To fill this gap, practice usually refers to the conventional system using the exclusive rights granted to the copyright owner as a loan backup.

\textsuperscript{136} Id.
\textsuperscript{137} Anson and Samala 2014 TLJ 1.
\textsuperscript{138} Anson and Samala 2014 TLJ 1.
\textsuperscript{139} Anson and Samala 2014 TLJ 2.
\textsuperscript{140} Anson and Samala 2014 TLJ 2.
\textsuperscript{141} Code de Propriété Intellectuelle Français, Article 5(1).
\textsuperscript{142} See, for example, De Visscher et Michaux Précis du droit d’auteur et des droits voisins, Bruxelles, Bruylant 55.
Since courts in Francophone African countries often refer to the position of French lawmakers to fill the gaps in national legal systems, it is important at this stage to highlight significant development in France concerning the securitisation of copyright assets.

French lawmakers have established the pledge of software exploitation rights and also the pledge of cinematographic works.

The pledge of software is a collateral agreement seeking to use software exploitation rights as a backup for a loan. The main purpose is to promote the financing of the creation of software. The rules of IP specify that in this case, the software is not transferred but the rights associated with it.

The law made the exigency of a written Act and registration at the special register of France National Institute of Intellectual Property (INPI). In case of default, the financing institution could exploit the rights. This was confirmed by France Cour de Cassation for the pledge of cinematographic works. The financing institution in this case is clothed with the legal capacity to recover the royalties of a defaulted debtor whose works have been duly registered. Recovery is up to the due amount, and according to the registration order.

In OHADA, where the registration to the special registry has expired, the sale of pledged assets become null and void.

Another difficulty relates to the fact that the bundle of rights subsisting in copyright is not evidenced by a document. They exist by the mere fact of the creation of the work. In the South African Copyright Act, the term author refers to the person who first makes or creates the work. The copyright is automatically granted at the creation of the work without any registration or other formalities, except for cinematograph films and traditional works. In the absence of formalities registration, concrete evidence of the existence of copyright proposed as debt backup is absent. In addition, in the case of transfer, a mere consensus translated through an agreement is enough to realise the cession. This state of regulation weakens the reliability of copyright as a backup in secured transactions. Unscrupulous copyright owners could transfer the same right to several authors without the knowledge of the lender. This is aggravated by the fact that there is no notification of the assignment of rights to third parties.

b) Difficulties Related to the Personal Nature of Copyright

The associated perception risks of intangible assets have greatly hampered their utilisation in capital markets.


150 Traditional works should be registered in a national database. See section 28C of the Copyright Act as amended by s.4 of IPLAA.

Copyright, in particular, does present odd risks as a form of real security.

Firstly, due to the abstract nature of intangible assets as non-physical property, it is often difficult to determine the nature and effect of security over these assets. The possibility to apply the general principles found in property law to intangible property and to use these to determine its suitability in secured transactions have been subject to doubts.\textsuperscript{154} The reason is that while adopting the principle of securitisation of incorporeal rights, there has not been an adoption of legislation that fits this special regime. To fill the gap, judges revert to the principles of the pledge, which is not always suitable.\textsuperscript{155}

Secondly, in South Africa, for example, legislators have not amended the corresponding dispositions of securitisation in the law of insolvency. Consequently, uncertainty arises in the case of the debtor’s insolvency. If the right passes to the financial institution during the assignment of rights, the property remains in the debtor’s estate in case of insolvency.\textsuperscript{156} This is far from favouring the lender’s interests. In the absence of a lien over the assigned rights, the debtor can cede those rights at will to a third party.

Thirdly, the status of moral rights during the assignment of copyright is another element acting against the use of copyright as collateral in secured transactions. Beyond the economic rights related to the commercial exploitation of the work, copyright does have a clearly recognised proprietary basis tied to the author’s personality. It is well established at the international level under international copyright conventions that independently of the author’s economic rights, and even after the transfer of the said rights, the author shall have the right to claim authorship of the work and to object to any distortion, mutilation or other modification of, or other derogatory action in relation to the said work, which would be prejudicial to his honour or reputation.\textsuperscript{157} Under the South African Copyright Act, an author may not prevent or object to modifications that are absolutely necessary on technical grounds or for the purpose of commercial exploitation of the work. The above applies exclusively when the author has authorised the use of his work in a cinematograph film or a television broadcast or an author of a computer program or a work associated with a computer program.\textsuperscript{158} The right to claim authorship of the work\textsuperscript{159} and the right to object to any distortion of the work are distinctive features of the moral rights in copyright.\textsuperscript{160} They are purely personal, non-economic rights and belong to the creator of the copyright work. As such, moral rights do not create any rights of property and are incapable of cession.\textsuperscript{161} How does the personal nature of moral rights hinder/promote the assignment of copyright as security in a loan transaction? Moral rights influence in a substantial manner the determination of copyright security during three important stages of the life of security:

1) prior to the grant when the debtor applies for the loan;
2) during the grant, when copyright management is needed; and
3) at the end of the loan period, in case of default payment and exploitation of the copyright work by a subsequent owner of the copyright.


\textsuperscript{155} Van den Heever JA in the case First National Bank of SA v The Master [1987](1) SA 276(A) assimilated for example the cession of rights to ‘the legal institution of corporeal things’. This mistake was later explained by the judge as ‘...scholars and lawyers trying to prise one legal concept into the gourd not ideally suited. Cited by Lubbe G, (n 34) 419.


\textsuperscript{157} Berne Convention for the Protection of 1971, Article 6bis.

\textsuperscript{158} The Copyrights Act, 1978, S 20(1).

\textsuperscript{159} Example, the removal of the publisher’s name infringed its moral right as author of the Programme in the case Technical Information Systems v Marconi Gildenhuyus JJ 1047 JOC (W) Witwatersrand Local Division, 16 March 2007.

\textsuperscript{160} WIPO Intellectual Property Handbook 46.

\textsuperscript{161} Visser and Pistorius Essential Copyright Law 1, 5 & 26.
Non- recognition of the copyright owner’s moral rights during a copyright cession will amount to infringement. The breach of rights of the copyright owner could impair the exploitation of the work in case of work related to the reputation of the author, or his physical performance, in such a way that the mention of his name will deter cash flow in the exploitation of the work, and therefore cause a default payment. To prevent such disagreements harmful to his financial interests, the creditor can require a waiver of moral rights at the time of the cession. It is important for authors to protect their reputation and integrity in the course of any transfer of copyright as security. In South Africa, the Copyright Act has decided in favour of the author’s interests. The proposed amendment to the South African Copyright Act has settled for the non-transferability of moral rights.  

In the OHADA regional IP code, the author’s moral rights subsist even after the assignment of the work. Independently of his economic rights, which have passed to the assignor, the author of a piece of work maintains his moral rights including (i) to claim authorship of his work, (ii) to have his name affixed to copies of his work and, (iii) to oppose any distortion, mutilation or other modification of his work.

Moral rights could stand as obstacles to the redeployment of works of art in case of transfer. This was confirmed by the French courts, usually referred to by OAPI States’ tribunaux. France Cour de Cassation has condemned in this sense a public officer who published the work of art transferred to him for violation of the artist’s moral right to publish his work.  

The author of an artistic work has the exclusive right to publish the work and determine the conditions under which the publication should be exercised. Pledge of the material embodiment of an artistic work by the owner to a third party does not necessarily imply the artist’s will to publish the work.

The law emphasises the automatic acknowledgement of moral rights upon creation of the work. Not doing so would amount to infringement of the copyright owner’s right. In Gabon, an OHADA State, in the case of Madam Christine ROSSANO v Société SOVINGAB, the court ruled that he who contributed to the creation of a work, and whose name has been omitted on the work, can file a lawsuit to have his name affixed on the work, and seek reparation for violation of his moral right to paternity. In the case of collective management of copyright, the transfer only operates for economic rights, but not moral rights, which remain with the author. In the case of copyright assignment, the assignee is responsible towards the assignor for the ways and manners the pledged copyright is exploited. He shall be held responsible when such exploitation infringes the assignor’s moral rights.

Fourthly, based on the divisibility of copyright, it is possible to have different rights in the same work, with numerous right owners for the same work. Professor Cornish explains the numerous ways of exploitation of copyright works; taking a novel as an example, it includes volume rights, serial rights, translation rights, film rights, dramatization rights, electronic rights, etc. To levy fraud and malpractice related risks during the assignment, the creditor needs to ensure that the debtor is effectively the

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162 See the proposed addition of section 20(4) to the Copyright Act as introduced by cl 15(c) of the Copyright Bill. Van der Merwe, et al., Law of Intellectual Property in South Africa 254.

163 Bangui Agreement of 1999, Article 8(1) Annex VII.

164 Chamber civil 1, du 29 November 2005, 01-17.034.

165 Chambre civile 1, du 29 November 2005, 01-17.034.

166 TGI Paris, 11 January 1971, JCP 1971, II 16697


170 Cour de cassation, civile, Chambre civil 1, 4 November 2011, 10-13-410-ess.

owner of the right offered as security. The Copyright Act carefully emphasises this point:

> An assignment or testamentary disposition of copyright may be limited so as to apply to some only of the acts which the owner of the copyright has the exclusive right to control, or to a part only of the term of the copyright [...]

Another aspect is the unsatisfactory character of the physical nature of copyright for the purpose of hypothecation through a deed of security. IP rights are traditionally classified into two broad categories: Industrial property comprised of trade secrets, patents, trademarks, industrial designs, etc., and rights related to intellectual creation comprised of copyright and related rights. In terms of intellectual assets, the Trade Mark Act regulates the hypothecation of registered trademarks. The text allows the hypothecation of a registered trademark. The exigency of attachment should be met in order to confirm jurisdiction for the purposes of legal proceedings.

The abovementioned application could be served on the registered proprietor and any other person recorded in the register as having an interest in the trademark. However, no similar provisions have been made in the case of copyright, which is by nature a similar IP right of an intangible nature. Copyright as a right is not accompanied by a physical manifestation that can serve as authentication of its existence, such as in the case of a trademark, except for certain forms of copyright such as cinematographic films, which usually are subject to registration. Karijiker emphasises that by the mere fact of the similarity between the two:

 [...] giving effect to a hypothecation or attachment of copyright can thus present practical problems, but this does not detract from the principle espoused.

This particular formalism pertaining to industrial property rights categories has been established in OHADA States. There are conventional rules of publicity recognised in OHADA and common to the pledge of business property on patent, trademark, service mark or trade name, designs and model, including:

- registration in the Trade and Personal Property Rights Register,
- be in conformity with the rules of publicity prescribed for deeds transferring ownership of IP rights and the rules of this Uniform Act relating to the pledge of any equipment forming part of the business property.

A special register of trademarks has been, for example, established in this vein in OHADA, as well as a recording of acts in the special register of patents. The regional Code of IP requires that:

> the Administrative Council shall draw up regulations concerning the acts to be recorded in the Special Register of Patents, on pain of their not being enforceable against third parties.

Unlike other types of IP rights, which are registered and therefore used as the object of hypothecation by means of a deed of security, copyright given as collateral can easily be disposed of in the absence of registration backup. It could therefore be a rightful concern for financial institutions in terms of copyright reliability and certainty in security law.

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172 The Copyright Act, 1978, s. 22(2).
173 Trade Mark Act No. 194 of 1993, s. 41.
174 Ibid. s.42(1)
175 Ibid. s.42(2)
176 Warner Brothers Inc. and Others v Melotronics (Pty) Ltd, Cape of Good Hope Provincial Division, where the court mentioned that South African copyright, in several films are usually registered under the Registration of Copyright in Cinematograph Films Act (No. 62 of 1977). In addition, s.26(9) of the Copyright Act creates certain presumptions in regard to the infringement of copyright in films registered in terms of the Registration Act.
177 Karijiker Handbook of South African Copyright Law 1-156.
178 OHADA Uniform Act organizing securities, Article 169.
179 OHADA Uniform Act organizing securities, Article 170.
180 Bangui Agreement 1999, Article 29(4) Annex III.
181 Bangui Agreement 1999, Article 25(1) Annex I
B. LIMITATIONS RELATED TO THE USE OF COPYRIGHT AS A GUARANTEE IN SECURED TRANSACTIONS IN OHADA

The 2011 security reform in OHADA has brought substantial positive changes in the securitisation of IP assets. This has inevitably led to security efficiency in terms of creation, realisation, and enforcement. Nevertheless, some limitations subsist, and which prevent copyright owners from accessing financing institutions for funding purposes:

a) Lack of Registration of Security and Registration of Copyright

Registration of property stands as evidence in case of default. Its absence could negate the creditor’s right.

The second limitation relates to the very recognition of the copyright itself. According to the Berne Convention for the Protection of Literary and Artistic Works\textsuperscript{182} regulating copyright, the enjoyment and the exercise of these rights shall not be subject to any formality. Copyright recognition is not subjected to any formalism, and protection is enjoyed ipso facto (by the mere fact of its creation).

Certain countries operate a register for copyrighted works, and the certificate issued in this context evidences the ownership of the right by the bearer of the certificate, as well as the existence of the copyrighted work.\textsuperscript{183}

However, the absence of proof of the existence of security over the IP and the existence of the right itself creates uncertainty and insecurity in the secured transactions.

b) Difficulties Related to the Perfection of the Security

The \textit{intuitu personae} nature of certain IP rights as copyright operates as an obstacle to the perfection of security. The fact that the creditor is subrogated in the rights of the copyright owner can give rise to abuses and dysfunction in the management of rights.

c) Limits Relating to the Registration of Privileges

In credit practice, the registration of a creditor in the register indicated by the regulations in force allows the creditor to retain his priority as the guarantor. The question of registration of privileges in the perspective of collateral on copyright in the OHADA region raises three issues:

(i) the trade or IP register assigned to copyright;
(ii) the feasibility of pledge of future works as a backup of current loan applications;
(iii) Harmonisation of the pledge of IP rights and collective management.

i) Registration of the pledge of copyright

In terms of the OHADA Revised Security Act, the pledge of intangible movable property is part of movable security. As such, it is subject to publicity and is therefore subject to registration in the register of commerce and securities. Article 170 of the same Act provides that IP rights must, outside the Trade and Personal Property Rights Register, be satisfied with the publication affecting the ownership of IP rights.

The Bangui Agreement, which has not yet ruled on the organisation of security interests in the field of copyright, does not organise the formalities related to the registration of these securities either. Thus, it is the copyright law of the Member States which is

\textsuperscript{182} Paris Act, 1971.

\textsuperscript{183} Bouchoux \textit{La Propriété Intellectuelle. Le droit des Marques, Le Droit d'Auteur, Le Droit des Brevets d'Invention et des Secrets Commerciaux} 201.
Our analysis shows the silence of copyright law in OAPI States with regard to the latter’s contribution as a credit guarantee.

In line with the regional IP Code applicable to OHADA Member States, the total assignment of future works is invalid. The same prohibition stands in member states such as Cameroon. Article 26 Law No. 2000/011 19 December 2000 of the Cameroonian law regulating copyright, the pledge of future works is null and void. Meanwhile, the pledge of copyright as security for future works is authorised by the regional security law. This antagonism between the security law and IP law in OHADA does not favour predictability and certainty in the local market. Pledge of future works as a loan backup is fundamental for the start-up of creative industries.

One of the major developments in the field of administration of copyright in OHADA is the organisation of collective management of authors’ rights. In Cameroon, for example, organisations derive from their members the most extensive powers to exercise their economic rights, such as the rights of reproduction, representation, distribution, and resale. The situation is similar in other States such as Mali, Benin, and Burkina Faso.

Should we conclude from this that any contribution in the guarantee of a national copyright body should be registered in these management bodies?

In order to protect both the financier and the debtor, an extensive legal system of secured financing must be developed. The following section analyses copyright as collateral in securities lending transactions in Africa, taking as an example the practical financing developed by South Africa.

D. CESSION AS SECURITY: FORMALITIES REQUIREMENTS

In the context of the pledge without dispossession, delivery of the instrument validating the right by analogy to the pledge of corporeal movable property symbolises the cession. In the case of shares, another type of movable incorporeal property, the share certificate can be delivered as evidence of the cession. However, in the case of copyright, the law does not make the exigency of registration for the right to come into being.

Such state of affairs negates the predictability of incorporeal as reliable security. This was supported by academic authors voicing against the feasibility of the pledge of incorporeal. Its theoretical unsoundness has been criticised, as well as the likelihood of the existence of real rights in intangible assets, dominium in a personal right, or the existence of a pledge in an asset incapable of being captured by the five senses. Nevertheless, and as above demonstrated, South African courts have opted for the legal recognition of security cession, despite its doctrinal problems.

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184 Bangui Agreement of 1999, Article 3(1), Title 1.
185 Rights relating to the fields of IP, as provided for in the Annexes to this Agreement, shall be independent national rights subject to the legislation of each of the Member States in which they have effect.
186 Revised Uniform OHADA Act organising Securities, Article 50.
187 Bangui Agreement of 1999, Article 37 Annex VII.
189 Bangui Agreement of 1999, Article 34(1), Annex 1:
“The acts referred to in the foregoing Article shall not be enforceable against third parties unless they are recorded in the Special Register of Patents kept by the Organisation. A record of such acts shall be kept by the Organisation.”
186 Du Bois F (n 94).
187 Dean OH (n 117) at 145.
182 De Wet & van wyk kontrakte reg 417-422, cited by Contracts, 497.
184 Van der Merwe Contract: General Principles 497.
The practice of imposing a duty to re-cede the copyright upon payment of the debt is a welcome initiative favouring the interests of copyright owners in financing transactions. It was purposely said by Wessels JA that:

The only manner in which a right of action (either secured or unsecured) can be furnished as security for a debt is by way of cession, i.e., by a transaction which in our law results in the cedent being divested of his rights and those rights vesting in the cessionary. Where the cession is said to be made as security for a debt, it does not, in my opinion, signify that the cedent in fact retains any right in the subject matter of the cession; his continued interest therein flows from the agreement, either express or implied, with the cessionary that the right of action will be ceded back to him upon the discharge of his debt.195

4. CONCLUSIONS

Copyright: Fugitive or Secured Asset? The purpose of this discussion has been to illustrate the related concerns in taking copyright as security in secured transactions in Africa as a foyer of creative industries. The analysis has taken into account two specific jurisdictions in Africa: OHADA Member States and South Africa. Many financing transactions, such as loans or securitisations, involve businesses focused on or have some substantial IP rights.196 Collateral security is an important feature of credit contracts and is used to provide security for a lender’s loan.197 Nevertheless, when the collateral is a copyright work, several questions arise about the IP security interest process. The weakness of the copyright asset in secured transactions is evident in Africa based on its immateriality and the incertitude and unpredictability surrounding its securitisation, but also based on the history of legal traditions – Roman-Dutch and Napoleonic Civil Code – influencing the security law applicable in these regions. Using copyright as collateral in secured transactions might mean a bank loan in return for a share of any IP profits or with the lender holding the copyright as security for repayment.198

South Africa has made use of security cessions for pragmatic reasons to solve problems related to the use of incorporeal properties as securities. OHADA lawmakers on another side have departed from the Napoleonic possessory ownership to embrace a full recognition of intangible assets as property. In both cases, legislators have to step in and remedy legal inadequacies to enable economic growth through funding. It is this paper’s position that this is standardly capable of enabling development and an illustrative example for other African nations without a supportive economic system of security over intangibles. The common law dynamic is to encourage, with its pragmatic and dimensional way of seeing things, instead of committing itself to supposed universals, seeks to develop piecemeal solutions in response to distinct types of disputes and problems.199

Many owners of intangible assets in Africa, such as artists, musicians, painters, book writers, do not own movable property capable of delivery as security. They rely on rights granted over works, including paintings, musical compositions, crafts, movies, and qualified as copyright under law. Monetising them is of the essence. Unleashing their economic value requires an adequate legal framework to embrace knowledge-based economies.

195 Lief N v Dettmann op cit, 271.
197 Sena V, Credit and Collateral (1st edn, Routledge 2007).
5. **RECOMMENDATIONS**

In today’s knowledge-based economy, intangibles have become more and more important in business.\(^\text{200}\) The relevance of intangibles in the financing sector as securitizable assets should be supported by appropriate legislative framework. The conditions set under security laws of developing countries should enable the rise of knowledge-based economies. This will involve risk management through a more practical financing system. South Africa's system of lending transactions in the case of copyright is an example susceptible to inspire other African nations, as well as OHADA law reform to set an adequate legal framework. The dominance of creative industries makes copyright an important tool for credit bargain. Just as physical assets were used to finance the creation of more physical assets during the industrial age, intangible assets should be used to finance the creation of more intangible assets in the information age.

The following recommendations can be made for the betterment of securitisation of Copyright in Africa:

1. **Granting security over future-owned copyright assets to uplift the economy in African nations.** This would imply broadening the scope of copyrightable works in the regional IP code in OHADA.

2. **The legal obligations arising out of copyright securitisation are \textit{erga omnes}, i.e., enforceable against all; henceforth, the need of ample transparency ascertaining the existence of the right.** Registration for example ensures third parties of the successful constitution of the limited real right, and therefore its enforceability.\(^\text{201}\) Registration of works has been restricted till now\(^\text{202}\) to cinematographic works. Holders of copyright in cinematographic films in South Africa must apply for registration to the Registrar of Copyright, while any contract transferring copyright over cinematographic films shall be recorded. Recordation serves as advertising and protection of the interests of the IP rights, together with any other parties recorded as having an interest in the IP right. Additionally, it enables enforceability \textit{vis-à-vis} third parties, which is important for financial institutions in need of predictability and security in credit-related transactions. It is important for the financier risking his money in a loan transaction to notify the rest of the world of his interest in the copyright object of security.

3. **Harmonise the scope of IP rights in African legislations with the scope of security laws.** Contradictions between both documents should be levelled by lawmakers.

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5. IP, ANTI-MONOPOLY LAW, AND SUSTAINABLE DEVELOPMENT IN CHINA

Joy Y. Xiang

ABSTRACT

This paper explores whether and how China’s anti-monopoly law can be leveraged to improve access to sustainable technologies and therefore, foster sustainable development in China. As the world’s second-largest economy and a top greenhouse gas emitter, China must promote sustainable development. Accordingly, it has announced ambitious goals for tackling climate change and building sustainable development by investing heavily in sustainable technologies. Meanwhile, it has also been building up its intellectual property (IP) regime in both IP registrations and enforcements and is on its way to becoming an IP powerhouse. In addition, China promulgated its first Anti-Monopoly Law (AML) in 2008. The law has expansive objectives which go beyond the conventional goals for competition law. It explicitly recognizes refusal to deal and excessive pricing without justified reasons as actionable causes. Furthermore, in November 2020, China published the Provisions on Prohibition of Abuse of IP Rights to Eliminate and Restrict Competition which recognizes IP rights as essential facilities. China’s approach seems quite different from that of the two leading competition law jurisdictions: the United States (US) and the European Union (EU). While the US antitrust law regime has walked away from considering IP rights as essential facilities, the EU competition law regime is open to do so only in exceptional circumstances. Therefore, the Chinese AML regime may have a higher tendency to find restriction of access to IP-protected technologies as actionable under its anti-monopoly laws and regulations. As a large developing country, China’s approach may be considered by other developing countries which need access to essential technologies but experience several challenges such as failing to get a license or facing unreasonably high prices.

Keywords: intellectual property, Competition Law and Policy, refusal to license, essential facilities, excessive pricing, sustainable technology, sustainable development, climate change.

1. INTRODUCTION: SUSTAINABLE DEVELOPMENT INITIATIVES GLOBALLY AND IN CHINA

Sustainable development is development balanced with economic, ecological, and social considerations so that we may meet our present material needs while ensuring that future generations retain the ability to do the same. The concept of sustainable development started in the 1986 United Nations Declaration on the Right to Development. Its latest manifestation is the United Nations Agenda 2030 (Agenda 2030), a voluntary agreement calling for the global community to fulfil seventeen sustainable development goals (SDGs) by 2030. Sustainable development is becoming an integral part of national development. According to a 2019 study, over 70% of the Organisation for Economic Co-operation and Development’s (OECD) 90 partner countries have incorporated the Agenda 2030 indicators for sustainable development into their national strategies. Most of the remaining countries are likely to do so when they move into their next national development planning cycle.

1 ‘Report of the World Commission on Environment and Development: Our Common Future’ (1987) UN Doc A/42/427 (The report was and is commonly called the ‘Brundtland Report’ in recognition of former Norwegian Prime Minister Gro Harlem Brundtland’s role as Chair of the World Commission on Environment and Development).
As the world’s second-largest economy and currently, a top greenhouse gas emitter, China must promote sustainable development. In 2014, it became the world’s largest overall energy consumer followed by the US, EU and India. In 2019, it led the primary energy consumption, consuming nearly 50% more than the next runner-up, the US. China has announced ambitious goals for curbing greenhouse gas emissions and building sustainable development. It regards sustainable development as a basic national policy and has promised to achieve the SDGs by 2030. In its innovation-driven national development strategy announced in 2016, China placed the research and development (R&D) of sustainable technologies such as smart and clean manufacturing, agriculture, energy, and information communication technologies, in prominent roles. According to an Elsevier report, by 2020, China ranked among the top 10 nations that produced the most research publications for 15 SDG-related fields.

Meanwhile, China has been building up its intellectual property (IP) regime, both in IP registrations and enforcements. According to the World Intellectual Property Organization (WIPO), the Chinese patent office received 43.4% of worldwide patent applications in 2019. In October 2020, China issued the fourth amendment to its patent law, which included several changes that are friendly to patent owners. For example, the new patent law quintuples the maximum statutory damages for patent infringement (from USD 150,000 to USD 750,000). It also establishes punitive damages which can increase damages awards to five times upon finding wilful infringement. Such evidence indicates that China is becoming an IP powerhouse and the country may experience a boom in IP licensing activities.

In addition, China established its first competition law, the Anti-Monopoly Law (AML), in 2008. The AML aims to uphold consumer and public interests, besides protecting fair market competition and enhancing economic efficiency which are conventional objectives for competition laws. Moreover, the Provisions on Prohibition of Abuse of IP Rights to Eliminate and Restrict Competition (Provisions on IP Abuses), which was published in November 2020, reveals China’s openness to consider IP rights as essential facilities. In contrast, the US antitrust law regime currently refuses to recognize or adopt the ‘essential facilities’ doctrine. The EU competition law regime limits the use of the doctrine to exceptional circumstances. In comparison, the Chinese AML regime is likely to have a higher tendency to scrutinize conducts such as refusal to license, refusal to access essential facilities, or excessive pricing. Hence, this paper explores whether and how we may leverage China’s AML regime to address unreasonable restrictions in accessing (IP-protected) sustainable technologies to facilitate China’s sustainable development.


5 Leading countries in primary energy consumption worldwide in 2019 (Statista, 2020) <https://www.statista.com/statistics/263455/primary-energy-consumption-of-selected-countries/> accessed 15 July 2021 (‘China is the largest consumer of primary energy in the world, using some 141.7 exajoules in 2019. The majority of primary energy fuels are derived from fossil fuels. China’s primary energy mix has shifted from a dominant use of coal to an increase of natural gas and renewable sources.’).


Meanwhile, some developing countries have been complaining that IP rights function as a significant barrier for them to access sustainable technologies that are needed to address ozone-layer leaks and mitigate or adapt to climate change. For instance, developing countries are said to face an oligopoly structure in the photo-voltaic industry.\(^{14}\) A small group of multinational companies that own the sustainable technologies needed by developing countries, were criticized for using the technologies to control production, thereby limiting the transfer of these technologies.\(^ {15}\) Local firms in India indicated that the patent owners of ozone reduction technologies refused to license these technologies for fear of increased competition.\(^ {16}\)

These alleged conducts in restricting access to sustainable technologies – typically via refusal to license or excessive pricing by technology owners – can be addressed by the abuse of dominant position provision in competition laws if deemed as anti-competitive. Therefore, the other motivation of this paper is to see whether developing countries could learn from China's AML set-up for improving their access to the desired sustainable technologies to facilitate their sustainable development which, in turn, would benefit the entire global community.

2. WHETHER CHINA MAY LEVERAGE ITS ANTI-MONOPOLY LAW TO IMPROVE ACCESS TO SUSTAINABLE TECHNOLOGIES

The answer to the above is in the affirmative. Such a conclusion results from examining the design of the AML, including China’s objectives for the AML and the law’s positions on sustainable development as well as controversial topics such as the interplay between competition law and IP. Many sustainable technologies in China would be under IP protection, given China’s heavy investments in sustainable technologies and efforts to strengthen its IP regime.

A. AML DEVELOPMENT

China promulgated the AML in 2008. It was China’s first competition law, resulting from efforts ongoing since 1987. China developed the AML by consulting several multilateral organizations such as the World Trade Organisation (WTO), the OECD, and the United Nations Conference on Trade and Development (UNCTAD), leading competition law jurisdictions such as the EU and US, and neighbouring jurisdictions in the Asia-Pacific region.

It is worth noting that the EU’s competition law regime had much influence during China’s preparation of the AML. The EU provided systematic technical assistance to China for developing the AML. The EU-China Competition Dialogue initiated in 2004 directly impacted the AML’s development.\(^ {17}\) The EU competition law’s civil law influence and its reliance on public administrative enforcement are elements that are more compatible with China’s legal system and its market regulatory framework.\(^ {18}\)

B. EXPANSIVE PURPOSES

Nonetheless, China’s formulation of the AML also incorporated domestic considerations reflecting China’s economic, social, and political contexts. For example, China expanded its purposes for the AML beyond what is conventional. The AML aims to prevent and curb

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\(^{18}\) Wu QL, Competition Laws, Globalization and Legal Pluralism – China Experience (Hart Publishing 2013) 129.
monopolistic conduct, protect fair market competition, and enhance economic efficiency. These are conventional objectives for competition law. However, China has further declared that the AML will also maintain consumer and public interests and promote the healthy development of the socialist market economy.

It is the second set of objectives in the AML that induced the author to explore whether the AML could be leveraged to facilitate access to sustainable technologies and hence promote sustainable development in China.

In the AML’s 13-year enforcement period, limited cases have interpreted what consumer interests mean and there are even fewer cases on the meaning of public interests.

In reviewing merger and acquisition proposals, Chinese AML administration agencies have repeatedly added restrictive conditions over the proposals to prevent the intended mergers and acquisitions from damaging consumer interests. The usual concern is that a merger and acquisition may give the resultant business operator a dominant position in the relevant market, thereby restricting competition in such market and consequently, damaging consumer interests. In these cases, the Chinese AML administration agencies interpreted consumer interests as consumers’ right to fair transactions. Damages to such a right can come from price increases (including increasing industry costs and indirectly raising commodity prices) or deterioration of quality of goods or services at the same prices. Consumer interests may further include consumers’ right to choose freely damages to which can come from restricting the range of brands and commodities that consumers can access.

For example, the State Administration for Market Regulation (SAMR) – China’s current governmental authority covering the administrative enforcement of the AML – ruled in April 2021 that the e-commerce giant Alibaba’s anticompetitive practice in its online retail platform since 2015 abused its dominance and harmed consumer interests. The SAMR found harm to consumer interests in this case on three fronts. First, Alibaba’s practice in preventing its merchants from using other online e-commerce platforms restricted consumers’ right to choose freely by reducing the brands and products that consumers could access and select on other competitive platforms. Second, Alibaba’s behaviour denied consumers’ right to fair transactions. Consumers could only passively accept Alibaba’s transaction conditions and not enjoy the more competitive prices and services of other platforms.

The SAMR’s third reason in the Alibaba case is particularly relevant to the discussion of this paper. Consumer interests may also include consumers’ expectation of benefits, the hindrance to which may come from impairing or inhibiting either technological innovation or the optimization and development of an industry. In the Alibaba case, the SAMR considered that Alibaba’s anticompetitive practice in its online retail platform since 2015 abused its dominance and harmed consumer interests in this case on three fronts. First, Alibaba’s practice in preventing its merchants from using other online e-commerce platforms restricted consumers’ right to choose freely by reducing the brands and products that consumers could access and select on other competitive platforms. Second, Alibaba’s behaviour denied consumers’ right to fair transactions. Consumers could only passively accept Alibaba’s transaction conditions and not enjoy the more competitive prices and services of other platforms.

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level of social welfare in the long run. The SAMR foresaw that the effect of such damage would reach consumers, harming both consumers’ actual interests as well as expected interests.24

Similarly, in the case against Qualcomm in 2015, the AML administrative system ruled that Qualcomm charged unfair and high-priced patent license fees.25 Such unfair high pricing practices increased the costs of the wireless communication terminal manufacturers, which were eventually transmitted to the consumers and therefore, harmed consumer interests. The AML administrative system also concluded that Qualcomm’s behaviour forced alternative technologies that competed with Qualcomm’s technologies to lose the opportunity and possibility to participate in the competition. The AML administrative system deemed that such an outcome severely eliminated and restricted competition in the relevant market and hindered and inhibited technological innovation, ultimately harming consumer interests.26

In interpreting AML violations that may harm public interest, the SAMR has deemed that such harm may come from increasing the cost of social expenditures, such as the harm caused by the increase in national medical insurance expenditures due to rising drug prices.27 Such harm may also include, as exemplified by Alibaba’s anticompetitive practice in online retail platforms, impairing the development of an industry, such as the ability to optimize and develop the industry.28

Given the benefits of sustainable development to the society as a whole as well as individual wellbeing, improving access to sustainable technologies should be under the coverage of the AML. Improving access to sustainable technologies is likely to benefit public interests and consumer welfare as well as lead to the healthy development of the socialist market economy. Article 15 of the AML explicitly exempts monopoly agreements serving public interests in energy conservation and environmental protection from prohibition, if such agreements do not substantially restrict competition and enable consumers to share the resultant benefits.29 This exemption thus indicates that the Chinese AML regime recognizes public interests in sustainable development efforts such as energy conservation and environmental protection and considers such efforts beneficial to consumers.

C. THE INTERFACE WITH IP

Meanwhile, with China’s investments in the R&D of sustainable technologies and its strengthening of the IP regime, many sustainable technologies would be under IP protection. How the AML engages with IP rights is another angle for exploring whether the AML could be employed to improve access to sustainable technologies.

The relationship between IP and competition laws is debatable. Some opine that the two regimes supplement each other as both encourage innovation. Others, however, view them to be in conflict as IP laws provide legal monopolies that may reduce competition. Through the Guidelines on Intellectual Property Rights published by the SAMR in September 2020 (AML-IPR Guidelines), China deems that its AML regime and its IP regime share the same goal. Both regimes protect competition, encourage innovation, improve economic efficiency and safeguard consumer and public interests.30

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24 Ibid (Alibaba Monopoly Case).
25 Monopoly Case Concerning Qualcomm Inc. (National Development and Reform Commission, 9 February 2015) <https://law.wkinfo.com.cn/administrative-punishment/detail/MkUxMDAwMDAyNTY2Mjgz?searchId=86d8b9def474abdaf8a75e59744c73&index=6&aq=%E5%9E%84%E6%96%AD%20&module=> accessed 20 May 2021.
26 Ibid.
28 Alibaba Monopoly Case (n 23).
29 AML, Article 15(4).
Meanwhile, China will not apply the AML to IP practices consistent with the relevant IP laws and administrative regulations. It will be applicable to IP right abuses deemed to exclude or restrict competition.\(^{31}\) Such IP right abuses include using IP, a monopoly agreement, and a dominant position in the relevant market in a way that violates the AML.\(^{32}\)

In deciding whether a business operator abuses IP rights to exclude or restrict competition, authorities will consider the effect that the behavior in issue has on market competition and innovation and efficiencies.\(^{33}\) In analyzing the effect that the behavior in issue has on market competition, they will consider the current market competition conditions and the particular behavior in issue. And in analyzing whether the behavior in issue has a positive effect on innovation and efficiencies, they will consider whether the behavior promotes the technology's diffusion and deployment as well as improves efficiency in resource utilization.

Article 6 of the AML-IPR Guidelines enumerates the factors that the behavior in issue must meet to be deemed pro-competitive. These factors include:

(i) The behavior has a causal relationship with promoting innovation and improving efficiency;

(ii) Compared with other behaviours that promote innovation and improve efficiency, within the scope of reasonable commercial choices of the business operators, the behavior has less impact on the elimination and restriction of market competition;

(iii) The behavior will not exclude or severely restrict market competition;

(iv) The behavior will not seriously hinder the innovation of other business operators; and

(v) Consumers can share the benefits of the behaviour’s effect on promoting innovation and improving efficiency.\(^{34}\)

Therefore, China’s AML regime may find anti-competitive conduct in enforcing IPR as violating the AML. Hence, China may leverage the AML to address anti-competitive IP licensing behaviours concerning sustainable technologies to facilitate sustainable development.

3. HOW CHINA MAY LEVERAGE ITS ANTI-MONOPOLY LAW TO IMPROVE ACCESS TO SUSTAINABLE TECHNOLOGIES

At the implementation level, China may leverage the AML to improve access to sustainable technologies through the abuse of dominant position theory. The notion covers the two situations IP users have most frequently complained about in accessing desired technologies – refusal to license and excessive pricing. The paper next discusses how the AML defines abuse of a dominant market position, the approaches in adjudicating issues relating to refusal to license and excessive pricing and the corresponding remedies. In addition, as China is open to leverage the ‘essential facilities’ doctrine in the refusal to license inquiry, China may improve access to sustainable technologies or associated resources when they are deemed crucial for sustainable development.

A. ABUSE OF A DOMINANT MARKET POSITION

China’s anti-monopoly law scrutinizes four types of monopoly behaviours: forming a monopoly agreement, abusing a dominant market position, concentrating business operators, and abusing administrative power to exclude and restrict competition. Among them, the abuse of market dominance scrutiny is most relevant for access to technologies.

In the AML regime, a business operator is in a dominant market position when the business operator can control the prices or quantities of commodities or other transaction terms in a relevant market or prevent or exert an influence on other business operators’ access to the

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\(^{31}\) AML, Article 55.

\(^{32}\) Provisions on IP Abuses, Article 3.

\(^{33}\) AML-IPR Guidelines, Article 3.

\(^{34}\) AML-IPR Guidelines, Article 6.
relevant market. Article 18 of the AML enumerates certain factors for determining whether a business operator is in a dominant market position:

1) its share in a relevant market and the competitiveness in the market;
2) its ability to control the sales market or the purchasing marker for raw and semi-finished materials;
3) its financial strength and technical conditions;
4) the extent to which other business operators depend on it in transactions;
5) the difficulty that other undertakings find in entering a relevant market; and
6) other factors related to the determination of the dominant market position held by an undertaking.

Meanwhile, Article 19 of the AML provides an analytical framework for deducing a dominant market position from specific circumstances:

1) the market shares of one undertaking account for half of the total in a relevant market;
2) the joint market shares of two undertakings account for two-thirds of the total, in a relevant market; or
3) the joint market shares of three undertakings account for three-fourths of the total in a relevant market.

Upon defining the relevant market and finding a business operator that has a dominant market position, the AML may find the following conducts as abuse of dominant position: excessive pricing, predatory pricing, refusal to deal, exclusive dealing, tying, unfair trading conditions, discrimination, and others. Relevant to the paper’s discussion, the AML explicitly prohibits business operators with dominant market positions from engaging in refusing to deal without a valid reason or selling at unfairly high prices.

Meanwhile, the AML will not infer a dominant market position just because a business operator owns IP. IP ownership is one factor for determining market dominance, but not the only factor. Article 14 of the AML-IPR Guidelines enumerates factors that may be considered to hold a dominant market position. In determining whether a business operator has a dominant market position, we need to first identify the relevant market. The AML considers the relevant market for a dominant market position determination to cover ‘the range of the products for which, and the regions where, business operators compete with each other during a given period for specific products or services.’ Further, in considering AML enforcement against monopolies involving IP licensing, the AML regime considers the relevant product market as the technology market or the product market containing the particular IP right, and the relevant technology market as the market formed by competition between the technologies involved in the exercise of the IP right and the existing interchangeable technologies of the same kind.

In the contrary. If it succeeds in doing so, it would not be considered to hold a dominant market position.

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35 AML, Article 17.
36 AML, Article 18.
37 AML, Article 19.
38 AML, Article 19.
39 AML, Article 12.
40 Provisions on IP Abuses, Article 3(2).
41 AML, Article 17.
42 AML, Article 17; China’s approach here is similar to the EU in identifying conducts that may be considered abusive. The US antitrust law provides a general prohibition of abuse of dominant position i.e. anti-competitive ways to conspire for, establish, or maintain monopolization (The Sherman Act (15 U.S.C. § 1, 2)).
43 AML-IPR Guidelines, Article 2.
considered for determining dominance when IP is involved. They include:

1) the possibility and switching cost of the transaction counterparties turning to substitute technology or commodity;

2) the dependence of the downstream market on the goods provided by the use of the IP right at issue; and

3) the ability of the transaction counterparties to negotiate with the business operator.\(^\text{45}\)

The paper will next examine the AML’s approach in adjudicating refusal to license and excessive pricing, two conducts prohibited under the abuse of a dominant market position scrutiny and complained most by developing countries in accessing technologies.

**a) Refusal to License**

The general attitude in competition law toward a refusal to license is that a resource owner, especially an IP owner, is free to choose whether to license the resource or not. China, however, explicitly states that refusal to deal without justifiable reasons by a business operator in a dominant market position is actionable under the AML.\(^\text{46}\) It considers the following factors in determining whether a refusal to license an IP is actionable under the AML:

1) Whether the business operator made a promise for the license;

2) Whether other business operators must have the license to enter the relevant market;

3) Whether and to what extent the refusal to license will have an impact on market competition and whether the potential licensee has the ability to innovate;

4) Whether the refused party lacks the ability or willingness to pay for a reasonable license fee;

5) Whether the business operator made a reasonable offer to the refused party; and

6) Whether the refusal to license the IP will harm consumer welfare or public interests.\(^\text{47}\)

It has been established in Part I.B. that the Chinese AML explicitly recognizes public interests and consumer welfare in sustainable development efforts relating to energy conservation and environmental protection. Hence, a refusal to license IP for sustainable technologies may be deemed to harm consumer welfare or public interests in sustainable development and therefore would be actionable. China’s approach here may be a distant cousin of the EU approach, which scrutinizes refusals to license, for example, when they restrict innovation.\(^\text{48}\) Innovation may enhance public interest and consumer welfare. China’s approach for refusal to license, hence, is more distanced from that of the US which considers refusal to license as an IP owner’s right and something that needs to be upheld to promote investments in innovation.

In addition, China deems that a business operator’s refusal to license could be explicit or implicit. Implicit refusal to license can include substantially reducing the volume of existing transactions with the counterparty, delaying or interrupting existing transactions with the third parties, or refusing new transactions with the third parties. It may also include setting restrictive conditions (such as excessive pricing) to make it difficult for third parties to transact with them or refusing to allow third parties to use their essential facilities in production and business operations under reasonable conditions.\(^\text{49}\)

Here, China counts denying access to facilities essential for production and business operations as an implicit

\(^{45}\) AML-IPR Guidelines, Article 14.

\(^{46}\) AML-IPR Guidelines, Article 16.

\(^{47}\) ibid.


\(^{49}\) The Interim Provisions on Prohibiting Abuse of Dominant Market Position, Article 16.
form of refusal to license, recognizing the controversial ‘essential facilities’ doctrine.

b) Essential Facilities Doctrine

The essential facilities doctrine is an exception to the general approach that a resource owner, especially an IP owner, is free to choose whether to license the resource or not. When a good, service or technology developed by a private-sector or public-sector entity is widely adopted, access to it becomes necessary for others to conduct business in the relevant market.50 A facility is essential if a competitor of the facility owner needs access to the facility to compete.51 The lack of viable alternatives is a crucial characteristic of an essential facility. Hence, IP rarely is an essential facility as multiple design-arounds may be available as substitutes of an IP-protected technology. The US antitrust law regime does not favor the ‘essential facilities’ doctrine. On the other hand, the EU competition law regime uses it only in exceptional circumstances.

The Interim Provisions on Prohibiting Abuse of a Dominant Market Position amended in 2020 enumerates factors that Chinese authorities will consider when third parties are refused use of essential facilities. Such factors include the feasibility of separately building the facilities with reasonable investment, the degree of dependence of the third parties on said facilities for effectively carrying out production and business operation activities, the possibility of the business operator for providing said facilities and the resultant impact on its production and business operation activities.52

As stated, China explicitly acknowledges that IP can be essential facilities in the Provisions on IP Abuses. The IP in issue needs to satisfy three criteria to be deemed essential facilities. First, the IP should have no reasonable substitute, and must be indispensable for other operators to compete in the relevant market. Second, refusing to license the IP should negatively impact competition and innovation in the relevant market and be detrimental to consumer welfare or public interest. Thirdly, licensing the IP should not cause the IP rights owner unreasonable harm.53 When an IP is deemed as an essential facility for production and operation activities, the owner (who is thus considered to be in a dominant position) shall not refuse other business operators, without justifiable reasons, to use the IP under reasonable conditions.54

Here, certain key issues are yet to be disputed and interpreted. For example, would a business operator holding an essential facility necessarily be in a dominant market position and therefore be subjected to scrutiny when refusing to license the essential facility? Further, what would be considered as a ‘reasonable substitute’ of the IP in issue, a ‘relevant market’ for the IP, and a ‘justifiable reason’ for refusal to license the IP? In addition, what would be the ‘reasonable conditions’ for the grant of license, and what would be deemed as causing the IP rights owner no ‘unreasonable harm’?

In April 2021, China issued a first-instance judgment in the first case that utilized the Chinese AML regime’s stance on recognizing IP as essential facilities. The plaintiffs in the case had requested the Ningbo Intermediate People’s Court to license non-standard essential patents (non-SEP) based on the ‘essential facilities’ doctrine.55 The plaintiffs argued that the

50 United Nations Environment Programme (UNEP), ‘Using Antitrust law to Promote Access to Health Technologies – a Guidebook for Low- and Middle-Income Countries’ (2014) 78; In the technology area, this phenomenon is sometimes referred to as the ‘network effect’ – the more widely adopted a technology becomes, the more important it is for doing business.


52 The Interim Provisions on Prohibiting Abuse of Dominant Market Position (n 49).


54 Ibid.

defendant Hitachi Metals’ patent portfolio on neodymium-iron-boron (‘NdFeB’) magnets should be an essential facility for the industry because the patent portfolio cannot be substituted or avoided. The court determined that Hitachi Metals had a dominant position in the relevant technology market. The court concluded that Hitachi Metals’ patent portfolio of NdFeB magnets was an essential facility for the industry based on the following reasons:

1. The facilities were essential for other undertakings to participate in the competition;
2. The defendant, as the holder of the IP rights, controlled the facilities in dispute;
3. Other competitors could not duplicate the same facilities within a reasonable scope;
4. The defendant refused to let a competitor use the facilities when the plaintiff had expressly requested a license and was willing to pay reasonable royalties; and
5. It was possible for the defendant to grant the patent license to the plaintiff, and there was no justifiable reason for the defendant’s refusal. The court, therefore, held that Hitachi Metals’ relevant conduct constituted a refusal to license under the AML. The case thus declared that non SEPs can be deemed as essential facilities, indicating and raising alarm about the distance the Chinese AML regime may go in treating IP as essential facilities.

Therefore, there is a need to observe, with alertness, the effect of China’s approach in being opened to treating IP as essential facilities. Some scholars argue that forced IP sharing or price caps for IP would impair incentive to invest in IP and innovation. Hence, the process needs to be carefully administered and the doctrine must be used with extreme care.58

**c) Excessive Pricing**

Excessive pricing occurs when the commodity’s price is so high that it has no reasonable connection with the cost of developing and making the product – for example, a good, service or technology. As mentioned above, excessive pricing can be regarded as implicit refusal to license, which can be deemed anti-competitive and hence, actionable, if unjustified. Such a pricing conduct alone may constitute an abuse of dominant position if the consumers have no viable alternative. IP-related excessive pricing as an actionable abuse of dominant position needs to meet two criteria: the IP right owner has a dominant position in the market, and the price is objectively excessive.60

China explicitly declares an unfair high price charged against a product or service as abuse of dominant market position. In judging whether there is abusive pricing (unfairly high, unfairly low) in general, China considers the following factors:

1. Requiring the counterparty to grant back exclusively the technologies improved;
2. Prohibiting the counterparty from challenging the validity of its IP rights;
3. Restricting the counterparty from using competing products or technologies without infringing upon any IP rights after the licensing agreement expires;

...
continuing to exercise any IP rights with an expired term of protection or determined as invalid;
5) prohibiting the counterparty from trading with any third party; or
6) requiring the counterparty to attach any other unreasonable restriction.\(^{62}\)

In analysing whether the licensing of IP is at an unfairly high price, China considers the following factors:

1) The method for calculating the license fee and the contribution of the IP to the relevant product's value;
2) The business operator's prior promise concerning the IP license (e.g., commitments made in a standard-setting process);
3) The license history of the IP or standard of licensee fee of comparable references;
4) The license condition(s) that causes unfairly high price, including demanding license fee outside the IP's geographical area or product area; and
5) Whether wholesale license was used to demand license fee on expired or invalid IP.\(^{63}\)

China also analyses whether a business operator licenses SEP at unfair high prices with considerations such as the overall license fees borne by the commodities that meet the relevant standards and their impact on the normal development of related industries.\(^{64}\)

China only published the Provisions on IP Abuses and the AML-IPR Guidelines in late 2020. Since drafts of these regulations were in circulation earlier, decisions made by the Chinese jurisdiction have reflected the essence of these regulations. For example, in its judgment for one of the two *Huawei Technologies v InterDigital* cases, the Guangdong High Court of China held that the US-based company InterDigital (IDC) abused its dominant market position by refusing to license SEP for 3G wireless communication devices on fair, reasonable and non-discriminatory (FRAND) terms. The High Court not only affirmed the lower court's finding that IDC set a discriminatory and unreasonably high royalty rate for its Chinese SEP and non-SEP but also supported the lower court's order that IDC cease such conduct and that a USD 3.1 million in damages be awarded to Huawei.\(^{65}\)

In the 2015 decision against Qualcomm, a Chinese AML administrative agency found that Qualcomm charged unfairly high royalties for its SEP. The finding was based on several facts, such as:

- (1) the base for calculation of royalties was the wholesale price of wireless terminal devices, which contained many parts not related to the licensed wireless SEP;

\(^{63}\) AML-IPR Guidelines, Article 15.
\(^{64}\) Ibid.

Further, the Interim Regulations on National Standards Involving Patents requires that patents included in national standards be licensed on FRAND terms. It also requires that the relevant government authorities negotiate with a patent holder on divesting the patent if the patent is essential for a mandatory national standard and the patent holder does not agree to license on FRAND terms.\(^{68}\)

Similarly, in the 2015 decision against Qualcomm, a Chinese AML administrative agency found that Qualcomm charged unfairly high royalties for its wireless SEP. The finding was based on several facts, such as:

- (1) the base for calculation of royalties was the wholesale price of wireless terminal devices, which contained many parts not related to the licensed wireless SEP;

\(^{66}\) Ibid.
\(^{68}\) Administrative Regulation on National Standards Involving Patents-Interim (Interim Regulations) 2014.
licensed patents included expired patents; and (3) Qualcomm required its licensees to provide free grant backs, and also did not consider the value of its licensees’ own patents cross-licensed to Qualcomm.69

B. REMEDIES

The AML prescribes the remedies available for abuse of dominant market position. They include ordering the business operator to cease illegal activities, confiscating illegal gains and imposing a fine between 1% and 10% of the relevant sales in the previous year.70 At the judicial front, when a court finds that a defendant has conducted monopolistic activities and caused losses to the plaintiff, the court may order the defendant to bear civil liabilities such as cessation of the infringement and compensation for losses based on the plaintiff’s litigation request and the facts ascertained.71

Courts may also deny a business operator’s request for injunctive relief against the alleged infringer. The AML-IP Guidelines, for example, state that a court needs to balance several considerations when receiving an injunctive relief request from a SEP holder who forces a licensee to accept an unfairly high license fee or other unreasonable license conditions.72 Such considerations include:

1) The behaviour of the two parties in the negotiation process and their real wishes;
2) The relevant commitments of the necessary patents of the applicable standards;
3) License conditions proposed by both parties in the negotiation process;
4) The impact of requesting the court or relevant department to make or issue judgments, rulings or decisions prohibiting the use of the relevant IP right and the impact of the same on downstream market competition and consumer interests.73

In summary, China’s scrutiny for abuse of dominant market position is explicit in prohibiting anti-competitive refusal to license and unfair high pricing. China is also open to considering the ‘essential facilities’ doctrine in dealing with refusal to license and is open to treating IP as essential facilities. These approaches may enable China to address anti-competitive barriers against access to sustainable technologies effectively.

4. CONCLUSION: COMPETITION LAW, IP, SUSTAINABLE DEVELOPMENT, AND THE CHINA APPROACH

Sustainable development is vital because it enables us to have a sustainable future. Meanwhile, we need to develop and deploy sustainable technologies to realize sustainable development. Both IP and competition laws can encourage innovation in sustainable technologies and improve access to sustainable technologies. IP laws may incentivize investment in the R&D for sustainable technologies, and the attraction of patent protection, in particular, may enhance the disclosure of the resultant inventions. Competition laws, on the other hand, can enhance competition and thereby, innovation in the relevant markets. In addition, competition laws addressing IP right abuses such as unjustified refusal to license or excessive pricing may improve access to sustainable technologies. Judiciously employing the ‘essential facilities’ doctrine may enhance access to sustainable technologies that are deemed as crucial or essential infrastructures necessary for the development and deployment of sustainable technology development.

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69 Monopoly Case Concerning Qualcomm Inc. (n 25).
70 AML, Article 47.
71 The Provisions of the Supreme People’s Court on Several Issues Concerning the Application of Law in the Trial of Civil Disputes Caused by Monopoly Acts (the Supreme People’s Court, 2020), Article 14.
72 AML-IPR Guidelines, Article 27.
73 Ibid.
China’s design of its AML regime may facilitate access to necessary sustainable technologies and hence, empower its drive for sustainable development. It includes expansive objectives for its AML which aims not only to facilitate market competition and economic efficiencies, but also consumer welfare and public interests as well as the healthy development of the socialist market economy. The AML recognizes public and consumer interests in sustainable development efforts such as energy conservation and environmental protection. The AML also explicitly prescribes that refusal to license without justifiable reasons and excessive pricing be considered as actionable causes. The AML regulation on IP right abuses also establishes that IP may be considered as essential facilities. Hence, unjustified refusal to access such IP would be actionable. These features in the Chinese AML regime may offer one example to countries (especially developing countries) in leveraging competition law to improve access to sustainable technologies that are essential for facilitating national sustainable development.

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6. IF NOT NOW, WHEN? ACCESS TO COVID-19 TREATMENT AND PATENT LAW

Bassem Awad*

ABSTRACT

The COVID-19 pandemic has brought many intellectual property (IP) access issues to the forefront of international debate. While wealthier countries race to deliver vaccines to their residents, treat their patients and recover economically, developing countries struggle to access the knowledge and technologies to do the same. Once again, the balance between protecting IP rights and providing needed technology access and knowledge transfer has been called into question. Within international treaties and domestic laws, there are several methods in place that can be invoked to lawfully breach IP rights, ranging in degree of intrusiveness. This paper outlines the need for equitable global access to treatment and underlines the danger of vaccine nationalism. The paper responds to the concern of how to facilitate access to COVID-19 treatments given the current international framework. The paper describes two non-voluntary mechanisms related to the TRIPS Agreement: the compulsory licensing under Article 31bis, and the recent waiver proposal aiming to suspend IP rights related to the prevention, containment, or treatment of COVID-19. The implementation of these non-voluntary mechanisms is necessary to appropriately respond to the mitigation of COVID-19 globally and the paper advocates for a compulsory trade secrets license to facilitate developing countries’ access to medical information and technologies. The paper ends with describing insights to consider these methods of access for the benefit of international healthcare in times of crisis in the future.

Keywords: COVID-19; vaccine nationalism; compulsory license; TRIPS waiver; compulsory trade secrets license; technology transfer.

1. INTRODUCTION

First identified in December 2019, the World Health Organization (WHO) declared the coronavirus (COVID-19) outbreak a pandemic in March 2020. According to the WHO Coronavirus Dashboard, there were over 182 million confirmed cases of COVID-19 and more than 3.9 million deaths as of 28 June 2021.

Developing countries have been disproportionately affected by the COVID-19 pandemic during the past two years. The World Bank identified that in the average developing country, 36% of respondents stopped working when their country’s social distancing measures were most stringent, and 64% of households reported decreased income. During school closures, only 41% of children from lower income countries continued to engage in learning activities, partly due to lack of internet, computer, television or radio access. If advanced economies fail to ensure equitable access to COVID-19 vaccines for developing countries, global costs could total USD 9.2 trillion, with advanced economies bearing up to half of the costs. Therefore, until the vaccine is widely available in developing countries, the

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4 Ibid.

Pandemics usually pose global public health problems leading governments, health technology and pharmaceutical companies to increase efforts to invent ventilators, diagnostic tests, pharmaceutical drugs, disinfection technologies, vaccinations, personal protective equipment, and other medical technologies to combat infectious disease outbreaks. Many components of newly developed vaccines and related tools are protectible or protected by one or more patents.

Patents are legal instruments intended to encourage innovation by providing exclusive rights to the inventor to help recover research and development (R&D) expenses in return for the disclosure of the invention. Between 1999 and 2018, over 11,000 inventions for technologies capable of combating COVID-19 were patented globally, with 8,452 attributable to an institution. China and the United States (US) have largely led the growth among leading countries for pandemic-mitigating technologies.

Under the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement of the World Trade Organization (WTO), patent owners may prevent others from making, using, offering for sale, selling, or importing a patented invention without their permission for a period of 20 years. However, several developing countries and civil society advocates argue that intellectual property (IP) monopolies are blocking the rapid scale-up of vaccine manufacturing. The COVID-19 pandemic revealed issues of uncertainty and tension surrounding the role of IP rights, particularly patent laws, in hindering access to COVID-19 treatment and critical related products, from diagnostic kits to medical equipment, tracking systems, and other medical supplies. The UN Committee on Economic, Social and Cultural Rights released a statement in April 2021 that the unequal global distribution of vaccines not only represents discrimination in terms of the right to access vaccinations at the global level, but also undermines progress on the UN Sustainable Development Goals (SDG), particularly SDG 3, 10, and 17.

WAYS TO FACILITATE DEVELOPING COUNTRIES ACCESS TO COVID-19 TREATMENTS

Access to COVID-19 treatments can be facilitated through two contrasting avenues. On the one hand, there is voluntary provision of access via licensing agreements or collaborative mechanisms of innovation such as patent pools. Voluntary licensing refers to the practice of IP holders voluntarily granting licenses to their patents or other IP rights. The license usually sets quality requirements and defines markets where the licensee can sell the product(s). Another form of voluntary collaboration to embrace knowledge-sharing efforts in

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9 Ibid.
13 Voluntary licenses are, in essence, private commercial contracts that enable third parties to sell generic versions of a patented product. In the past, voluntary licenses have been used to mitigate the impacts of several pandemics or, in some cases, used as a bargaining tool in response to threats of compulsory licensing. See Raju KD, ‘Compulsory v Voluntary Licensing: A Legitimate way to Enhance Access to Essential Medicines in Developing Countries’ (2017) 22 J IP Rights 23; Médecins Sans Frontières, ‘Voluntary Licenses and Access to Medicines’ (Technical brief, October 2020) <https://msfaccess.org/voluntary-licenses-access-medicines> accessed 26 June 2021.
response to the COVID-19 pandemic is the patent pools. They are defined as ‘an agreement between two or more patent owners to license one or more of their patents to one another or to third parties’.14 Patent pools can benefit innovation and competition by promoting the voluntary sharing of IP assets, improving the efficiency of developing goods and services, reducing transaction costs, and reducing the need to seek alternatives to existing patents.15

On the other hand, the non-voluntary mechanisms to facilitate access to COVID-19 treatments can be invoked in situations when a voluntary license agreement or collaboration is not viable. These non-voluntary mechanisms range from compulsory licensing under Article 31bis and the security exception under Article 73 of the TRIPS Agreement to the recently proposed COVID-19 waiver aiming to suspend IP rights related to the prevention, containment, or treatment of COVID-19.

This paper begins with underlining the danger of vaccine nationalism and outlines the need for equitable global access to treatment (II). The paper then explores two of the non-voluntary legal mechanisms that may be adopted by countries to facilitate access to COVID-19 treatment and medical technologies. First, it analyses the compulsory license system and the government use or the crown privilege for non-commercial use to reduce vaccine scarcity (III). Second, the paper examines the TRIPS Waiver proposal submitted by India and South Africa to temporarily suspend certain TRIPS obligations related to the prevention, containment or treatment of COVID-19 (IV). The paper concludes with insights on the way forward for striking a balance between protecting IP rights through patent law and making knowledge transfer available in times of crisis (V).

2. VACCINE NATIONALISM

While the vaccines developed by several pharmaceutical companies seemed to be beacons of hope upon their creation, the world is facing a new wave of vaccine hoarding.16 Countries are prioritizing their national interests and acquiring stocks of vaccines and related technologies that exceed the necessary amounts for their populations. In February 2021, the UN Secretary-General declared that 10 countries had administered 75% of all vaccinations, while over 130 countries had not yet received a single dose of a COVID-19 vaccine.17 In December 2020, wealthy nations representing 14% of the world’s population had bought up to 53% of the most promising vaccines.18

Vaccine Nationalism, or the ‘my country first’ approach, occurs when governments sign agreements with pharmaceutical manufacturers to supply their own populations with vaccines ahead of the vaccines becoming available for other countries.19 These pre-

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15 In May 2020, the WHO and other partner organizations launched the COVID-19 Technology Access Pool (C-TAP) to facilitate access to COVID-19 health products. This voluntary patent pool, signed on to by 40+ countries, aims to leverage collective research and incentivize international cooperation by reducing license-related transaction costs. Implementing partners of C-TAP include the Medicines Patent Pool (MPP), the Open COVID Pledge and the Tech Access Partnership (TAP). See WHO, ‘How WHO C-TAP Works? Commitments to share knowledge, IP and data’ (27 October 2020) <www.who.int/initiatives/covid-19-technology-access-pool/what-is-c-tap> accessed 26 June 2021.


19 Vaccine Nationalism is different from Vaccine Diplomacy where vaccines are used to improve a country’s diplomatic relationship and influence with other countries. The vaccine is used as a vehicle to assist countries that may not otherwise have access to emerging vaccines. Vaccine Diplomacy allows some countries to strengthen bilateral and regional ties and enhance their international relations. See Balasubramanian S, ‘Vaccine Diplomacy: A New Frontier in International Relations’ (Forbes, 24 February 2021) <www.forbes.com/sites/sabila/2021/02/24/vaccine-diplomacy-a-new-frontier-in-international-relations/?sh=58642a6622bc> accessed 26 June 2021.
production agreements reserve a substantial number of emergent vaccines for domestic use or for a limited number of jurisdictions.20 Several vaccine manufacturers received funding internationally from governments and public sector entities to develop a COVID-19 vaccine while providing the funding countries with preferential treatment such as the right to pre-purchase vaccines in development or priority access to emerging vaccines.21

Vaccine Nationalism can also, as Evenett, et al., describe, take the form of overt export bans or limits to increase the domestic availability of vaccines at the expense of foreign supply.22 Faced with domestic vaccine shortages, several countries established a formal export control system to limit the commercial exports of COVID-19 vaccines out of their territory. In early March 2021, Italy and the European Union (EU) blocked a shipment of over a quarter million vaccine doses produced by AstraZeneca-Oxford destined for Australia from leaving the EU.23 The EU is the only jurisdiction to introduce an export authorization regime for COVID-19 vaccines.24 More recently, in April 2021, the Indian government temporarily banned the exports of the active pharmaceutical ingredients (API) and injections of the anti-viral drug remdesivir due to the rise of COVID-19 cases in the country.25

The export bans can also be less formal and could include administrative delays in shipments or using other regulations to prioritize domestic consumption.26 For example, to accelerate mass domestic vaccinations, the US President invoked the Defense Production Act, allowing the government to control distribution and direct suppliers to fulfil certain contracts ahead of others.27

Vaccine Nationalism is not a novel concept. During the H1N1 pandemic in 2009, developed countries directly negotiated pre-production contracts with manufacturers of H1N1 vaccines. This resulted in the UN being unable to purchase vaccines, causing a delay of global distribution and many lives being unnecessarily lost.28 After the WHO requested donations, Australia, Canada, the US and six other countries agreed to share 10% of their H1N1 vaccines, only after they first met their domestic needs.29 Similarly, in the context of the current pandemic, the WHO Director-General has warned that if vaccine nationalism continues, it could exacerbate inequalities.

24 The European export control regime for COVID-19 put in place a measure requiring vaccine exports to be subject to an authorisation by the EU Member States. The objective of this measure is to ensure timely access to COVID-19 vaccines for all EU citizens and to address concerns over the lack of transparency around the ways some companies are operating in relation to vaccine exports outside the EU. See Commission Implementing Regulation (EU) 2021/111 of 29 January 2021 making the exportation of certain products subject to the production of an export authorisation (2021) OJ L 311 (EU Regulation).
27 The Defense Production Act gives the US President powers to allocate “materials, services, and facilities” and award contracts that take priority over any other contract to “promote the national defense.” In extreme situations, the law can also be used to prevent companies from exporting certain goods to keep them within the US territory. See Isaac Stanley-Becker, ‘Biden harnesses Defense Production Act to speed vaccinations and production of protective equipment’ (The Washington Post, 5 February 2021) <www.washingtonpost.com/health/2021/02/05/biden-vaccines-tests-gloves> accessed 26 June 2021; The Defense Production Act of 1950, Pub L No. 81-774, 64 Stat 798 (codified as amended at 50 USC § 4501–4568 (2018)) (United States).
that lower-income countries already face in terms of acquiring doses.\textsuperscript{30}

The re-emergence of vaccine nationalism will have devastating global health and economic consequences on both the Global South and the Global North.\textsuperscript{31} The spread of the pandemic in the South without sufficient vaccines will disturb cross-border supply chains and global trade.\textsuperscript{32} Furthermore, inoculating the population of a single country may not lead to sustainable protection if the virus is able to spread and mutate somewhere else unchecked.\textsuperscript{33} The urgent need for COVID-19 treatments in the Global South has once again raised questions about the effectiveness of non-voluntary IP mechanisms in responding to global challenges.

3. COMPULSORY LICENSE AND GOVERNMENT USE

Under the TRIPS Agreement, WTO Members have several obligations in relation to patents. Members are obligated to provide patent protection for any invention, whether it is a product (such as medicine, drugs, vaccines) or a process (such as a method of producing the chemical ingredients for a medicine), so long as it is novel, involves an inventive step, and is capable of industrial application.\textsuperscript{34}

Members may invoke a regulatory exception set out in Article 30 to permit the use of patented inventions for research in order to understand inventions more fully or to obtain marketing approval from public health authorities. Once a patent is granted, compulsory licensing and government use of patented inventions without the voluntary authorization of the right holder may be permitted in circumstances such as national emergencies, subject to the provisions in Article 31 which protect the legitimate interests of the right holder.\textsuperscript{35} This section briefly examines the historical background of non-voluntary licensing and provides examples of past and present use of compulsory licenses in times of crisis. This section concludes with advancing a proposal for non-voluntary licensing of trade secrets.

A. RATIONALE AND HISTORICAL BACKGROUND OF COMPULSORY LICENSING

A compulsory license is an authorization given for public policy reasons by a national authority to a natural or legal person for the exploitation of the subject matter protected by a patent without the right holder’s authorization.\textsuperscript{36} Compulsory licenses are a legitimate and effective tool in supporting equitable distribution of medicines, access to COVID-19 treatments and patented technologies for research. However, there is concern that compulsory licensing may not be a sustainable method of encouraging long-term innovation as it may disincentivize private investment in R&D.\textsuperscript{37} In the meantime, compulsory licensing might provide solutions to the right holder’s exclusive rights. Nevertheless, access to vaccine technologies and information sharing of undisclosed information remains a critical and fundamental problem that needs additional measures.

The rationale for non-voluntary licensing related to patent law resides in prioritizing the public’s interest of accessing an invention over the private interests of patent owners seeking to exploit their exclusive rights. Failure to exploit the invention in the countries granting patents can result in states ordering a compulsory license as a sanction for non-working patents in their territory or


\textsuperscript{32} Çakmaklı C (n 5).

\textsuperscript{33} Rutschman AS, ‘The Reemergence of Vaccine Nationalism’ (n 20).

\textsuperscript{34} TRIPS Agreement, Article 27.1.

\textsuperscript{35} TRIPS Agreement, Articles 30 and 31.


preventing abuses of the patentee’s exclusive rights. Historically, compulsory licensing of patented inventions existed in 15th century Venetian law and in British law in the 19th century.28 In order to defend the public interest, the Crown reserved the right to use patented inventions without compensation or consent of the patent holder. The concept was later introduced in the multilateral system in the Paris Convention for the Protection of Industrial Property during the 1925 Hague revision.29 However, recourse to compulsory licensing was only allowed after a period of four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever date came second.30

The opposing views taken by developed and developing countries in the 1980s and early 1990s on the powers that governments should possess to issue these compulsory licenses interrupted all efforts to revise the Paris Convention.41 The failure of these Diplomatic efforts persuaded technology-exporting countries to link future negotiations concerning international IP protection to the Multilateral Trade Negotiations.42

The Uruguay Round (1986-1994) became the next available forum to review the compulsory licensing mechanisms. The negotiation concluded with the signature of the Marrakesh Agreement Establishing the WTO in 1994 and its Annex IC, the TRIPS Agreement.43 According to the TRIPS Agreement, the patentee’s exclusive rights can be waived in certain circumstances where it is in the public’s interest, often involving non-commercial government authorization or use.

Article 31 sets forth the preconditions and procedural requirements for issuing a compulsory licence.44 Although the TRIPS Agreement does not explicitly use the term ‘government use’, many domestic laws – mainly in Commonwealth countries45 – distinguish between a compulsory license and the English common law regime, the Crown’s privilege, or the public non-commercial use of Article 31(b). The compulsory license procedure can be initiated either by a government entity or upon a third party request. A compulsory licence is issued only after an applicant has attempted to negotiate a voluntary authorization of a licence within a reasonable period of time, with the exception of cases of

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28 In 1474, the Venetian Patent Act reserved a compulsory license to the state to manufacture, use, and distribute the patent when needed. The compulsory assignment of patents that failed to be used by the patentee was also codified in Venetian law. See Mandich G, ‘Venetian Patents (1450-1550)’ (1948) 30 J Pat Off Soc’y 166, 194 and 206–07; Ulf Anderfelt, International-Patent Legislation and Developing Countries (Martinus Nijhoff 1971). Beginning in 1919, UK “licences of right” provisions gave patentees the ability to voluntarily endorse their patents or required patentee endorsement by law (remedy for abuse), as being available for third party exploitation. The terms were either pre-fixed by the patentee or determined by the Comptroller-General of Patents. See Brennan DJ, ‘The First Compulsory Licensing of Patents and Copyright’ (2017) 17 Legal History 1, 2; Yang CC, ‘Crown Use and Government Use’ in Hilty RM, Liu KC (eds), Compulsory Licensing: Practical Experiences and Ways Forward (22 MPI Studies on IP and Competition Law, Springer Berlin 2015).

29 According to Article 5A(2), Paris Union Members with the right to take legislative measures for granting compulsory licenses to prevent the abuses which might result from the exclusive rights conferred by the patent. Paris Convention (as amended on 28 September 1979), 20 March 1883, Article 5A(2) <https://wipo.int/en/treaties/texts/textdetails/12633> accessed 26 June 2021; Brennan DJ (n 38) 3, citing Ricketson S, The Paris Convention for the Protection of Industrial Property: A Commentary (Oxford University Press 2015) 82.

30 Such a compulsory licence shall be non-exclusive and shall not be transferable. See Paris Convention, Article 5A(4).


44 These conditions begin by requiring that prior to the use of the patented technology, the applicant must have made some effort to obtain consent from the patent holder on reasonable commercial terms and was not successful in obtaining voluntary authorization of a licence within a reasonable time period. These requirements may be waived in cases of public non-commercial use, situations of extreme urgency or national emergency, or remediating anti-competitive practices. Regardless, the patent holder should be notified as soon as reasonably possible and should be paid equitable remuneration, considering the economic value of the compulsory licence authorization. The duration and scope of the uses are limited to the authorized purpose and are non-exclusive and non-assignable.

extreme urgency or a national emergency. On the other hand, a government use is a form of compulsory licence that can only be initiated by the government or its entities. This form of licensing is issued to acquire a patented drug or process to be made available for public interest reasons through domestic productions and importations. This is referred to as ‘public non-commercial use’. Under the government use license, prior consent or negotiations with the patent holder are not required, however, adequate compensation to the patent holder is still required, regardless of the reason for the compulsory licence (Article 31(b), (h)).

The post-TRIPS period witnessed considerable challenges related to the implementation of Article 31 in countries with insufficient or no capacity to manufacture the drugs in question. The TRIPS provisions initially restricted the use of compulsory licenses to serve predominantly for domestic market supply. Furthermore, countries with manufacturing capacity could not assist other countries by issuing a compulsory license with the view to export the drug.

For several years, this restriction presented a barrier to facilitating access to essential medicines and technology for developing countries and least developed (LDCs) that lacked the means of domestically producing these much-needed medications. In the 2001 WTO Ministerial Conference, the Doha Declaration on TRIPS and Public Health reaffirmed the rights of Members to utilize TRIPS flexibilities to promote access to medicines for all.48

The Doha Declaration opened a pathway for WTO Members with insufficient domestic manufacturing capabilities to produce medicines.49 Paragraph 5 of the Doha Declaration reaffirmed the right of each Member to ‘determine what constitutes a national emergency or other circumstances of extreme urgency.’ Paragraph 5(c) specifically mentions ‘public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.’ Since the COVID-19 pandemic is, in fact, a public health crisis, the use of compulsory licensing will therefore be justified.

The Declaration also addressed the constraint on exports set out in Article 31(f). The TRIPS Council adopted a waiver in August 2003, which became permanent in December 2005, allowing compulsory licensing for the purpose of producing and exporting generic versions of pharmaceutical products to Members with insufficient domestic manufacturing capacity.50 This led to the insertion of Article 31bis into the TRIPS Agreement, which entered into force on 23 January 2017.51


48 In the context of public health, clause 4 reads ‘We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all.’ See WTO, ‘Declaration on the TRIPS agreement and public health’ (Ministerial Conference, Fourth Session, Doha, 20 November 2001), WTO Doc WT/MIN(01)/DEC/2 <www.wto.org/english/tratop_e/trips_e/public_health_e.htm> accessed 26 June 2021 (Doha Declaration).


51 Article 31bis states that the obligations of an exporting Member under Article 31(f) shall not apply with respect to the grant by it of a compulsory licence to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s) in accordance with the terms set out in paragraph 2 of the Annex to this Agreement.
B. PAST EXPERIENCES WITH PATENT COMPULSORY LICENSING

Following the TRIPS Agreement and the Doha Declaration, the non-voluntary authorization to use patents has been invoked in both developed and developing economies, with a majority of licenses issued in relation to HIV/AIDS treatments.\(^{52}\) In doing so, countries have been able to significantly lower costs for critical healthcare and medicine access.

Between 1969 and 1992, Canada made extensive use of non-voluntary licensing of patented inventions to import or manufacture medicines.\(^{53}\) Canada largely relied on statutory regulation for both abuse of patent rights (failure to exploit patents locally) and public interest objectives.

In the 2000s, compulsory licensing and government use licenses were used in the HIV/AIDS epidemic to improve access to antiretroviral drugs. Brazil (2003), Ecuador, Ghana (2005), Guinea (2005), Indonesia (2004), Malaysia (2004), Mozambique (2004), Thailand (2006), Swaziland (2004), Zambia (2004), and Zimbabwe (2004) each issued at least one compulsory or government use license for one or more antiretroviral drugs to respond to the spread of HIV/AIDS in their respective countries.\(^{54}\) In 2007, Rwanda made use of paragraph 6 of the Doha Declaration and issued a compulsory license for the HIV/AIDS drug TriAvir that it could not produce locally. A few months later, Canada issued a compulsory license allowing Apotex, a Canadian pharmaceutical company, to use nine patented inventions for manufacturing TriAvir for Rwanda.\(^{55}\) More recently, the German Federal Court of Justice in 2017 confirmed a compulsory license granted in preliminary proceedings as a defence against alleged patent infringement\(^{56}\) for an antiretroviral drug for people living with HIV/AIDS.\(^{57}\) These past experiences can be leveraged to respond to COVID-19 on a global scale to provide access to affordable treatment options through compulsory licensing.

C. CURRENT USE OF COMPULSORY LICENSING FOR COVID-19

With the spread of COVID-19 around the globe, countries have taken various legislative and regulatory measures to facilitate access to patented medicines and equipment or to ensure the possibility of issuing compulsory licenses.\(^{58}\) In March 2020, Israel was the first country to issue a coronavirus-related compulsory license as part of their COVID-19 response.\(^{59}\) This government intervention came as a result of insufficient supplies of an HIV drug, initially viewed as a possible treatment for COVID-19, from the American pharmaceutical company AbbVie. The government obtained the right to import generic versions

\(^{52}\) Approximately 20 countries have either issued or publicly entertained issuing a compulsory licence for one or more pharmaceutical products since the founding of the WTO. See Reed Beall, Randall Kuhn, ‘Trends in Compulsory Licensing of Pharmaceuticals Since the Doha Declaration: A Database Analysis’ (2012) 9(1) PLoS Med e1001154 <https://doi.org/10.1371/journal.pmed.1001154> accessed 26 June 2021; Wong (n 56).


\(^{54}\) See Beall (n 60), Wong (n 56), Hilly (n 43) 64.

\(^{55}\) WTO, ‘Canada is first to notify compulsory licence to export generic drug’ (4 October 2007) <www.wto.org/english/news_e/news07_e/trips_health_notif_0ct07_e.htm> accessed 26 June 2021.

\(^{56}\) The German Federal Patent Court is a specialized IP court composed of judges with both legal and technical training and dealing with industrial property rights, such as patents, trademarks and designs. It is also the competent court to issue compulsory licenses. The Federal Patent Court’s decisions can be appealed to the Federal Court of Justice. See Patent Act (Patentgesetz, PatG) as published on 16 December 1980 (1981 Federal Law Gazette I, 1), as amended by Article 4 of the Act of 8 October 2017 (2017 Federal Law Gazette I, 3546), s 24 (Germany).


\(^{58}\) Domestic and regional IP offices have also taken administrative measures in response to the COVID-19 pandemic such as deadline extensions, remote work, fee relief, etc. This paper does not cover these administrative measures and focuses only on the legislative and regulatory measures. The operational changes and measures taken by national and regional IP offices can be viewed on WIPO, ‘COVID-19 IP policy tracker’ <www.wipo.int/covid19-policy-tracker/ip-operations> accessed 28 June 2021.

of Ritonavir/Lopinavir, branded as Kaletra, from India for the sole purpose of treating COVID-19 patients. While most of the vaccination in Israel was carried out with vaccines from leading pharmaceutical companies (Pfizer, Moderna, etc.), this move has created a significant pressure on vaccine producers to provide an early access and to guarantee the supply of COVID-19 treatments in the country.

Many governments have introduced emergency legislation in relation to IP rights to ensure the opportunity to issue compulsory licenses in response to the COVID-19 pandemic. The goal of these regulatory interventions is to clarify the current regulatory framework in the country, reiterate the opportunities for research and experimental use, and facilitate the process of obtaining a compulsory license to protect public health. In collaboration with the European Medicines Agency and the European Medicines Regulatory Network, the European Commission developed guidelines for stakeholders on adaptations to regulatory frameworks to address challenges arising from the COVID-19 pandemic, with a particular focus on crucial medicines for treating COVID-19 patients.60

Canada was among the first movers to amend its domestic compulsory licensing system through emergency legislation titled the COVID-19 Emergency Response Act.61 Part 12 of the emergency legislation amended the Patent Act by adding section 19.4 to the compulsory license and government use regime, accelerating and simplifying the application process. Under the new section, the government and any person specified by the government in the application can obtain a one year licence to ‘make, construct, use, and sell a patented invention to the extent necessary to respond to the public health emergency’.62 The license issued is non-transferable and will be valid for one year from the granting date or once the Minister of Health notifies the Commissioner that the authorization is no longer necessary, whichever comes first.63 According to the new measures, the Canadian government can issue compulsory licenses without protracted negotiations over the terms of access to vaccines or other related technologies.64 DeBeer and Gold raised two main concerns with the Canadian measures. First, the one year authorization is restrictive and can be uneconomical for companies to start production on generics.65 Second, Canada’s compulsory licensing provisions are likely more useful for existing devices or the new use of known drugs rather than for new vaccines or antivirals.66 In other words, the measures can be used to facilitate access to equipment and tools already in the market but likely may not apply to any new vaccine(s) that might emerge from ongoing R&D as patent applications generally take years to be examined and granted by the patent office. Regardless of the potential benefits or drawbacks, the amendment included a sunset clause that expired at the end of September 2020 and was not renewed or extended.

In Europe, France enacted the Emergency Law No. 2020-290 dated 23 March 2020, introducing Article L3131-15 into the Public Health Code to combat the COVID-19 pandemic. This gave extraordinary powers to the French Prime Minister, enabling him to, amongst other things, bypass the general provisions in the IP Code to impose compulsory licences where necessary.67 Germany adopted similar provisions in the Act on the Protection of the Population in the Event of an Epidemic Situation of

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63 Ibid s 19.4(3).
66 Ibid.
National Importance on 27 March 2020, which gave the Federal Ministry of Health additional powers to invoke Section 13(1) of the German Patent Act and limit patent rights for certain inventions to be used in the interest of public welfare or national security.68

Both public welfare and security concerns can be cited during a pandemic to justify the issue of a compulsory license. For example, the Russian Federation issued an ordinance for a compulsory license for inventions related to the production of remdesivir on 31 December 2020. 69

According to Decree 3718-r, Pharmasyntez JSC, a Russian generic company, was granted a compulsory one year license to use Gilead’s patents, subject to fair compensation.70 The Russian generic manufacturer filed a request with the government for a compulsory license after a few unsuccessful attempts to obtain a voluntary license from Gilead. In Latin America, the National Assemblies of both Chile and Ecuador requested their respective governments to grant compulsory licenses and facilitate access to vaccines, drugs, diagnostics, and other technologies related to the prevention and treatment of COVID-19.71

The COVID-19 pandemic has led to increased demand for therapeutics, vaccines, and diagnostics worldwide, especially among developing countries and LDCs. As a result, Article 31bis made the use of compulsory licenses more accessible and opened the door to using them for exporting pharmaceutical products to countries that lack domestic manufacturing capacity. However, with the perceived need for compulsory licenses comes the problem of accessibility to undisclosed information necessary to manufacture the licensed technologies.

D. COMPULSORY TRADE SECRETS LICENSING

While the use of compulsory licensing might allow access to vaccine technologies and provide a solution to the exclusive rights provided to the patent holder, undisclosed information that encompasses the information needed to manufacture and distribute medical treatments remains another significant obstacle to access COVID-19 medical treatments.72

Undisclosed information, including both trade secrets and test data submitted to government agencies, covers information that can range from genomic data and results of clinical trials,73 to manufacturing know-how and research dead-ends.74 Unless a trade secrets owner licenses the information, the secret remains locked up by the owner.

The current system of compulsory licensing is limited to granted patents that protect COVID-19 medical treatments against fulfilling certain conditions, and there is no equivalent mechanism in IP laws to oblige trade secrets owners to share their technology.75 Therefore, there is a need for compulsory trade secrets licensing in the interest of global public health crises that allows researchers and governments to access the protected information.76 Meanwhile, trade secrets owners will be

72 Undisclosed information provides an economic or competitive advantage to their owner and are unlimited in time as long as the conditions for its protection continue to be met.
73 According to Article 39(3): “Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use”.
compensated for the investments conducted to develop and compile this undisclosed information.\(^{77}\) The compulsory trade secrets license can find grounds in paragraph 4 of the Doha Declaration which states that ‘the TRIPS Agreement does not and should not prevent members from taking measures to protect public health’. Unlike trademarks, there is no specific exclusion of a compulsory trade secrets license in the TRIPS Agreement.\(^{78}\)

Governments can then grant a hybrid compulsory licence for patents and associated undisclosed information required to manufacture the critical and lifesaving technology. Independent discovery and reverse engineering can also complement the government efforts to obtain access to information and data needed to manufacture the vaccines and other medical technologies.

Like with compulsory patent licensing, the implementation of compulsory trade secrets licensing could find grounds in the ‘public interest’ concept to justify the disclosure of undisclosed information. A sufficient public interest has been recognized by courts in the US to grant access to trade secrets. In *Detroit Medical Center v GEAC Computer Systems*,\(^{79}\) the court found that a general interest in confidentiality agreements was outweighed by the public interest of receiving adequate medical care and ordered the trade secret holder to provide access to the confidential information. In Europe, the 2016 Trade Secrets Directive exempted the national rules requiring trade secret holders to disclose for reasons of public interest from the protection against the unlawful acquisition, use and disclosure of trade secrets.\(^{80}\)

This public interest factor may be relevant in terms of the urgency of COVID-19 and the global interest in vaccine production. A public interest consideration for compulsory trade secrets licensing does not conflict with the TRIPS flexibilities to protect public health and can be used as a ground to justify the grant of a compulsory license similar to the government use of patents.

Due to the complex nature of trade secrets, the non-voluntary license of trade secrets should be exclusive to the licensee, non-transferable to third parties, limited in time, bounded by the same requirements for protection, and must include a precise definition of the licensed subject matter. The confidential information should be destroyed at the end of the license term and the government could be liable to the trade secrets owner against any breach of the confidential information even after the license term.

With demonstrated success of using compulsory licenses in the past, countries have seen the direct connection between the need for finding affordable and timely access to medical resources and the overall societal impact against the rights of patent owners. Some may argue that having these types of provisions within international agreements could lead towards a slippery slope in devaluing IP protection and disincentivizing research and innovation. However, the supporting provisions in the Doha Declaration and use of compulsory licensing are clearly intended to be used sparingly and only when necessary to protect public health. The novel COVID-19 pandemic exemplifies the type of emergency that would warrant the use of compulsory licensing for global knowledge transfer. Ultimately, while the ability of governments to determine the grounds upon which they may grant compulsory licensing is domestically driven, the TRIPS Agreement should be revised to include provisions authorizing the issue of a compulsory licensing of trade secrets.


\(^{78}\) Article 21 states that it is ‘understood that the compulsory licensing of trademarks shall not be permitted’.


4. TRIPS WAIVER

Globally, there has been increasing concern over affordable, equitable access to treatments, diagnostics, and especially vaccines for COVID-19. Accordingly, on 2 October 2020, India and South Africa submitted a proposal to the WTO for a temporary waiver from certain provisions of the TRIPS Agreement for the prevention, containment, and treatment of COVID-19 (the Waiver).81 The proposal allows WTO Members to not enforce or implement obligations pertaining to four sections of the TRIPS Agreement, with a view to facilitating greater access to COVID-19 related technologies: Section 1 on copyright; Section 4 on industrial designs; Section 5 on patents; and Section 7 on the protection of undisclosed information.82 The Waiver is meant to be a temporary measure until widespread vaccination is implemented worldwide and global herd immunity has been achieved.83

Since its introduction, the proposal gained widespread support from WTO Members and non-governmental organizations (NGO).84 The prospect of a waiver has once again thrown the international norms of the patent system and its impacts on health and technological development to center stage. The current proposal created two different camps: on the one hand, those opposed to the Waiver who prioritize the importance of preserving incentives for research and innovation, and on the other hand, those in favor of granting the Waiver to meet global needs and secure equitable access to affordable health products and technology. The following section will first explore the arguments raised in support of the Waiver, followed by those in opposition.

The primary justification behind the Waiver proposal is that it would be an effective response to the global need for affordable medical products and technology transfer during the pandemic, given the limitations in the TRIPS Agreement that hamper and prohibit developing countries from taking advantage of existing flexibilities. The goal of the Waiver, therefore, is to ‘ensure that complications arising from IP rights protection do not delay response or lead to a suboptimal response from the countries around the world affecting lives of all people’.85 Past experiences demonstrated that patent rules impeded developing countries’ access to affordable vaccines, such as pneumococcal conjugate vaccines (PCV), and human papillomavirus (HPV) vaccines, which delayed generic alternatives.86 These

82 The initial proposal submitted on 2 October 2020 included reference to related rights. However, the revised decision text submitted to the TRIPS Council on 25 May 2021 excluded the protection of performers, producers of phonograms and broadcasting organizations from being waived. The revised decision text was submitted at the request of the delegations of the African Group, Bolivia, Egypt, Eswatini, Fiji, India, Indonesia, Kenya, the LDC Group, Maldives, Mozambique, Mongolia, Namibia, Pakistan, South Africa, Vanuatu, Venezuela and Zimbabwe. See WTO, Waiver From Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19, Revised Decision Text (May 2021), IP/C/W/669/Rev.1<https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669R1.pdf&Open=True> accessed 26 June 2021.
83 The revised text added a paragraph on the duration of the Waiver and proposed that the General Council assesses the existence of the exceptional circumstancesjustifying the Waiver after a minimum period to determine the date of termination. Paragraph 2 of the revised text states that ‘this waiver shall be in force for at least three years from the date of this decision. The General Council shall, thereafter, review the existence of the exceptional circumstances justifying the waiver, and if such circumstances cease to exist, the General Council shall determine the date of termination of the waiver’. On 16 October 2020, Kenya and Eswatini became official cosponsors of the proposal. Approximately 100 countries supported the Waiver in the following months in addition to several intergovernmental civil societies. More recently, Canada, US, Russia, China, and other developed countries that initially opposed the Waiver joined the proposal. Nevertheless, the EU submitted on 4 June 2021 a proposal seeking WTO Members to commit to a multilateral trade action plan to ensure fair and universal access by expanding the production of COVID-19 treatments and vaccines. The EU’s proposal urges governments worldwide to achieve three goals: (1) Ensure that COVID-19 vaccines, treatments, and their components can cross borders freely; [2] encourage producers to expand their production, while ensuring that those countries most in need of vaccines receive them at an affordable price; and (3) facilitate the use of compulsory licensing within the TRIPS Agreement. The TRIPS Agreement already provides this flexibility, which is a legitimate tool that can be used swiftly where needed. See WTO, Urgent Trade Policy Responses to the COVID-19 Crisis: Intellectual Property (4 June 2021), IP/C/W/680<https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W680.pdf&Open=True> accessed 24 June 2021.
84 On 16 October 2020, Kenya and Eswatini became official cosponsors of the proposal. Approximately 100 countries supported the Waiver in the following months in addition to several intergovernmental civil societies. More recently, Canada, US, Russia, China, and other developed countries that initially opposed the Waiver joined the proposal. Nevertheless, the EU submitted on 4 June 2021 a proposal seeking WTO Members to commit to a multilateral trade action plan to ensure fair and universal access by expanding the production of COVID-19 treatments and vaccines. The EU’s proposal urges governments worldwide to achieve three goals: (1) Ensure that COVID-19 vaccines, treatments, and their components can cross borders freely; [2] encourage producers to expand their production, while ensuring that those countries most in need of vaccines receive them at an affordable price; and (3) facilitate the use of compulsory licensing within the TRIPS Agreement. The TRIPS Agreement already provides this flexibility, which is a legitimate tool that can be used swiftly where needed. See WTO, Urgent Trade Policy Responses to the COVID-19 Crisis: Intellectual Property (4 June 2021), IP/C/W/680<https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W680.pdf&Open=True> accessed 24 June 2021.
86 Médecins Sans Frontières (MSF), ‘A Fair Shot for Vaccine Affordability: Understanding and addressing the effects of patents on access to newer
exclusive rights are thus increasing the risks to life and health for many who experience treatable or preventable illnesses in developing countries. Furthermore, several COVID-19 technologies and vaccines are protected by more than one patent or a mixture of patents and trade secrets.\(^8^7\) As a result, the knowledge required to produce a vaccine or a medical technology can be dispersed among several right holders, often requiring separate negotiations and additional layers of complexity in the process to develop a single treatment or vaccine.\(^8^8\)

Second, the mechanisms of issuing compulsory licenses under the TRIPS Agreement are complex, and many developing countries face institutional and legal difficulties when invoking TRIPS flexibilities.\(^8^9\) To issue a compulsory license, a patent must already have been granted for the product or process in question, which might not be the case for most of COVID-19-related technologies and medicines, as they are relatively new and constantly developing. Patent applications are typically published and disclosed 18 months after filing and are not yet publicly available.\(^9^0\) The inadequacy of disclosures in patent applications is another issue, as patent claims tend not to contain all the necessary information required to actually replicate a vaccine.\(^9^1\)

Moreover, the unnecessary administrative delays in obtaining a compulsory license and the possibility of judicial review may unduly hamper a country that urgently needs to manufacture a patented drug and inhibits the ability of manufacturing countries to export products to countries in need.\(^9^2\)

Furthermore, Waiver proponents claim that voluntary sharing mechanisms are not working as designed and that the public funding available for inventing COVID-19 technologies is benefitting the pharmaceutical industry more than the public.\(^9^3\) The WHO COVID-19 Vaccines Global Access (COVAX)\(^9^4\) not only falls short of needed population coverage, but also continues to underdeliver vaccines. This is due to the short supply of vaccines globally and vaccine nationalism discussed earlier. Some voluntary agreements, such as AstraZeneca-Serum Institute of India, BioNTech-Fosun Pharmaceuticals joint venture in China, Fiocruz in Brazil, and Merck-Johnson & Johnson, are contributing to reducing vaccine scarcity. Nonetheless, these voluntary efforts are not sufficient to meet the world’s needs during this pandemic.\(^9^5\)

Moreover, studies have shown the significant role of public funding by governments and universities in vaccine research and technologies.\(^9^6\) The findings of a recent vaccines’ (Report, 21 September 2017) 5. [https://msfaccess.org/fair-shot-vaccine-affordability] accessed 26 June 2021.


\(^9^4\) COVAX is a public-private initiative designed to meet the immediate needs of the world as nations come together and purchase vaccines through self-financing and funded countries. COVAX is the vaccines pillar of the Access to COVID-19 Tools (ACT) Accelerator. ACT is a ground-breaking global collaboration to accelerate the development, production, and equitable access to COVID-19 tests, treatments, and vaccines. COVAX is co-led by Gavi, the Coalition for Epidemic Preparedness Innovations (CEPI), and WHO. Its aim is to accelerate the development and manufacture of COVID-19 vaccines, and to guarantee fair and equitable access for every country in the world. See WHO, ‘COVAX: Working for global equitable access to COVID-19 vaccines’ [www.who.int/Initiatives/act-accelerator/covax] accessed 28 June 2021.

\(^9^5\) See Thambisetty (n 103).

\(^9^6\) Cleary EG, et al., ‘Characterizing the public sector contribution to drug discovery and development: the role of government as a first investor’
study on the Oxford/AstraZeneca vaccine confirmed that the majority of the money to develop the vaccine came from UK government departments, British and American scientific institutes, the European Commission and charities including the Wellcome Trust.97

WTO Members opposed to the Waiver have advanced several arguments. First, they argue that there is no concrete evidence indicating that IP rights have been a real barrier to accessing COVID-19 related technologies. There are various major factors hindering access to COVID-19 treatments and technologies, including the lack of manufacturing capacity (facilities, equipment, raw materials and storage) and researcher capability to implement the knowledge transferred, and these factors will not be resolved by waiving IP rights.98 Certain technology related to COVID-19 can be easily replicated and produced for the urgent need of developing countries, but not the manufacturing of COVID-19 vaccines, which requires specialized knowledge and large investments. Given the low prices of generic vaccines, advanced generic manufacturers in a limited number of countries may be the primary beneficiaries of the Waiver, not the countries who rely on imported supplies due to inadequate manufacturing, storage, and transport capabilities.99 In April 2021, Moderna announced that there is a shortfall in previously estimated doses, despite best efforts. The Company attributes this to supply chain issues and stated that, ‘vaccine manufacturing is a highly complex process and a number of elements, including human and material resources, have factored into this volatility’.100 Similar supply issues have occurred with the Johnson & Johnson vaccine in the US, and AstraZeneca production in India.101

Furthermore, suspending the enforcement of IP rights would hinder R&D and affect the spectrum of innovation. The rationale for IP rights is built around the idea that creativity and innovation are rewarded. The IP system provides innovators with a set of exclusive rights as incentives to taking risks and spending time and funds on R&D activities. While in the short-term, waiving IP rights may accelerate distribution for COVID-19 vaccines, technologies, and treatments, it may hinder the research of new technologies and treatments in the long-term.102 Waiving IP rights during this pandemic would impact preparedness for the next crisis. Venture capitalists would be less interested in investing in R&D and innovation without the prospect of a return on investment, guaranteed by exclusive rights for commercialization.103 However, this argument does not consider the scale of the outbreak and economic impacts, or the public funding spent on R&D. Waiver sponsors argue that the pharmaceutical industry should not reap off all the benefits involved in inventing treatments given the significant public funding that has backed such efforts.104 The financial incentive of manufacturers and the goals of globally fighting the pandemic are currently in conflict, especially as COVID-19 becomes an endemic. The IP system as it currently operates should not only

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100 Mercurio (n 105) 10–11.
promote profit-based incentives and monopolies but should also take into consideration public health and the overall societal good. Eventually, the main advantage of the Waiver proposal resides in the fact that patentee’s exclusive rights can be postponed in time of crisis. However, the fundamental problem remains in how to obtain the know-how and data required to manufacture the products. Emergency laws such as the French law or the US Defense Production Act discussed earlier can facilitate access to undisclosed information, but an effective mechanism does not always exist in domestic legislation. The Waiver does not require developed countries to transfer technologies and know-how to developing countries.

5. CONCLUSIONS: MOVING FORWARD

International treaties are developed to proactively protect public interests during times of crisis and global emergencies, with the COVID-19 pandemic as a prime example of such a time. This pandemic has created an opportunity to test these measures and it has become evident that they are ill-designed to respond to the extent required to combat COVID-19 globally.

Protecting IP rights internationally is clearly an important priority as it incentivizes future R&D of innovative technologies and encourages researchers to publicize their inventions. However, against global needs for access to life-saving technologies, these IP rights should be limited for the purposes of societal good. The existing flexibilities as well as the proposed Waiver aim to limit the intrusion upon protected IP rights only to the extent necessary to respond to COVID-19. The use of compulsory licensing for patents granted, as outlined in Article 31bis and reinforced by Clause 5 of the Doha Declaration, is a mechanism available for States to respond to national emergencies at their discretion. This mechanism should be augmented by a compulsory trade secrets license ensuring access to information and data necessary to implement medical technologies. This paper suggests revisiting the international standards of the TRIPS Agreement to include an additional mechanism of compulsory trade secrets licensing.

In the context of the COVID-19 pandemic, the urgent need to access COVID-19 treatments warrants an efficient mechanism to access IP, often from multiple rights holders in multiple countries. With growing international support, this TRIPS Waiver aims to mitigate delayed responses to combatting COVID-19 caused by IP protection complications. This Waiver recognizes the shortcomings of the current flexibilities in the TRIPS system and aims to provide a temporary solution to waive IP rights until widespread vaccination is implemented worldwide and global herd immunity has been achieved.

Looking towards the future, however, the long-term solution for facilitating access to COVID-19 technologies, requires a compulsory licensing system for trade secrets. The current compulsory licensing regime may fall short to respond immediately to a global crisis but presents an option for governments to issue a license for domestic use related to the public’s health. Compulsory licensing has garnered international validation through the TRIPS Agreement and Doha Declaration and has been implemented within several domestic legislations to respond to matters of emergency or public health. It is a feasible tool to limit the patentee’s exclusive rights that need to be reinforced by a compulsory trade secrets license enabling access to undisclosed information.

Looking at the current situation, the Waiver presents an unparalleled opportunity to share knowledge and provide access to licenses to respond effectively to the severe supply shortage of global vaccines as a result of vaccine nationalism. The Waiver allows for an expedited process foregoing the bureaucratic burdens that compulsory licenses face and avoids the divisive nature of the use of a national security exception. The immediate need for vaccines is clear, and the Waiver is the tool that will provide the most affordable and most timely solution to the global problem of inequitable access to COVID-19 treatment. If the current pandemic does not justify the limitation of IP rights to provide equitable access to life-
saving technologies, it is hard to imagine a situation that could ever warrant a mechanism such as the one proposed. If not now, when?

**BIBLIOGRAPHY**


7. COVID-19 PANDEMIC: CONGENITAL FLUIDITY OF PROPOSAL FOR WAIVER OF IP RIGHTS AND THE ROAD AHEAD

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ABSTRACT

This paper argues that the proposal for waiver from the obligation to implement or apply certain provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is neither a complete solution nor the only solution to deal with the crisis of COVID-19 pandemic mainly because the waiver proposal has congenital fluidity. It is further argued that the solution lies in the effective enforcement of existing provisions of the TRIPS Agreement. It is also argued that the world needs more and not less patents on pharmaceutical products during the pandemic to help scale up production, improve global supply chain and promote competition to ensure equitable access to such products by all. The paper seeks to highlight congenital fluidity of the waiver proposal and demonstrates how existing provisions of the TRIPS Agreement can be effectively used during pandemics. However, the TRIPS Agreement would have been more efficacious had it expressly provided for pandemics. In hindsight of the COVID-19 pandemic, future pandemics cannot be ruled out. Time has come which demands that provisions on pandemics should be incorporated in the TRIPS Agreement. However, explicit mentioning of pandemics in the TRIPS Agreement alone cannot be sufficient to deal with pandemics. Therefore, it is further suggested that instead of piecemeal and ad hoc arrangements, the World Health Organization (WHO), the World Intellectual Property Organization (WIPO) and the World Trade Organization (WTO) should collaborate to develop an effective international legal framework to deal with both present and future pandemics.

Keywords: COVID-19 pandemic, pharmaceutical products, intellectual property rights, TRIPS, waiver proposal, WHO, WIPO, WTO.

1. INTRODUCTION

The COVID-19 pandemic¹, amongst other things, brought divergent views of WTO Members at the center stage in regard to the implementation of certain provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). On 2 October 2020, India and South Africa requested the TRIPS Council to recommend to the General Council waiver from obligation to implement or apply Sections 1 (Copyright and Related Rights), 4 (Industrial Designs), 5 (Patents), and 7 (Undisclosed Information) of Part II of the TRIPS Agreement or to enforce these Sections under Part III of the TRIPS Agreement in relation to the prevention, containment, or treatment of COVID-19² (original proposal). Since then, several communications supporting and opposing the waiver proposal have been made to the TRIPS Council.³

At a formal meeting of the TRIPS Council on 23 February 2021, Members discussed the temporary waiver of the TRIPS obligations but were unable to reach

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any concrete decision.\textsuperscript{4} Members only agreed on an oral status report to the General Council reflecting the state of discussions and the lack of consensus on the waiver proposal.\textsuperscript{5}

At a formal meeting of the TRIPS Council on 8-9 June 2021, Members moved closer to a ‘text-based’ process.\textsuperscript{6} Members reiterated their well-known differences on where the emphasis should be placed to ensure their shared objective on a rapid and effective response to the pandemic.\textsuperscript{7} They expressed their willingness to engage constructively in a discussion based on two proposals:

(i) revised proposal co-sponsored by over 60 delegations for ‘Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19’,\textsuperscript{8} and

(ii) communication from the European Union (EU) on ‘Urgent Trade Policy Responses to the COVID-19 Crisis: Intellectual Property’.\textsuperscript{9}

The questions are whether: (i) the waiver proposal is born with congenital fluidity, (ii) the existing provisions of TRIPS Agreement can be effectively used to mitigate so-called rigors of intellectual property (IP) rights, (iii) the world needs patents on pharmaceutical patents during pandemics, and (iv) more can be done to deal with present and future pandemics.

The waiver proposal seems to present a picture as if IP rights are part of the pandemic crisis. The reality, however, is entirely different. Mismanagement of COVID-19 pandemic is because of a myriad of factors including lack of cooperation amongst world leaders, relatively dysfunctional international systems,\textsuperscript{10} rise of nationalism\textsuperscript{11} and deglobalization, dearth of availability of active pharmaceutical ingredients (API),\textsuperscript{12} and lack of capacity of certain countries to manufacture health products. Therefore, to call patent an accomplice of the crisis is not fair.

Besides its congenital fluidity, the waiver proposal creates fear of patent. This fear is baseless for several reasons. One, the waiver proposal ignores the legal nature of patent right which is only an ‘exclusive and negative’ right and not a positive right to make, use, offer for sale, sell, import, or export health products can be exercised by a patentee or other persons only after getting approval of the national drug authority.

\begin{footnotesize}
\begin{itemize}
\item[\textsuperscript{5}] WTO, ‘Members discuss TRIPS waiver, LDC transition period and green tech role for small business’ (11 March 2021) <https://www.wto.org/english/news_e/news21_e/trip_11mar21_e.htm #="text%20meeting%20of%20the,to%20cover%20small%20business%20and"> accessed 12 March 2021.
\item[\textsuperscript{7}] Ibid.
\item[\textsuperscript{9}] WTO, Communication from the EU to the TRIPS Council (4 June 2021), IP/C/N/680 <https://docs.wto.org/dol2fe/Pages/directdoc.aspx?filename=q:/IP/C/W680.pdf&Open=True> accessed 27 June 2021.
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Two, it ignores the law that patent is a territorial and conditional right. Global, international and world patents simply do not exist. Three, in furtherance of Article 8, Members may take consistent measures relating to patented health products provided they grant patent on such health products. Four, a patent on health products does not worsen the health conditions of patients, rather such patents create hope for at least those who can afford patented items. The necessity and significance of invented health products cannot be overemphasized, especially during the pandemic situation. Fear of patent on health products is likely to have a negative impact on investment on research and development (R&D) of health products in the absence of incentive in the form of patent. Five, there is no cause-and-effect relationship between patent and high prices of health products as there are off-patented medicines having high price tag. The problems of equitable access and affordability to health products are mainly because of global poverty and governance deficit. It is a well-known fact that people cannot afford even one square meal a day, paying for health products would be even more difficult. Therefore, the waiver proposal has at least abovementioned five congenital fluidities and hence requires a closer and deeper look.

The paper begins by highlighting the congenital fluidity of the waiver proposal. Then, it moves on to demonstrate how existing TRIPS provisions can be effectively used during pandemics. In the next leg, an attempt has been made to develop a model road to avoid or at least minimize the devastating impact of pandemics at least in the future.

2. CONGENITAL FLUIDITY OF WAIVER PROPOSAL

The original waiver proposal seems to have generated more heat than light. Every successive proposal and counterproposal added to the fluidity of the original proposal. As noted above, in the formal meeting of the TRIPS Council on 8-9 June 2021, Members moved closer to a ‘text-based’ process on two proposals and the paper seeks to highlight the congenital fluidity of these.

The revised proposal noted that ‘exceptional circumstances exist for justifying waivers from TRIPS obligation’. The Draft Decision Text annexed to the revised proposal may be summarized as follows. One, the scope of the operative paragraph (1) as to waiver from obligation under Sections II and III of the TRIPS remained the same as the original proposal. The scope of the subject matter has however been narrowed down to only ‘health products and technologies’ for the prevention, treatment and containment of COVID-19.

Two, the waiver shall be available for at least three years from the date of decision and thereafter the General Council shall review the existence of exceptional circumstances and if such circumstances cease to exist, the General Council shall terminate the waiver.

16 March 2021 global poverty update from the world bank provides an estimate of global poverty as follows: below USD 1.90 per day 696 million people, below USD 3.20 per day 1821 million people and below USD 5.50 per day 3269 million people. By this estimate, a total of 5786 million people, roughly around three fourth of the population, are living below USD 5.50 per day. Castaneda Aguilar RA, et al., ‘March 2021 Global Poverty Update From The World Bank’ (World Bank Blogs, 16 March 2021) <https://blogs.worldbank.org/opensdata/march-2021-global-poverty-update-world-bank> accessed 22 June 2021.

17 Text-based discussions (n 6).

18 Revised Decision Text (n 8) and EU Communication (n 9).

19 Revised Decision Text (n 8) last preambular text.

20 It was noted that original decision text was too broad. ibid, para. 4.

21 The term ‘health products and technologies’ has been used to include ‘diagnostics, therapeutics, vaccines, medical devices, personal protective equipment, their materials or components, and their methods and means of manufacture’. ibid, para. 1.

22 ibid, para. 2.
the General Council shall review the waiver annually until the waiver terminates.\textsuperscript{24}

It is clear from the revised proposal text that the original proposal was too broad. The revised proposal text, though claimed to be narrowed down, still remains too wide and self-contradictory. It is unfathomable how copyright in artistic, musical, dramatic work and cinematograph films impede access to health products and technologies. How does the protection of industrial design that covers only the visual features of articles which appeal to the eyes become a roadblock for the right to vaccination? Is the container of vaccine coming in the way of the vaccination? Undisclosed information remains protected as long as it is a secret or has not been misappropriated. If trade secret is known by honest means through reverse engineering, law does not come in the way of such reverse engineering. Therefore, it would have been fairer and more feasible had the proposal been confined to the waiver from obligation to implement, apply and enforce patent rights under Sections II and III of the TRIPS Agreement. A strategy guided by greed rather than by need is likely to fail. Focus on ‘possibility’ of success of the proposal instead of ‘desirability’ considerations could have been a more workable strategy. In the alternative, developing countries could have approached the WTO Dispute Settlement Body (DSB) for the enforcement of Article 7 for the transfer and dissemination of patented technology. Working within the system and seeking to bring about change from within is a more practical method than questioning the system from outside. The waiver proposal seems to be guided by political desirability than legal possibility. Hence, the waiver proposal may be appropriately described as congenitally fluid.

The EU and other developed countries which have granted patents on pharmaceutical products and technologies, are arguing from within the TRIPS system. As noted above, the TRIPS Council has taken the EU communication along with the revised proposal to move towards a ‘text-based’ discussion.

The EU communication may be summarized as follows: One, the WTO must step up its efforts to ensure that the rule-based global trading system plays its role in response to the pandemic.\textsuperscript{25} Two, the most urgent challenge is to ensure rapid and equitable rollout of vaccines and therapeutics globally.\textsuperscript{26} Three, there is an urgent need for multilateral Trade and Health initiative. EU has been engaged in discussions on a temporary IP waiver and has supported the initiative to consider practical ways to enhance production capacity and cooperation with the private sector.\textsuperscript{27} Four, there is an urgent need to agree on the global trade initiative for equitable access to COVID-19 vaccines including clarification and facilitation of the TRIPS Agreement flexibilities relating to compulsory licences.\textsuperscript{28} Five, the role of IP is not only limited to incentivizing the development of vaccines as it also plays an important role in enabling equitable access to vaccines.\textsuperscript{29} Six, public health crisis requires both acceleration of vaccine production and its equitable global distribution.\textsuperscript{30} Seven, 2001 Doha Declaration on the TRIPS Agreement and Public Health clarifies the links between the TRIPS Agreement, its flexibilities and public health.\textsuperscript{31} Eight, limit the use of compulsory licensing. However, as the pandemic is a circumstance of national emergency, therefore the requirement to negotiate with right holders may be waived and the remuneration for patent holders should reflect such affordable prices.\textsuperscript{32} Nine, the EU is ready to consider which actions and what support the TRIPS Council and each Member individually can provide to other Members to facilitate the use of Articles 31 and 31bis.\textsuperscript{33} Ten, a proposal for a

\textsuperscript{24}ibid, para. 5.
\textsuperscript{25}EU Communication (n 9) para. 1.
\textsuperscript{26}ibid, para. 2.
\textsuperscript{27}ibid, para. 3.
\textsuperscript{28}ibid, para. 4.
\textsuperscript{29}ibid, para. 6.
\textsuperscript{30}ibid, para. 7.
\textsuperscript{31}ibid, para. 8.
\textsuperscript{32}ibid, paras. 9, 10, 11 and 12.
\textsuperscript{33}ibid, para. 13.
comprehensive WTO initiative for equitable access to COVID-19 vaccines and therapeutics should facilitate finding a common solution among Members and bring about a concrete urgent response to the COVID-19 crisis.\textsuperscript{34}

The EU communication does not support the waiver proposal as it states that the pandemic crisis should be dealt from ‘within’ the existing framework of the TRIPS Agreement. A real problem arises when the EU communication seeks to limit the use of compulsory licences on pharmaceuticals. This TRIPS flexibility is already available to Members. It can only mean that the EU is desirous of taking away the existing TRIPS flexibility relating to grant of compulsory licence. Further, the EU appears to offer a flexibility wherein the EU communication states, ‘[t]he pandemic is a circumstance of national emergency and therefore the requirement to negotiate with the right holder may be waived.’\textsuperscript{35} There is nothing new in this offer as this flexibility is already exists in Article 31(b).

The fundamental difference between the revised proposal and the EU communication adds to the congenital fluidity of the waiver proposal. The EU is using both legal and political methods in discussions relating to the pandemic and patent waiver. On the one hand, the EU is emphasizing the importance of global cooperation and a rule-based global trading system. On the other, the EU wants to restrict the existing TRIPS flexibilities. The EU proposal may be described as unfair for the reasons stated above but feasible because the EU stands to lose nothing even if its proposal is not accepted. The objective of the EU will be served if it succeeds in delaying or blocking the waiver proposal. Under the given scheme of things, the EU communication has succeeded in establishing that the waiver proposal is congenitally fluid.

It appears that the proponents of the waiver proposal are on the right platform but are trying to board the wrong train. This train will move only if there is a consensus between Members. On the face of it, the waiver proposal is both congenitally fluid and unfair. It is fluid because Members, particularly the EU and other developed countries, are unlikely to accept the proposal. Feasibility of acceptance of the proposal seems to be a remote possibility as evolving consensus on this contentious issue is, at best, a long-drawn process. It is unfair as it asks for more than what is necessary, ignores the interest of a patentee and raises serious doubts about the patent system itself. The waiver proposal could have been limited to patents. The waiver proposal misses a vital point as to the territoriality of patent rights. Assuming that the waiver is accepted, how will it serve the interest of Members who have not granted patents on pandemic related health products? Patent waiver can help only those countries who granted patents on these health products. Even without accepting the waiver proposal, Members granting a patent have enough flexibilities under the TRIPS Agreement to limit patent right on grounds of public health. Had patent right been global, such proposal would have been desirable. Hence, there cannot be an international waiver of patent right as there is no international patent right. Given the existing approach of the EU, proponents of the waiver proposal may lose already existing TRIPS flexibilities like the grant of compulsory license on health products.

Though some developed countries, including the United States (US), have extended their support for text-based negotiation,\textsuperscript{36} and negotiation at the international fora is a long drawn process given the consensus-based approach. Garnering consensus in support of the waiver proposal is not only difficult but also impossible. A thing which is not doable because of its congenital defects should not be pursued at all. Endeavor should be made to do what is doable. Working within the existing framework

\textsuperscript{34} ibid, para. 14.

\textsuperscript{35} ibid, para. 9a.

of the TRIPS Agreement is doable. In the following section, an attempt is made to develop an argument that existing TRIPS provisions can be and should be effectively used by Members to deal with the pandemic crisis.

3. ADEQUACY OF THE TRIPS AGREEMENT TO MITIGATE THE RIGORS OF PATENT RIGHTS DURING PANDEMICS

It is argued that TRIPS provisions are adequate to mitigate the rigors of patent rights during pandemics. The TRIPS Agreement creates certain equitable and fair obligations but also provides certain flexibilities. This Section deals with only those obligations and flexibilities relating to the patent dimension of the pandemic.

First and foremost, the obligations of Members is called ‘Objectives’ and enunciated in Article 7. Article 7 may be described not only as the heart and soul of the TRIPS Agreement but also as its conscience keeper. These objectives are in the nature of obligations. Neither protection nor enforcement of IP rights are the objectives of the TRIPS Agreement. They are only a means to achieve the objectives for the ‘promotion of technological innovation and the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare’. Therefore, if either protection or enforcement of IP is not contributing to (i) promotion of technological innovation, or (ii) transfer and dissemination of technology, then such a protection or enforcement of IP frustrates the very objectives of the TRIPS Agreement. The word ‘should’ instead of the word ‘shall’ in the objectives seems to have been used for reasons of deference to sovereigns and to envision aspirations of the people of the world. It appears that Members are not giving due attention to the Article 7 to promote the transfer and dissemination of COVID-19 related health products. Article 7 should be read with Article 29.1 which requires that ‘an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art’. If a patent is granted on health products by any Member, then the information relating to it falls in public domain. If another Member has not granted a patent on the said product, then the TRIPS Agreement does not make it obligatory for any Member to grant a patent on such products merely because such patent has been granted by another Member. In other words, Members may use the invention under TRIPS flexibilities to deal with the COVID-19 crisis. Though it may be fairer that other Members first grant a patent and then use the TRIPS flexibilities.

Article 1.1 states ‘Nature and Obligations’ and gives Members an option to ‘implement in their law more extensive protection than required by this Agreement’ which ‘does not contravene the provisions of this Agreement’. There are only two WTO cases making reference to Article 1.1. In European Communities – Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs, the Panel interpreted Article 1.1 as follows:

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37 Article 7 is in the nature of obligation by virtue of Article 1.1 which inter alia provides, ‘Members shall give effect to the provisions of this Agreement’. TRIPS Agreement (n 14).
38 All references to ‘Article’ are references of the TRIPS Articles unless otherwise stated.
39 The only WTO case making reference to Article 7 is DS408: European Union and a Member State — Seizure of Generic Drugs in Transit WT/DS408 <https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds408_e.htm> accessed 6 May 2022. The latest update on the case shows that the consultation has been requested on 11 May 2010.
40 Apart from Article 7, the word ‘should’ have been used two more times in subparagraphs 2(b)(i) and 5 of Annex to TRIPS Agreement. Ibid.
41 No WTO case is available on Article 29.1.
43 DS290: European Communities (n 44).
The first sentence creates an obligation for Members to give effect to the provisions of the TRIPS Agreement and the second sentence recognizes Members’ freedom to implement more extensive protection, subject to a condition. After the expiry of the transitional arrangements in Articles 65 and 66 (and 70.8 and 70.9), as applicable, a Member is obliged to give effect to the provisions of the Agreement with respect to each category of IP right, irrespective of whether it implements more extensive protection in the same or another category of IP right.

Exercising this flexibility may not be an appropriate measure to deal with the pandemic as a more extensive protection may impede scaling up production of health products, resulting in adverse effect on global supply chain of patented products. Article 1.1 also provides freedom to Members to ‘determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice’. Use of this flexibility may help promote large-scale production of patented health products at least for domestic use.

Article 8.1 allows Members to ‘adopt TRIPS consistent measures necessary to protect public health. . . , and to promote the public interest in sectors of vital importance to their socio-economic and technological development, […]’ Public health and public interest are both victims of COVID-19. Members may fruitfully use Article 8.1 to amend their laws to deal with the COVID-19 crisis, both at national and international levels. Article 8.2 may be used by Members to prevent:

(i) abuse of patent right on health products by patentees, and
(ii) practices which unreasonably restrain trade or adversely affect the international transfer of technology related to health products. International transfer of technology is not only an objective but is also an obligation.

A law, whether national or international, generates respect from people when it remains true and honest to its stated objectives. Members, while granting a patent on health products, may make it mandatory for a patentee to: (i) grant voluntary licence on fair, reasonable and non-discriminatory (FRAND) model to all the eligible pharmaceutical entities, and (ii) fully and completely disclose all the essential and non-essential features of health products and should not protect the same such invention both as patent and trade secret to help avoid undue experimentation for replication purposes.

Article 27.2 allows Members to ‘exclude from patentability inventions, . . . which is necessary to protect ordre public or morality, including to protect human’. Article 27.3(a) further allows Members to exclude from patentability ‘diagnostic, therapeutic and surgical methods for the treatment of humans.’ Exclusion of health products from patentability may be a prescription worse than the disease during the pandemic. Health products should not be excluded from patentability in the absence of any alternative mechanism to incentivize research and invention. Mechanism should be evolved to further promote R&D in pandemic related health products. In hindsight, it can be safely said that invention begets invention, patents beget patents and technology begets technology. Invention can be hardly encouraged or promoted by excluding pandemic related health products from patentability.

Article 30 allows Members to provide reasonable and ‘limited exceptions to the exclusive rights conferred by a

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45 No specific WTO case is available on Article 8.1. The only case available on Article 8 is DS408: European Union and a Member State (n 41).

46 WTO cases are not available on Articles 27.2 and 27.3.

47 No WTO case is available on Article 30.
Article 31bis\(^50\) carves out certain exceptions to Article 31 and makes provisions for grant of compulsory licence in patented pharmaceutical products. Paragraph 1 of Article 31bis creates an exception to Article 1(f) and allows the Members to grant compulsory licence ‘for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s)’. The Annex to the TRIPS Agreement further explains the provisions of Article 31bis. The Appendix to the Annex to the TRIPS Agreement makes provisions regarding the ‘Assessment of Manufacturing Capacities in the Pharmaceutical Sector’. Article 31bis when read together with the Annex and its Appendix make it abundantly clear that pharmaceutical patents have been given special treatment. Article 31bis places health of the people first. It seeks to provide the least developed countries (LDCs), developing countries, and developed countries equitable and fair treatment without sacrificing the interest of the patentee. Members granting patents on health products may invoke this Article to effectively deal with the pandemic crisis.

Instead of making a fluid waiver proposal, Members particularly from the developing countries, could have introduced ‘Fast Track Patent Prosecution Procedure’ for granting patents on COVID-19 health products by amending their laws within the TRIPS flexibilities. Instead of waiting for patent applications from inventors of health products, these countries could have requested these inventors to file patent applications. Patents on such products could have been granted in an expedited manner on the basis of patents granted in other countries for reasons of national emergency and extreme urgency. These countries could have declared the COVID-19 pandemic as a national emergency. Whether any developing country has granted a patent on any COVID-19 vaccine is an open question and information in this regard is not readily available. After granting patents on health products, developing countries could have used all the TRIPS flexibilities to deal with the crisis both domestically and globally. In the alternative, developing countries and their pharmaceutical entities could have approached patent holders seeking voluntary licences to make and sell health products in their domestic market. This could have been done and could still be done. Developing countries will be better off if they start investing more in R&D to build their technological capacity. Instead of asking for waiver of obligation under the TRIPS Agreement, it would be better to focus on the implementation of TRIPS provisions, in letter and spirit, particularly as to the obligation of transfer and dissemination of technology. It will still be better for

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\(^{50}\) No WTO case is available on Article 31bis.
developing countries to invest more on education and research to become producers of new knowledge and useful technology. Being only a permanent importer of new knowledge and technology produced by developed countries is the surest prescription for permanent dependency by developing countries. This road of dependency will only lead to colonization of health.

Pandemic situations require more inventions of health products. It follows that the world requires more patents than less. More patents on pharmaceutical products means more producers and suppliers which will promote competition. Competition will check the abuse of dominant position by one or few pharmaceuticals. Competition will also ensure that better quality products are available at reasonably affordable prices. However, both the patentee and Members granting patents on pharmaceuticals owe not only a moral duty but also a legal duty to humanity. Legal duty of the patentee is to serve and promote social good by making patented health products available to the public at reasonably affordable prices by entering into voluntary licences on fair, reasonable and non-discriminatory terms and conditions so that demand of humanity can be met. If a patentee lacks the capacity to scale up production of health products, he must resort to licensing on fair, reasonable and non-discriminatory terms and conditions. Such an arrangement is bound to produce only winners and no losers.

The above analysis reveals that the TRIPS provisions as such are adequate and sufficient to deal with the so-called rigors of IP during pandemics. However, the time has come for evolving an international legal framework especially designed to deal with pandemic situations.

4. WHAT MORE NEEDS TO BE DONE: THE ROAD AHEAD

COVID-19 is a clarion wake-up call to get ready and prepare for future pandemics and evolve mechanisms to deal with the present crisis and future pandemics. Perhaps because of undue focus on the waiver proposal, lack of resources and capacity, policy paralysis and governance deficit, developing countries could not take refuge under the existing TRIPS provisions to deal with the pandemic crisis. Had the TRIPS Agreement made explicit mention of the pandemic, handling of COVID-19 might have been more convenient. During the Uruguay Round Negotiations on IP, the problem of a pandemic of such a catastrophic magnitude was not foreseen. Perhaps a pandemic itself was not foreseeable. It may be noted that the expression ‘public health’ has been used six times in the TRIPS Agreement, but the word ‘pandemic’ has not been used anywhere. What was not foreseeable during the Uruguay Round Negotiations or in the Doha Declaration is now facing us. COVID-19 makes out a very strong case for explicit inclusion of ‘pandemic’ in the TRIPS Agreement to provide for international measures for international emergency. It is suggested that the following provisions may be inserted in the TRIPS Agreement to deal with pandemic situations in a more efficient and equitable manner:

1. Members shall provide ‘Fast Track Patent Prosecution Procedure’ in their laws for pandemic related health products and technologies and should grant patents on such products or processes in an expeditious manner if such products or processes are approved by the WHO;

2. In furtherance of the objectives in Article 7, Members shall require the patent holders of pandemic related health products and

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technologies to grant voluntary licences on fair, reasonable and non-discriminatory terms and conditions to all pharmaceutical entities having the capacity to manufacture such patented health products and technologies;

3. Members shall evolve a mechanism to give primacy to patent protection over trade secrets of health products and shall promote reverse engineering of unpatented health products; and

4. Subject to Article 29, during pandemic situations, Members shall require that an applicant for a patent on health products shall fully and completely disclose:

(a) All the know-how, trade secret, and technology relating to claimed invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art. Nondisclosure or insufficient disclosure of any information relating to the claimed invention shall be sufficient ground for denial of patent application and revocation of patent; and

(b) Full and complete audited books of accounts showing all the capital and revenue expenditures incurred in the R&D of the claimed invention so that reasonable amount of compensation may be determined to reward the inventor/patentee.

Full and complete disclosure of claimed invention, in the real sense, is necessary for the following reasons:

1) Despite the requirement of sufficiently clear and complete disclosure of invention as envisaged under Article 29 and the identical requirement under national laws, patent applicants generally do not disclose all the essentials of the invention in the patent specification. Patent specification and claims may be drafted in such a language that it conceals more and reveals less. Standard approach of patent application in these cases is that ‘I did not claim this essential of invention, therefore I did not disclose it’. The point is that the essence of the invention which has not been claimed may be essential to replicate the patented invention without undue experiments;

2) Protecting an invention or certain essential features of the invention as trade secret is standard industry practice; and

3) Patent protection is generally sought when decoding the essentials of invention by reverse engineering techniques does not require undue experimentation by competitors.

The argument is not that the invention should not be protected as trade secret. Trade secret is a recognized form of IP both in Article 39 and national laws. The argument is that when the inventor is choosing patent over trade secret for her invention, she should disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art indicating the best mode for carrying out the invention known to the inventor. The practice of using both trade secret and patent to protect the same invention should be abandoned. Invention must become patent (open) in all respects after the grant of patent. An inventor has at least three choices as to her invention. One, she may voluntarily disclose the invention by way of publication or otherwise. Two, she may protect her invention as trade secret. Three, she may protect her invention as patent. Inventor is the master of her invention. Law does not compel an inventor to protect or not to protect her invention. Once, the inventor decides to use patent protection for her invention, she must come with clean and open hands. She should not be allowed to keep her cake as trade secret and eat it too as patent.

The main point of argument is that TRIPS should explicitly provide for pandemic situations and create mechanisms to use patent as the predominant solution. At the minimum, the word ‘should’ used in Article 7 should be
read as ‘shall’ during pandemic situations. Full and complete disclosure of all the essentials of the claimed invention including technical know-how, trade secret and other technology will make the meaning of ‘patent’ really open.

There is also a need to evolve an international legal framework to deal with pandemic situations. Such a framework should envisage the following:

1) A World Pandemic Organization (WPO) through a multilateral agreement should be established at the international level. Detailed structure, objectives, powers and functions of WPO should be worked out under the umbrella of the United Nations (UN) and WTO; and

2) A Permanent World Pandemic Fund (PWPF) should be created and may be jointly managed by the WTO, WIPO and WHO. Every country should be required to make an annual contribution to PWPF as may be agreed. Countries should contribute a portion of money collected in the form of taxes, or otherwise, for the existence and healthy survival of people. Philanthropists and donors may be encouraged to contribute to this fund. A certificate of recognition may be issued to such philanthropists and donors to encourage them. Corporations may be encouraged to contribute generously to this fund as part of their corporate social responsibility. A mechanism of giving tax exemptions to such corporations may be evolved to encourage contribution to this fund. PWPF may be used to:

(i) Promote R&D in pharmaceuticals both at international and regional levels;

(ii) Provide reasonable and adequate compensation to patent holders who volunteer to transfer their patented products and technologies relating to the prevention, treatment and containment of a pandemic;

(iii) Provide prizes and awards to persons and entities who voluntarily disclose their trade secrets and know-how relating to pandemic related health products and technology so that such health products may be manufactured at large scale and made available to the world population at reasonably affordable prices; and

(iv) Provide during a pandemic, vaccines, medicines, and diagnostics to the world population as quickly as possible. Timely vaccination is the essence of the matter.

The aforementioned suggestions may be used to initiate discussion for evolving an international framework to tackle present and future pandemic crises.

5. CONCLUSIONS

The waiver proposal creates unwarranted fear of IP rights. The proposal is not only congenitally fluid but is also unfair. The proposal (i) is still too wide and self-contradictory; (ii) ignores the interest of IP holders; (iii) raises serious doubts about the necessity and utility of the patent system in particular and the IP system in general; (iv) is asking for more than what is necessary to deal with the pandemic situation; (v) should have been limited to patents; (vi) misses vital points as to exclusivity and territoriality of patent right; (vii) neglects that a patent applicant does not come with clean and open hands as patent specifications generally do not disclose all the essential and non-essential features of claimed invention and the patent applicant generally discloses only as much as she thinks is necessary and protects certain features of claimed invention as trade-secret; (viii) does not give due weight to the TRIPS Agreement in general and TRIPS flexibilities in particular; and (ix) considering the well-known differences between Members and also the consensual mechanism of the WTO in such matters, makes the proposal even more fluid. Instead of the waiver proposal, a workable solution could have been to file a complaint with the WTO DSB for
enforcement of obligations under Article 7 against Members who have granted patents on health products. Because of its fluidity, the waiver proposal may become part of the problem instead of solving it.

The EU communication argues within the TRIPS framework. It is workable because the EU stands to lose nothing even if the proposal is not accepted. The purpose of the EU proposal will be served if it succeeds in delaying or blocking the waiver proposal. Unfairness of the EU communication is clear as it seeks to place more restrictions on existing TRIPS flexibilities, particularly on the use of compulsory licence.

It will be in the interest of both the patentee and the people if Members implement Article 7. Protection and enforcement of patent right are against the objectives of the TRIPS Agreement if it does not promote the transfer and dissemination of patented technology globally. Therefore, TRIPS provisions as such can be effectively used by enforcing these in letter and in spirit to overcome the pandemic crisis. An analysis of the TRIPS provisions reveals that even without a waiver, Members granting a patent have enough flexibilities to limit patent right on several grounds. However, the granting of a patent is a condition precedent for use of such flexibilities. Under TRIPS flexibilities, Members could use ‘Fast Track Patent Prosecution’ for expeditious grant of patent on health products during pandemics. In the alternative, Members and their business entities can seek voluntary licenses from the patent holder and can manufacture and sell the patented health products.

Given the silence in the TRIPS Agreement on pandemics, it is suggested that the TRIPS Agreement may be amended to explicitly provide for pandemic situations. It is further suggested that (i) a WPO be established at the international level; and (ii) a PWPF be established to deal with present and future pandemics.

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8. INTERACTION BETWEEN IP LAW AND ENVIRONMENTAL LAW ON PLANT GENETIC RESOURCES FROM INTERNATIONAL AND NATIONAL PERSPECTIVES – A CASE STUDY: IRAN

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ABSTRACT

The potential commercial value of plant genetic resources (PGRs) has led to an increased tendency to grant property rights to these resources. PGRs also play a significant role in achieving sustainable development in the agricultural sector. This implies an inevitable interaction between intellectual property (IP) law and environmental law. This study shows two different legal approaches to PGRs based on the principles involved in the interactions between these branches of law. Based on international and Iranian legal instruments, this paper first compares state sovereignty with PGRs with their ownership and then analyzes some principles of international environmental law, particularly in the context of IP rights. It is argued that national legal systems should explicitly provide the criteria that allows a country to determine whether a national decision made on plant genetic innovations – based on some potential environmental risks – is proportionate and not wholly contradictory to IP rights. Indeed, if the principles of international environmental law are applied appropriately in national legal systems, particularly, in cases of environmental ‘risks’, environmental ‘dangers’ and sovereignty over ‘natural’ genetic resources, IP law could be used more effectively to protect green technologies such as modern biotechnology and achieving sustainable development goals. In other words, the coexistence and co-targeting of IP law and environmental law in the field of PGRs is fruitful not only for earning profit and promoting innovation but also for guaranteeing environmental protection and sustainable use of such resources.

Keywords: intellectual property rights, environmental law, ownership, plant genetic resources, sovereignty, sustainable development, Iran.

1. INTRODUCTION

In the hierarchy of legal norms, the principle of international law takes precedence over national law in cases of conflict. However, many States are partly monist and partly dualist in their actual application of international law in their national systems. For instance, according to Principle 77 of the Constitution of the Islamic Republic of Iran, treaties, transactions, contracts, and all international agreements must be ratified by the Islamic Consultative Assembly. Once approved, an international legal norm becomes an integral part of Iranian law and must be applied and complied with by national organizations. The application of general principles of international environmental law stipulated in international environmental treaties, to which Iran has acceded by a national law, follows the same rule. In this respect, although it seems that the Iranian Biosafety Law is absent from any explicit stipulation on the precautionary principle, however, this principle has been officially recognized by the Iranian law for accession to the 2000 Cartagena Protocol on Biosafety (Cartagena Protocol on Biosafety, 2000).
Plant Genetic Resources (PGRs) as an important point of interaction between environmental law and intellectual property (IP) law increases the importance of an appropriate and effective application of the mentioned principles in national legal systems. In this context, it is also crucial to develop a common legal language on such principles that could successfully bridge environmental law and IP law. Indeed, if the principles of international environmental law are applied proportionally in national legal systems, particularly in cases of environmental ‘risks’, environmental ‘dangers’ and sovereignty over ‘natural’ genetic resources, IP law could be used more effectively to protect green technologies such as modern biotechnology and achieving sustainable development goals (SDGs).

To illustrate such interactions concerning PGRs, this paper firstly examines the sovereign right of States to dispose of their wealth and their natural resources which has been recognized by various national and international legal instruments. At the international level, both environmental law and IP law address the control, conservation, access, and benefit sharing of PGRs. The primary objectives of environmental law are biodiversity conservation, sustainable use as well as global access to PGRs. The two major international treaties on this issue – the 1992 CBD and the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) – address state sovereignty in deciding how to control the access to genetic resources and attempt to design mechanisms for achieving these goals. On the other hand, we aimed to examine IP law which protect and enforce the rights of breeders and inventors who have developed new plant varieties or made new and useful inventions in this field. In order to meet environmental priorities, the issues of environmental protection and sustainable development have also been considered on the grounds of public order and morality in IP law. However, since legal treatment of PGRs is different in environmental law and IP law, as our next step, we will investigate such different approaches within these branches of law. This difference stems mainly from the possibility of ownership or non-ownership of these resources. Therefore, it seems necessary to distinguish between state sovereignty over ‘natural/wild’ PGRs under environmental law and ownership of ‘improved/invented’ PGRs under IP law. In order to achieve the SDGs, it is also necessary to adopt an appropriate legal approach by which all rights associated with these resources and their applications can be assured. The research method is descriptive analysis. Analysis of some principles of international environmental law – including the principle of integrity, the precautionary principle and particularly, the principle of proportionality – could lead us to understand how and to what degree, IP law and environmental law mutually interact in the context of PGRs. In fact, the optimal management and reasonable exploitation of PGRs, along with their conservation, play a significant role not only in improving the quality and quantity of agricultural production but also in achieving sustainable development in this sector.

8 Malik SS, Singh SP, ‘Role of Plant Genetic Resources in Sustainable Agriculture’ (2006) 12/2 Indian Journal of Crop Science, 21-28
2. STATE SOVEREIGNTY OVER NATURAL RESOURCES IN INTERNATIONAL LAW AND IRANIAN LEGAL SYSTEM

A. CONSERVATION OF GENETIC RESOURCES IN INTERNATIONAL ENVIRONMENTAL LAW

State sovereignty over ‘natural’ resources or specifically ‘wild’ resources as a general principle of international environmental law has been clearly expressed in various United Nations General Assembly (UNGA) resolutions, and in particular, paragraph 1 of Article 2 of the Charter of Economic Rights and Duties of States, which was adopted by the UNGA on 12 December 1974. According to this Charter, ‘Every State has and shall freely exercise full permanent sovereignty, including possession, use and disposal, over all its wealth, natural resources and economic activities’. This rule has led to a direct response to the efforts of developed countries to integrate biodiversity into the common heritage of humanity. This argument can similarly be found in the 1982 Convention on the Law of the Sea, which is based on the fact that the mineral resources of the international seabed area are considered as a ‘common heritage of mankind’. However, according to a complementary aspect of sovereignty in international law, States are also committed to protecting the rights of other States within their territories.

In the same way, the principle of responsibility and good governance is developed through international environmental instruments and jurisprudence over the compensation of trans-boundary environmental damages. For instance, Principle 21 of the 1972 Stockholm Declaration emphasizes the right of States to rule over and exploit their own natural resources in accordance with environmental policies. This concept was reinstated in Principle 2 of the 1992 Rio Declaration (Rio Declaration), which emphasizes not only a state’s responsibility over any activity within its territories based on its development policies, but also consideration of any transboundary environmental damage as the international responsibility of States. In fact, this perspective emphasizes the right of States to ‘reasonably and appropriately’ exploit their own natural resources. Moreover, it can be generally understood that state sovereignty over natural genetic resources is finally aimed at the sustainable development and conservation of such resources and its biodiversity. This argument can also be valid because of their affirmation of ‘state sovereignty over natural resources’ under paragraph 18 of the 2030 Agenda for SDGs.

Apart from the conservation of biodiversity and sustainable use of genetic resources, the fair and equitable sharing of benefits arising out of the utilization of genetic resources is clearly stated in the objectives of the CBD which was endorsed at the 1992 United Nations Conference on Environment and Development. The
CBD also emphasizes the rules governing the rights of indigenous and local communities, the right to access genetic resources and the fair sharing of benefits. Moreover, the ITPGRFA, signed in November 2001, specified that the conservation and sustainable use of PGRs and the fair and equitable sharing of the benefits arising out of their utilization should be done in accordance with the provisions of the CBD. The ITPGRFA, which has a similar legal framework to the CBD, intends to enhance the cooperation and collective action of States in the context of permanent sovereignty over natural genetic resources to provide access to PGRs and to allow distribution of these resources for food and agriculture. The ITPGRFA also creates a fund-sharing system which accords users of genetic resources the opportunity to create mechanisms with unrestricted access to the genetic base of the country of origin, in order to improve future crops for sustainable food and agricultural security.

Notwithstanding that the conservation and sustainable use of natural genetic resources in appropriate ways must be completely assured by national competent authorities and formulation of laws and regulations is required to facilitate investment in this field. In this context, it is necessary to point out that State sovereignty over natural genetic resources and the set of rules and regulations governing the access to these resources in accordance with the purpose of the CBD are a fortiori concerned with ‘wild or natural genetic resources.’ Accordingly, the access to and authorized utilization of ‘improved’ or ‘genetically modified resources’ are regulated primarily by IP law. Therefore, the role of States is not only to assure a sufficient level of IP rights and benefit sharing arising out of the utilization of improved or genetically modified resources but also to comply with their environmental obligations through establishing and maintaining an appropriate link between IP law and environmental law as discussed in more detail in section 4.

B. STATE SOVEREIGNTY OVER NATURAL RESOURCES IN IRANIAN LEGAL SYSTEM

As mentioned before, according to the principle of state sovereignty, a State has the power and authority to determine how natural genetic resources shall be utilized and exploited in its territory. Article 50 of the 1979 Iranian Constitution also affirmed the principle of environmental conservation. The implementation of the first principle is also in accordance with the 1945 United Nations Charter and the principle of state sovereignty in public international law. Therefore, the government of Islamic Republic of Iran has sovereignty over natural genetic resources by directly exploiting these resources or by delegating the task of exploiting these resources to other subjects in exchange for an economic return, etc.

22 ITPGRFA, signed in November 2001.
25 According to Article 50 of the 1979 Iranian Constitution ‘The preservation of the environment – wherein the present as well as the future generations have a right to a flourishing social existence – is considered as a public duty in Iran. Economic and other activities that involve pollution of the environment or cause irreparable damage to it are therefore forbidden’ <http://www.servat.unibe.ch/icl/ir0510e.pdf> accessed 2 November 2020.

According to Article 45 of the Iranian Constitution, public properties and assets such as rivers, seas and other public waterways, forests, uncultivated lands, mines, and marshlands shall be at the disposal of the government to be utilized in accordance with public interest. Moreover, according to Article 1 of the 1963 Nationalization of Forests and Pastures Law, Iran's forestlands are considered as ‘public property' and belong to the State. Article 5 of the 1980 Law on Assignment and Reclamation of Lands also considers natural forests and groves as ‘public wealth'. Therefore, in line with the same considerations in the CBD and ITPGRFA, ‘wild and natural genetic resources’ in Iran are considered as ‘public property' and the manner and extent of access and exploitation of these resources is determined under the authority of the Iranian government. Based on this approach, it should also be mentioned that Note 1 under Article 3 of the 2003 Act of Plant Varieties Registration, Control and Certification of Seeds and Seedlings explicitly states that:

Non-improved and wild plant genetic resources shall be considered as national genetic resources and by any means, the private sector is not allowed to register them. Pursuant to the request of public sector, such resources can be registered in the name of the Government of Islamic Republic of Iran.

Therefore, it seems generally that for the proper performance of the principle of State sovereignty over natural resources, the interaction between conservation and exploitation is inevitable.

3. GENETIC RESOURCE AS AN ‘INTELLECTUAL PROPERTY’ IN INTERNATIONAL LAW AND IRANIAN LEGAL SYSTEM

International environmental law is essentially based on non-reciprocal obligations and universal benefits. However, IP law depends on obligations, which are more mutually beneficial. However, IP law can be considered as one of the economic and social instruments in conservation and exploitation of genetic resources. The 1974 United Nations Charter of Economic Rights and Duties of States in Article 13(2) stipulates that all States should promote international scientific and technological co-operation and the transfer of technology, with proper regard for all legitimate interests including, inter alia, the rights and duties of holders, suppliers and recipients of technology. The critical role of IP rights in the context of transferring environmentally friendly technologies and protecting the associated traditional knowledge of genetic resources, which is also essential for sustainable development, represents the interaction and inter-relationship between IP law and environmental law.

In this context, the 2030 Agenda for SDGs in paragraph 70 states that technology transfer and innovation cooperation around thematic areas for the implementation of the SDGs require a collaborative multi-stakeholder forum with participation of all stakeholders and United Nations (UN) agencies, including the World Intellectual Property Organization (WIPO). The phrase of ‘stakeholders’ can also refer to holders of traditional knowledge. Nevertheless, it is important to mention that we need, in fact, to make a complete integration between traditional knowledge and scientific knowledge societies associated with genetic resources for an appropriate and effective protection of the rights of different stakeholders and achieving sustainable development.

<https://jlq.ut.ac.ir/article_55031_92e3f272e70f4ebe75d54f75a34c72a.pdf> accessed 27 January 2021.

28 Charter of Economic Rights and Duties of States (n 10).
Considering the provisions of the introduction and paragraph 1 of Article 15 of the CBD, a fundamental change is observed in the status of genetic resources. Prior to the ratification of the CBD, genetic resources were considered as the ‘common heritage of mankind.’ However, this concept is mentioned as a ‘common concern for all humanity’ in the introduction of the CBD in the context of a more general concept of biodiversity in which genetic resources are considered as one of the main components of biodiversity.\(^29\) Article 1 of the CBD defines biodiversity as its objective but the need to respect all rights over genetic resources and to technologies, and in particular, according to paragraph 2 of Article 16, the need to respect the IP rights associated with these resources have also been explicitly emphasized. Nevertheless, it is important to note that under paragraph 5 of Article 16 of the CBD, IP law should be supportive of and not run counter to the objectives of the CBD.\(^30\)

In general, four models can be conceived for managing PGRs and innovations resulting from them: open sources, collective ownership, individual ownership, and public ownership. These four models are the basis for the study and evaluation of the legal regimes governing genetic resources.\(^31\) In this perspective, application of the traditional concepts of ownership (property rights) on genetic resources has faced some legal challenges and difficulties. However, current legal approach to new genetic resources as ‘intellectual assets’ has led to the recognition of the new concept of ownership of genetic resources in the IP system. In other words, due to the potential commercial value of such resources, there is an increasing tendency to recognize exclusive rights for inventors or breeders of new plants or new plant varieties. In this context, IP law and international trade law have also facilitated the acquisition of exclusive rights to such resources. In this section, we are going to study the IP system for protection of improved or genetically modified plant resources in terms of the international IP law and the Iranian legal system.

A. EXCLUSIVE RIGHTS ON ‘IMPROVED’ OR ‘GENETICALLY MODIFIED’ PLANT RESOURCES IN INTERNATIONAL IP LAW

The most important international instruments in this area are the Paris Convention for the Protection of Industrial Property (Paris Convention), the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), and the International Union for the Protection of New Varieties of Plants (UPOV Convention).

The Paris Convention was the first multilateral international instrument to protect industrial property rights. The Paris Convention recognizes the broadest concept of ‘industrial property’. As per Paragraph 3 of Article 1, ‘industrial property’ includes not only industry and commerce proper but also agricultural and extractive industries and all manufactured or natural products, for example, wines, grain, tobacco leaf, fruit, cattle, minerals, mineral waters, beer, flowers, and flour.\(^32\) Thus, the Paris Convention, through the inclusion of agricultural products in the conceptual umbrella of industrial property, has made it possible to protect new PGRs.\(^33\)

Although the Paris Convention provides the general possibility of protecting agricultural products through the patent system, at the time of its adoption, there was no


political will or specific stipulation for the universal application of patents to plant products. For this reason, it is also important to observe other related international instruments.

The TRIPS Agreement includes three stipulations related to agricultural products: geographical indications (Articles 22-24); patent protection of agricultural chemical products (Article 70.8) and plant variety protection (Article 27.3(b)). The Agreement also stipulates some environmental considerations for acquiring IP rights over new genetic resources. In fact, due to the unique status, importance and characteristics of PGRs, legal instruments tend to approach the conservation of these resources from the environmental considerations and the sustainable development point of views on one hand, and protection of the improved or genetically modified plant resources as intellectual assets on the other hand. The relationship between the TRIPS Agreement and CBD is well demonstrated by the fact that one of the preconditions for granting or keeping exclusive rights over genetically modified plant resources is to respect environmental considerations for reasons of public order and morality. According to Article 27(2) of the TRIPS Agreement, Member States are authorized to exclude certain inventions from patentability in order to protect human, animal, or plant life or health or to avoid serious prejudice to the environment.

The TRIPS Agreement also allows Member States to protect the inventions of microorganisms and non-biological and microbiological processes for the production of animals and plants (as examples of agricultural genetic resources). Furthermore, the Agreement requires members to protect plant varieties using either patent rights or an effective sui generis system or some combination thereof. This flexibility in granting different types of protection to plant varieties (as a plant genetic source) indicates that there was no consensus between Member States to provide a specified legal system for protection of plant varieties. For example, in Europe, plant varieties are not protected through the patent system while they can be subject matters of patent protection in the United States (US) by plant patents (for new and distinct asexually reproduced plants) and utility patents (for eligible patent-related inventions including genes, traits, methods, and plant parts), and Japan.6

The TRIPS Agreement also authorizes Member States to exclude plants, animals, and essentially biological processes required for their production from patentability. It is important to mention that due to the different levels of development, different national policies may be adopted in this regard. While developed countries try to consider protecting inventions through the patent system, developing countries do not consider this kind of protection to be in their best interest. Developing countries which are generally the main owners of agricultural genetic resources, want to receive an appropriate share of the benefits arising from the utilization of their genetic resources. They also insist on the need to disclose the country of origin of genetic resources. Based on the mentioned considerations, we can generally conclude that improved and genetically modified plant resources are considered as ‘intellectual assets’ and can be protected under IP rights.

Accordingly, state sovereignty over natural genetic resources is practically exerted through application of the prior informed consent principle concerning the country of origin of genetic resources, material transfer and

26 MacManis CR (n 30) 260-279.
benefit sharing agreements. However, it also needs to be completed by facilitating the adoption and implementation of IP laws under public interest reasons for promoting innovations in the agricultural and food sector and protecting relevant new technologies such as genetic engineering, gene editing, etc.

The UPOV Convention, as another source of international IP law, relates to the protection of ‘improved’ and ‘bred’ PGRs categorized as plant varieties. This Convention was approved in Paris in 1961 and revised in 1972, 1978, and 1991. The purpose of this Convention is to protect new plant varieties and plant breeders. The International Union for the Protection of New Varieties of Plants (UPOV) is also an intergovernmental organization based in Geneva that was established by this Convention.39

As mentioned before, the TRIPS Agreement requires Member States to promote the protection of IP in the agricultural sector and assure the protection of new plant varieties through the patent system or an effective sui generis system or by any combination thereof. After the revision of the 1991 UPOV Convention and extending the scope of breeders’ rights not only to the propagating material but also to harvested material (including whole plants and parts of plants), multiple concerns have been raised in developing countries about the negative impact of IP protection on farm activities, including reuse and seed exchange by farmers.40 For this reason, many countries have joined the UPOV Convention while some others have adopted non-Conventional models such as the 2001 Act on the Protection of Plant Varieties and Farmers’ Rights of India (Indian Act).41 Indeed, the Indian Act seeks to recognize both breeder and farmer rights by allowing farmers to register the varieties they cultivate.

The Indian Act also contains benefit-sharing provisions that allow individuals and communities to claim compensation for their contributions to plant genetic diversity.42 In fact, because of the importance of farmer’s/breeder’s motivation in agricultural extension and resource availability, access and benefit sharing could be also considered as one of the mechanisms for achieving sustainable development and preserving biodiversity.

In addition, it should be noted that environmental considerations are also important in plant breeder rights. In paragraph 3 of Article 15 of the UPOV Convention, under the exemption of breeders, a breeder is authorized to use protected plant varieties for breeding other varieties. This could be an effective factor for conservation of PGRs and their improvement by incorporating climate change adaptation. On the other hand, public interest in environmental protection could also be one of the reasons for restricting the rights of plant breeders under paragraph 1 of Article 17 of the UPOV Convention. The second goal of the SDGs which focuses on food security, improved nutrition and sustainable agriculture, requires national and international commitments to maintain the genetic diversity of not only wild genetic resources but also cultivated and improved seeds/plants, considering their IP rights and fair and equitable sharing of benefits arising from utilization of such genetic resources.

B. IP RIGHTS ON PLANT GENETIC RESOURCES IN THE IRANIAN LEGAL SYSTEM

IP is one of the main issues underlying the new economic policy of Iran, and it is considered as a platform for development of the country. As mentioned above, the

TRIPS Agreement provides the possibility of protecting new plant varieties via the patent system, or an effective *sui generis* system, or by any combination thereof. Under Iran’s legal system, in order to enhance scientific capabilities in the field of agriculture and facilitate new plant innovations, the 2003 Act of Plant Varieties Registration, Control and Certification of Seeds and Seedlings (Act) was enacted to protect new plant varieties under a *sui generis* system. According to this Act, for the purpose of safeguarding national interests and organizing the process of controlling and certifying seeds and planting materials, the Ministry of Jihad-e-Agriculture is responsible for identifying and registering the newly produced plant varieties and takes actions to control and monitor the affairs related to Iran’s seed and seedling.

In this perspective, Article 5 of the Act stipulates that upon registration of an improved plant variety, its breeder (legal or natural person) is entitled to IP rights and shall be the sole commercial beneficiary of the variety for a maximum period of 18 years. The breeder can also assign these rights to any other natural or legal persons. Based on paragraph 1 of Article 10 of the implementing regulation of the Act, complied with paragraph 1 of Article 14 of the UPOV Convention, any use of propagating material of the protected plant variety shall require the authorization of the breeder.

However, according to paragraph (d) of Article 4 of Iran’s 2007 Patents, Industrial Designs and Trademarks Registration Act43 (Patent Act), ‘genetic resources and their genetic components as well as biological processes’ are excluded from patentability. In general, this exclusion has deprived many inventions of biotech scientists from patent protection. Nevertheless, note 1 of Article 3 of the 2003 Act of Plant Varieties Registration, Control and Certification of Seeds and Seedlings44 explicitly and more precisely considers only ‘non-improved’ and ‘wild’ plant genetic resources as national genetic resources on which the private sector is not allowed to get exclusive rights. Therefore, it seems that the general exclusion of genetic resources from being patented in paragraph (d) of Article 4 of Iran’s Patent Act is an inappropriate application of the exclusion stipulated in paragraph 3 of Article 27 of the TRIPS Agreement which allows for an optional exclusion of plants and animals from patentability.

Moreover, it is obvious that based on the subject matter and technical nature of innovations resulting from traditional (breeding) and modern biotechnology, different legal protection systems may be applied. In Iran, ‘innovations’ related to plant varieties can be protected under the 2003 Act of Plant Varieties Registration, Control and Certification of Seed and Plant Material if all requirements are met. However, legal protection of ‘inventions’ in genetic engineering using plant and animal genetic resources is unresolved for a variety of reasons, and such inventions are excluded from the national patent system under paragraph (d) of Article 4 of Iran’s Patent Act.

Opponents of patenting genetic resources raise moral arguments to justify the exclusion of genetic resources and their components from patentability, even under the Patent Act. According to them, with the exclusion of genetic resources and their components from the patent system, the legislature lives up to its responsibility of maintaining public order and morality.45 Nevertheless, accepting morality as an explicit reason to exclude any inventions contrary to public order and morality from

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being patented in paragraph (f) of Article 4 of the Patent Act does not justify why the legislature has also excluded genetic resources from patentability for the same reason. In other words, while a general rule is stipulated in paragraph (f), and its scope can also cover the genetic resources and its components, we cannot accuse the legislature of providing undue repeated provisions in this Act. Therefore, the philosophy behind the exclusion of genetic resources and their components set forth in paragraph (d) must be based upon a different mindset that set forth the exclusion in paragraph (f).

According to opponents of patenting genetic resources, the other reason for the exclusion relates to the necessity of conservation of genetic resources as public wealth (not private property) as well as the prevention of eventual biopiracy through uncontrolled access to such resources.\(^46\)

We argue that apart from the difference between the legal status of ‘natural’ genetic resources (under state sovereignty) and that of the ‘genetically manipulated’ resources (under IP rights), which was finally affirmed by the Iranian parliament through its inquiry on paragraph (d) submitted in 2010\(^47\), the phrase ‘genetic resources’ generally refers to any genetic material of actual or potential value. Genetic material refers also to any material of plant, animal, microbial, or other origin that contains functional units of heredity. Therefore, the question is how ‘plant/animal genetic resources’ can be considered as subject matters of protection under the 2003 Act of Plant Varieties Registration and the 2006 Law on Comprehensive System of Animal Husbandry\(^48\), but the same genetic resources are excluded from patentability for moral or bio piracy reasons under the Patent Act.

Although legal protection of genetic resources shall be tailored according to national economic, legal, political, and environmental conditions, but bringing them together only in the patent system, regardless of some legal uncertainties and overlapping areas, cannot morally and legally justify the exclusion of genetic resources and their component from the Patent Act. This practically leads to non-patentability of a large number of biotechnological inventions.

Meanwhile, the objectives of genetic resource conservation and prevention of biopiracy should be a priori met through the appropriate known mechanisms, such as those stipulated in the Nagoya Protocol on Access and Benefit-sharing, rather than through the exclusion of genetic resources from the patent system.\(^49\) It is worth mentioning that Article 4 of the Patent Act has been well revised under the Parliament Plan on Industrial Property, submitted in 2013 whose final ratification can partially be in favor of bio-patents and specifically, the patent applications on PGRs.

Meanwhile, Article 5 of the 2018 Law on Protection and Exploitation of Genetic Resources also prohibits the ownership of ‘natural’ genetic resources, or their constituents as found or protected in natural habitats or used by farmers and exploiters (natural and legal persons). Note 1 of this law considers genetic breeding and genetic manipulation methods to be protectable under IP laws.\(^50\)

In general, according to the Iranian legal system, unmodified and wild PGRs are considered as ‘public property’ and out of the domain of IP law. Given the fact that these resources constitute the raw materials of

\(^{46}\) Ibid 115.

\(^{47}\) The response of the parliamentary inquiry was that the exclusion of genetic resources from patentability includes natural genetic resources and components as well as natural biological processes. It does not include genetically engineered synthetic sources or artificial processes designed and constructed.


biotechnological innovations, the question that may arise is how to grant exclusive IP rights to the innovations that consist of genetic materials as public property. Therefore, because of the contribution of agricultural innovations to economic growth, environmental quality and food security recognizing temporary IP rights on modified genetic resources for public interest purposes can be also regarded as an economic and social necessity. Concerning plant innovations based on PGRs, it can also be argued that although the natural resources themselves are public property, any resulting innovations are different novel products that satisfy the legal requirements prescribed by the Patent Act or the 2003 Act of Plant Varieties Registration, Control and Certification of Seed and Plant Material. In addition, it is worth mentioning that granting IP rights to PGRs does not ignore or diminish the importance of public property. In fact, granting IP rights to PGRs has been officially authorized to ensure public interest, and the protected PGRs will finally be returned to the public domain after the expiration of IP protection period.51

After reviewing the issues related to the approaches of international environmental law and IP law on the legal status and manner of conservation and exploitation of PGRs, we intend also to study some principles of international environmental law and analyze their applicability in the IP system for more illustration of the interaction between the two branches of law.

4. DELIMITING THE SCOPE OF INTERACTION BETWEEN ENVIRONMENTAL LAW AND IP LAW

IN TERMS OF THE PRINCIPLES OF INTERNATIONAL ENVIRONMENTAL LAW

Principles of international environmental law are required to govern the intersections between global priorities and norms relating to biotechnology and sustainable development.52 Thus, in the context of biotechnological innovations, it is important to develop legal approaches and appropriate techniques for coordinating and, where necessary, integrating international IP and environmental regimes for address in multidisciplinary challenges.

A. PRINCIPLE OF INTEGRATION

Sustainable development at a minimum requires the integration of environmental concerns in decision-making. The right to development is addressed in paragraph 2 of the introduction of the Declaration on the Right to Development, adopted on 4 December 1986 by the UNGA. It states, ‘Recognizing that development is a comprehensive economic, social, cultural and political process, which aims at the constant improvement of the well-being of the entire population and of all individuals on the basis of their active, free and meaningful participation in development and in the fair distribution of benefits resulting there from’.53 In fact, the goal of sustainable development, which is also mentioned in the Rio Declaration, is that all activities that take place in the environment should take into account environmental considerations.54

The principle of integration, as stipulated in the Rio Declaration, addresses environmental concerns as a fundamental issue and considers the dependency of


environmental protection on the government and its legislative and economic instruments.\textsuperscript{55} The main goal of this principle is to integrate policies, economic and cultural actions with respect to environmental considerations.

In this regard, Principle 4 of the Rio Declaration affirms that States, in order to achieve sustainable development and environmental protection, should consider environmental protection as an integral part of the development process and should not consider them separately. Article 25 also stipulates that peace, development, and environment are interdependent and indivisible. This principle has also been affirmed in other international instruments. For example, the implications of interdependence and integration in paragraph 6 of the 1995 Copenhagen Declaration on Social Development indicates that economic development, social development, and environmental protection are interdependent and mutually they reinforce components of sustainable development.\textsuperscript{56} Moreover, paragraph 5 of the 2002 Johannesburg Declaration, regarding sustainable development, emphasizes a collective responsibility to advance and strengthen the economic development, social development, and environmental protection at the local, national, regional, and global levels as pillars of sustainable development.\textsuperscript{57}

Article 6 of the CBD also encourages Member States to adopt strategies, plans, and programs that are consistent with protecting the environment and contribute to the sustainable use of biodiversity. The key commitments of States to the sustainable use of biodiversity are highlighted in Article 10 of the CBD which implies the integration of domestic policies and decisions on the conservation and sustainable use of biological resources and the adoption of measures that avoid or minimize adverse impacts on biodiversity. Emphasis has been made on cooperation between governmental authorities and the private sector in developing methods for the sustainable use of ‘biological resources’, supporting local populations in developing countries, and implementing traditional cultural practices that are consistent with conservation and sustainable use requirements. SDG 13 also requires integration of climate change measures into national policies, strategies, and planning.

Therefore, it seems IP law and its related standards and policies are also not exceptions to this rule. In fact, environmental law does greatly influence the technologies available to society and the related regulations restrict the use of harmful technologies. In this regard, Article 8(1) of the TRIPS Agreement stipulates also that Member States, while formulating or amending their national laws and regulations, may adopt measures necessary to protect public health and nutrition and promote public interest in sectors vitally important to their socio-economic and technological development, provided that such measures are consistent with the provisions of the Agreement. In addition, Article 27(2) of the TRIPS Agreement also allows Member States to exclude patentability of inventions that will seriously prejudice the environment.\textsuperscript{58}

Although environmental considerations are not explicitly mentioned in Article 4(f) of the Patent Act, but the revised version included in the 2013 Parliament Plan on Industrial Property, recognizes the importance of these considerations in the framework of ‘public order,’ ‘morality,’ and ‘religious standards’ in Iran. In general, environmental reasons can always be a logical basis for preventing the grant of patent protection in both developed and developing countries.


\textsuperscript{58} Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), WIPO Lex No: TRT/WTD01/001 (WIPO) 1994.
However, it is important to note that the ambiguity of some terms such as ‘serious prejudice to the environment’ and lack of adequate clarifications on the related legal and technical factors of how this can be appropriately determined and applied, can be considered as the origin of different interpretations of Article 27(2) of the TRIPS Agreement. For example, if the criteria for determining a situation based on public order or morality is ‘serious prejudice’ to the environment, the threshold of prejudice and the legal approaches adopted to reject or accept some environmental risks, will certainly be different in each country. Based on this presumption, in decision T 356/93 the EPO’s board of appeal pointed out that although the documents submitted by the appellant provided evidence of possible hazards from the application of genetic engineering techniques to plants, they did not lead to the definite conclusion that the exploitation of any of the claimed subject-matter would ‘seriously prejudice’ the environment. 59

Apart from justifiable national cultural or religious differences, some national controversial or extreme approaches to environmental risks may also be the result of the inappropriate interpretations and mechanisms for raising public awareness and information access. For instance, whereas there is no scientific consensus on some environmental risks, it doesn’t seem logical and justifiable for claiming a particular level of risk and causing technophobia through its publication on social media sites. Hence, the integration of environmental considerations into IP law, and in particular, patent law, can be more effective if other related principles of international environmental law, such as precautionary principle, and proportionality principle can also be applied.

B. PRECAUTIONARY PRINCIPLE

The precautionary principle acts as one of the key principles in environmental conservation and sustainable development by preventing or minimizing potential environmental degradation. Compensation for serious prejudices to the environment, including the extinction of animal and plant species, soil erosion, or even the discharge of enduring pollutants in the sea, which create irreversible environmental situations, is principally impossible. Many international environmental instruments, such as the Rio Declaration, the 1992 Convention on Climate Change, and the CBD, have mentioned this principle. 60 As part of the introduction of the CBD, which emphasizes the precautionary principle, it is stipulated that where there is a threat of ‘significant’ reduction or loss of biological diversity, lack of full scientific certainty should not be the reason for postponing measures that would avoid ‘or minimize’ such a threat. In accordance with Article 15 of the Rio Declaration, in order to protect the environment, States shall apply the precautionary approach based on their capabilities and ‘environmental impact assessments’ in accordance with Article 17 of the Rio Declaration. This principle is also one of the pillars of the European Union’s environmental policy under the 1992 Maastricht Treaty. 61

The 2000 Cartagena Protocol has specifically emphasized the precautionary principle throughout its provisions. The Biosafety Protocol, which requires exporters to obtain prior informed consent from an importing country in order to regulate and control the transboundary movement of living modified organisms and to prepare and set up the documentation for risk assessment and risk management, has taken an effective step in using the precautionary principle. Article 4 of the Biosafety Protocol has also become a prerequisite for transboundary movements, transit, handling, and use of

all living modified organisms, which may have adverse effects on the conservation and sustainable use of biological diversity (including plant genetic diversity). The introduction of the Convention on Environmental Impact Assessment in a Transboundary Context (Espoo 1991) has also predicted the need for and importance of developing policies for the prevention, protection, reduction, and special care of the harmful effects of the environment in general, and in particular, in the transboundary movement.  

As clarified in the Biosafety Protocol, the subject of the precautionary principle seems to be different from the subject of the prevention principle. Indeed, the former refers to ‘risks’ with a potential characteristic while the latter refers to ‘dangers/harms’ with a definitive characteristic. Thus, it is important to mention that the effective and appropriate application of this principle in the context of IP law depends on some essential requirements. The first requirement is that the risks should be considered as potentially ‘in future’. This means that application of public order and morality under precautionary reasons in the patent system can be acceptable if the adopted measures are aimed at potential risks for the environment in the future. The second requirement is that the potential risks should be considered as ‘serious and important’. Accordingly, the precautionary principle can be applied to exclude some inventions from patentability under public order and morality reasons if the potential risks are considered legally and technically as important and serious for the environment, particularly through an appropriate and sufficient assessment of risks.

In fact, a link needs to be highlighted between the principle of precaution and the risk assessment and risk management mechanisms of the Cartagena Protocol. Meanwhile, an appropriate management of risks and uncertainties in the ecological system is also important for progressing the SDGs. Therefore, it seems that when risk management is well prepared and based on national technical capabilities, it does not necessarily need to take the preventive measures against patentability or exploitation of the relevant gene engineering technologies.

Such legal uncertainties may also arise from the difference in the precautionary approaches outlined in international environmental instruments (such as the Rio Declaration and the CBD) with some World Trade Organization (WTO) Agreements (such as the Agreement on the Application of Sanitary and Phytosanitary Measures – SPS Agreement). In fact, in accordance with the precautionary approach adopted by the Rio Declaration, the CBD, and the Cartagena Protocol, Member States have the possibility to take the preventive measures for an indefinite period in order to prevent or minimize potential environmental risks. However, according to the SPS Agreement, a Member State’s obligation is to adopt preventive measures by considering some important criteria such as the ‘provisional nature’ of the preventive measures and the adoption of preventive measures ‘only’ to the extent necessary to protect animal or plant life or health ‘supported by sufficient scientific evidences’. Hence, the application of the precautionary principle in the IP context could be also different based on the two mentioned approaches. However, any extreme...

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62 Habibi MH (n 15) 344-350.
65 SPS is the Agreement on the Application of Sanitary and Phytosanitary Measures. This Agreement entered into force with the establishment of the WTO on 1 January 1995.
approach of the principle is susceptible to have negative effects on the public interest as well as the fundamental right of access to new technologies.

Inappropriately, a high level of environmental protection seems to be achieved only through the adoption of preventive measures against not only the well-determined risks but also against those concealed by uncertainty even though they could be well managed. Moreover, the application of the precautionary principle shall be in proportion to other rights and obligations in the field of IP rights. For instance, the right to environmental protection shall be guaranteed, also taking into account the right to legal protection for biotechnological inventions without any discrimination as stipulated in paragraph 1 of Article 27 of the TRIPS Agreement. Therefore, the need to ensure and use of proportionality in regulatory decision-making which can enforce environmental rights, IP rights, and society rights lead us to also examine the principle of proportionality in order to maximize the environmental objectives and other related rights.

C. PRINCIPLE OF PROPORTIONALITY

The principle of proportionality in international environmental law is characterized by the ‘proportionate’ and ‘accurate’ application of environmental considerations, including the sustainable development and non-adverse use of biodiversity when interacting with other related rights. According to Article 2 of the CBD, the sustainable use of biodiversity is, in fact, the method that conserves biological resources to meet current and future generational needs and motivations. The sustainable use of biodiversity also relates to some human rights such as the right to food and food security for present and future generations. Generally, to balance environmental rights and other related rights, we need to actually draw boundaries and proportionally take into consideration all required subjects that intervene among them. Indeed, apart from the inherent priority of some human and environmental rights over other rights such as IP rights, it does not seem reasonable, in the event of conflict, that other rights might be completely ignored. The maximum respect for all kinds of rights is the main objective of the principle of proportionality.

In accordance with Article 10 of the CBD, each contracting party shall take ‘as far as possible’ and as ‘appropriate’ the measures in relation to the use of biological resources to avoid or minimize adverse impacts on biodiversity. The terms ‘as far as possible’ and ‘as appropriate’ specifically represent the principle of proportionality and mean that the implementation of preventive measures preliminarily requires the application of the proportionality in determining the type, time, and required extent of those measures.

Article 10 of the CBD also requires the integration of all considerations on the ‘conservation’ and ‘sustainable use’ of biological resources in national decision-making. In addition, other measures should be taken to minimize the adverse impacts on biodiversity and sustainable use of these resources in accordance with the traditional cultural practices. Thus, it is important to mention that the legal protection of indigenous populations for promoting sustainable development and the appropriate use of biodiversity is also a key factor in encouraging collaboration between public and private entities. This could be also another example for affirming the necessity of the application of the principle of proportionality, taking into consideration environmental law and IP law.

The principle of proportionality in WTO Agreements, such as in paragraph 1 of Article 2 of the SPS Agreement, is

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embodied in terms of ‘necessary to’, which refers indeed to a requirement for establishing causal links between actions and objectives. Moreover, according to Article 5.6 of the SPS Agreement, Member States are obliged to reduce negative effects to international trade. In fact, SPS measures in this regard, shall “not be more trade-restrictive than required to achieve” a Member’s appropriate level of SPS protection. The same approach has also been followed in the WTO jurisprudence. For instance, the Appellate Body in the Tobacco case (Australia) confirmed that tobacco plain packaging is not more trade-restrictive than is necessary to meet its legitimate public health objective.

Article 7 of the TRIPS Agreement interprets this principle as an affirmation that the promotion of technological innovation and transfer of technology is based on the principle of fairness and the protection of IP rights. In the same context, paragraph 2 of Article 8 of the TRIPS Agreement states that Member States should lay down the necessary provisions to protect public health and nutrition as well as to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of the Agreement.

5. CONCLUSIONS

One of the main goals of protecting and enforcing IP rights in the field of PGRs is to achieve sustainable development through a balance between different rights and duties.

The principles of environmental law aimed at biodiversity conservation and sustainable use of PGRs have been jointly considered in international legal instruments, such as the CBD, the 1972 Stockholm Declaration, the TRIPS Agreement and others. For instance, the obligation of States concerning environmental technology access and transfer is clearly expressed in Article 16 of the CBD stipulating that each Member State shall provide or facilitate the access and transfer of technologies for the conservation and sustainable use of biodiversity or the use of genetic resources. Moreover, IP law has also been recognized as an effective means for conservation of the environment through encouraging the development and transfer of green technologies, particularly agro-biotechnology.

In fact, sustainable development requires a set of interactive measures, including the protection of modern agricultural technologies; the acquisition of scientific knowledge for maximizing efficiency in the production of agricultural crops; the achievement of food security; and a facilitated cycle of science, technology, innovation, and commercialization. Therefore, the coexistence and co-targeting of IP law and environmental law in the field of PGRs is fruitful for not only earning profit and promoting innovation, but also for guaranteeing environmental protection and sustainable use of such resources.

However, there are some concerns about eventual reverse impacts on environment. For example, IP rights may motivate natural or legal persons to further use and acquisition of more economic benefits from PGRs which may lead to loss of biodiversity. There are also some concerns about the environmental risks that may result from the release of genetically modified organisms (GMOs) into the environment. In dealing with such uncertainties, it may be fruitful to adopt a multidisciplinary approach with emphasis on the principle of proportionality.

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72 Article 7 of the TRIPS Agreement states: ‘The protection and enforcement of IP rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.’ (TRIPS 1994).
In this context, national legal systems should specify appropriate methods that allow a country to determine whether a decision taken by the national authorities on plant genetic engineering, particularly on concerns of environmental risks expressed against modern biotechnology, is proportionate and not contradictory to other fundamental rights such as IP rights. This allows for a national understanding of how far public authorities may go when acting in the interest of environmental protection as well as other public interests.

Under the principle of proportionality, the content and form of measures shall not exceed what is necessary to achieve the objectives of the CBD and the TRIPS Agreement. A high level of environmental protection is generally indicated by the adoption of preventive measures against not only well-determined risks, but also against those concealed by uncertainty. However, the precautionary principle shall be appropriately applied on a case-by-case basis by considering other rights and obligations without any discrimination. Measures based on the precautionary principle must not be disproportionate to the desired level of IP protection and must not aim at zero risk. In general, all countries need to resolve overlaps or perceived conflicts between economic, social, and environmental concerns through either an appropriate interpretation of existing laws or the establishment of new ones that can balance the competing goals.

In this context, it is worth noting that the 2018 Iranian law on the protection and exploitation of genetic resources establishes new organization for managing agricultural genetic resources whose duties under Article 3 cover all aspects related to IP rights as well as environmental rights. Specifically, the law not only recognizes the rights of farmers, IP rights, and traditional knowledge associated with genetic resources but also requires necessary measures for identifying, preventing, and minimizing threats to genetic resources and genetic diversity.

Given the membership of the Iranian Department of Environment (DOE) in the National IP Policy Making Council, such multidisciplinary approaches, with an emphasis on the principle of proportionality, can be used practically in a way that will smooth the path toward development of agricultural biotechnology inventions, biodiversity conservation as well as proper management of PGRs.

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9. REALITY CHECK: CORPORATE GOVERNANCE TINGES ON THE COLLECTIVE MANAGEMENT ORGANIZATIONS IN KENYA

Stanley Mbugua Njoroge*  

ABSTRACT

This article discusses the application of corporate governance principles by the collective management organizations (CMO) in Kenya. It delves into issues that are affecting realization of corporate governance principles as espoused by the Organization for Economic Cooperation and Development (OECD), the United Nations (UN), and the Constitution of Kenya. The article highlights the historical epoch of CMOs in Kenya and seeks to identify the time when the rain started beating the sector. The role of the Kenya Copyright Board (KECOBO) has been prosecuted in the whole scheme of things with a focus on its administrative action and demonstration of how these actions have impacted on CMO operations. The academic enterprise elucidates status of CMOs as exposed by a forensic audit at the behest of KECOBO. The article also proffers the views and responses of indicted CMOs by highlighting issues that have been cited as having contributed to the current mayhem being experienced in the Kenya’s CMO sector. These discussions are hinged on OECD literature, Kenya’s 2010 Constitution, Copyright Act and related regulations that have enunciated the relevance of prudent management and leadership in the sector including the principles of corporate governance, disclosures, transparency and accountability. The paper elucidates the actions that players need to take in order to turn the tide in favor of copyright owners and users in equal measure. Lastly, the article makes recommendations that will elaborate on enhancing transparency, accountability and corporate governance among Kenya’s CMOs.

Keywords: royalties, copyright, corporate governance, accountability, transparency, collective management organizations.

1. INTRODUCTION: BACKGROUND

The Kenyan music and copyright sector has been blighted by numerous challenges that make it difficult for the sector to realize its full potential. Against this backdrop, the paper gives a snapshot of music and copyright sector and examine the reason behind dreary performance of the sector. Specifically, the paper addresses itself on the following areas of focus: an assessment of application of corporate governance principles by the collective management organizations (CMO); an evaluation of challenges befuddling CMO sector in Kenya; and proffering recommendations on how identified loopholes can be addressed.

The paper therefore seeks to situate nexus between efficacy of CMOs in the management of these rights on one hand and the question of how the CMOs are adhering to the principles of corporate governance and explore factors that are hindering efficacy and efficiency of CMOs in Kenya. The paper is based on qualitative research but from optics of doctrinal and comparative undercurrents. The secondary data is derived from the Constitution, Copyright Act, Copyright regulations, journals, media reports, case laws, and correspondences between Kenya Copyright Board (KECEBO) and CMOs. The collected data from those sources was analytically assessed and apposite critique is proffered.

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Collective management is a framework that enables owners of copyrightable works to authorize a CMO to monitor the use of their works. The concept of collective management has become an increasingly important niche of investigation for a vast array of legal and entertainment scholars.

The role of CMOs is realised through collectivization of management of rights through which members authorized them to manage these rights inter alia, enter into licensing agreements with the users and monitor exploitation of their works. This provides a structured platform for exploitation of these rights. Copyright like any other corporeal property can be licensed, assigned, or transferred by testamentary disposition or operation by law. However, licensing and assignment only apply to the economic rights, which can be transferred in part or in whole. In contrast, moral rights cannot be assigned or transferred. They are known as the rights to integrity and paternity. The economic rights include but not limited to reproduction in any material form; adaptation or translate; distribution to the public by way of sale, rent, lease, hire, loan, importation; broadcast whole or part of the work; communication to the public; public Performance; and importation. Due to complexities involved, the management, exploitation and remuneration of creative sectors rely exclusively on collective management frameworks.

The law has conceived CMO public entities that are subjected to the exactitudes of rule of law, good governance, integrity and transparency. There is an old aphorism that holds that, “From everyone to whom much was given, much will be expected. From the one who was entrusted with much, much more will be asked.” This aptly describes CMOs in as far as observance of rule of law and compliance with principles of accountability, transparency and good governance are concerned.

The genesis of collective management of copyright dates to the late 1700s. The practice begun earnestly in France in 1777 and it initially incorporated dramatic and literary works. Through the years, the practice has been accepted in many jurisdictions around the world with musical works taking a lion share of established CMOs. In Kenya and other Commonwealth countries, collecting societies are usually not-for-profit organizations that are responsible for protecting the rights of those they represent. They also take a percentage of the royalties they collect to pay their staff and overheads. Indeed, most CMOs are private in that they are set up and run for rights holders. They are not-for-profit in that the remuneration they collect is not the money of the CMOs, but money that they hold in trust for rights holders.

The existence of collecting society in Kenya can be traced back in 1914 when the Performing Right Society (PRS) for Music was established in London, United Kingdom. The PRS acted as de facto collecting Society in the United Kingdom and its colonies including British Protectorate comprising of Kenya and Uganda. The PRS continued to exercise its role even after Kenya became a colony in 1920. Its influence was felt during the colonial the colonial period and even after independence up to 1983 when the Music Copyright Society of Kenya (MSCK) was founded. The MSCK operated without oversight until 2006 when the Copyright law was operationalized. In 2007, MCSK was granted a CMO license to collect on behalf of authors and composers of musical works. The law had in 2001, created and donated copyright regulatory powers to the KECOBO.

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2 WIPO, the Importance of Collective Management of Copyright and Related Rights (WIPO National Seminar on Copyright, Related Rights, and Collective Management, Khartoum, 2005) 63.
3 Copyright Act, 2001. S. 33.
In 2008, KECOBO granted a CMO license to the Kenya Association of Music Producers (KAMP). Incorporated in 2003, KAMP collect communication to the public and broadcasting license fees on behalf of producers of sound and audio-visual recordings. In 2009, the Performers Rights Society of Kenya (PRISK) was incorporated and given a CMO license to collect license fees on behalf of performers in musical and dramatic works in 2010.

Over the years, users of copyrighted works have challenged individual collection by licensed CMOs. This birthed idea of joint licensing within CMO ecosystem especially after KAMP and PRISK were licensed as CMOs in 2008 and 2010 respectively. To start with, KAMP entered a Memorandum of Understanding (MOU) with MCSK for joint revenue collection in October 2008 whereby this partnership went on smoothly until March 2010.

Negotiations between MCSK, KAMP and PRISK to have a new MOU signed for joint revenue collection from both public performance and broadcasting were initiated in early 2011. The MOU was signed in May 2011 but soon after made null and void after MCSK’s license was revoked by KECOBO. With this new development, KAMP and PRISK embarked on a joint revenue collections initiative while MCSK continued to operate separately. In 2016, the discussions on revenue collections by the three CMOs were revived by KECOBO as a condition for licensing. However, the discussions towards KAMP-PRISK-MCSK tripartite licensing did not bear much fruit. In March 2017, a new CMO by the name Music Publishers Association of Kenya (MPAKE) was licensed to represent the rights of authors, composers, and publishers instead of MCSK. This new development paved way for renewed discussions on a tripartite revenue collection and licensing arrangement for the three licensed CMOs to wit; KAMP, PRISK and MPAKE from April 2017. The actual revenue collections under this arrangement kicked off in October 2017 and continued throughout 2018 until the legality of MPAKE’s licensing was successfully challenged by MCSK through a court process in Kakamega. In 2019, KAMP, PRISK and MCSK got their licenses from KECOBO following due process as per the legal provisions and soon embarked on a tripartite licensing structure by the three CMOs.

A. CMOs ACCOUNTABILITY THROUGH PRISMS OF CORPORATE GOVERNANCE

Corporate governance is the system of guidelines, rubrics, and procedures through which an association, organisation or a company is administered, managed, supervised, controlled, guided, governed, directed. Corporate governance encompasses harmonising the welfare and interests of investors, stockholders, board members, management, members, suppliers, society and those who do business with an organisation.

The Organization for Economic Cooperation and Development (OECD) has formulated principles of corporate governance that should be observed by public and private entities. These principles require such entities to ensure that: corporate governance framework is formulated in line with consideration of “overall economic performance, market integrity and the incentives it creates for market participants and the promotion of transparent and well-functioning markets.” The entities are also obligated to ensure that legal and regulatory requirements that affect corporate governance practices are consistent with the rule of law, transparency, and enforcement. Besides, the entities are called upon to have a clear division of labour and duties, roles, and responsibilities among different company organs for the interest of company and public at large. Regarding regulatory authorities, OECD principles of corporate governance requires them to exercise their authority diligently, transparently, and objectively.

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8 Muendo S, Rot in artiste’s bodies exposed as stakeholders face Senate, the Standard [Nairobi, 7 July 2021].
9 Laban Juma Toto & another v Kenya Copyright Board & 13 others [2017] eKLR.
Governments are required to resource regulatory bodies adequately in order to ensure that they execute their mandate professionally and efficient manner. In the last few years, values of rule of law, transparency, accountability, and good governance have become hallmarks of management and leadership and are continuously being ensconced in public and private spheres. At a global level, the United Nations (UN) conceived and unveiled the Sustainable Development Goals (SDGs) in 2015. There are a total of 17 SDGs that aim at promoting greater good and meaningful livelihoods among the world inhabitants. SDG 16 speaks directly to the issues of transparency, accountability, and good governance. This goal seeks to promote peaceful and inclusive societies for sustainable development by providing access to justice for all and by building effective, accountable, and inclusive institutions at all levels. It urges State and State-non actors to respect the rule of rule and to substantially reduce corruption and bribery in all their forms. It urges for development of efficient, effective, accountable, and transparent institutions at all levels. This will ensure responsive, inclusive, participatory, and representative decision-making at all levels, and broaden and strengthen the participation of developing countries in the institutions of global governance.

In the context of Kenya’s 2010 Constitution, national values and principles of governance are enshrined in Article 10 while values and principles of public service are encapsulated under Article 232. The Constitution lists several national values to include rule of law, good governance, integrity, transparency and accountability and sustainable development. Article 232 requires public officers and public entities exercise their mandate and authority efficiently, effectively through application of high standards of professional ethics. They are also obliged to be accountable for their administrative actions, be transparent while providing services and provide to the public timely and accurate information.

By dint of these provisions, the CMOs and KECOBO are bound by ligatures of corporate governance as espoused by OECD, SDGs, the Constitution of Kenya and other legal and policy instruments establishing these institutions.

B. COLLECTIVE MANAGEMENT OF RIGHTS IN KENYA

The doctrine of collective management of rights is well entrenched in Kenya. Courtesy of a robust constitutional, statutory and policy interventions, intellectual property (IP) rights are now firmly enshrined in the Constitution. These rights are well encapsulated under the 2010 Constitution. Further, the existence of CMOs is buttressed by Copyright Act which makes provisions for copyright protection in literary, musical, artistic works, audio-visual works, visual artistes, sound recordings, and broadcasts rights. The Act also makes provisions for setting up of CMOs. It also prescribes compliance, administration, and management requirements of these organizations.

Section 3 of the Copyright Act establishes the KECOBO as a body corporate capable of suing and being sued in its own name. Its functions are outlined in section 5 of the Copyright Act which include among others licensing and supervising the activities of CMOs. It also administers and enforce all matters copyright and related rights as provided for in the Act and to deal with ancillary matters connected with its functions.

Section 46(1) provides that no person or association of

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17 Ibid 15.
18 Ibid 15.
19 Ibid 16.
persons shall commence or carry on the business of a copyright CMO except under or in accordance with a certificate of registration granted under the Copyright Act. Section 46(6) of the Copyright Act permits the KECOBO to assist in establishing a CMO in case it deems expedient. KECOBO has so far licensed three CMOs namely KAMP, PRISK and MCSK. These CMOs are required to operate in line with established nuances of corporate governance.

The current structure of CMOs falls within jurisdictions of two Acts of Parliament namely the Copyright Act and the Companies Act. Each CMO has a Board of Directors with seven to nine members. The day-to-day operations are executed by a Secretariat headed by a Chief Executive Officer. CMOs are each issued with an annual license.

Since the enactment of the Copyright Act (2001), the CMOs have made noticeable achievements through entrenchment of corporate governance in their operations. The CMOs have established governance structures in line with the approved and adopted Memorandum and Articles of Association. This has ensured that all CMOs have a duly elected Board of Directors and Secretariat. In addition, the Board of Directors have established various committees as per the Company’s Act, KECOBO circulars and good governance principles to oversee and make sound decisions on various functions pertaining to the operations of the CMOs. In 2020, KECOBO issued Framework that inter alia requires CMO Board to establish a maximum of four Board Committee to wit: Audit, Risk and Legal Committee; Licensing Committee; Finance, Human Resources and Administration Committee; and Membership, Public Relations and Marketing Committee.

In addition, KECBO requires CMOs to meet certain corporate governance preconditions before being issued with annual CMO license. These conditions include but not limited to holding of annual general meeting; Allocation of 70% of revenue for royalty payments. Any request for amounts above 30%, must be approved in writing by the KECOBO Chairperson having received valid reasons upon demonstrating efforts to reach the threshold; payment of all applicable taxes; submission of Board Calendar of Meetings; demonstrable efforts of cost cutting measures to the Board of Directors; implementation of the CMO Policy in toto; submission of annual Audited Accounts; and an obligation to collect royalties jointly under a tripartite arrangement.

The joint revenue collections venture is governed through a tripartite Board comprising of respective CMOs Board. The Board membership include seven Board members from KAMP, seven from PRISK and eight from MCSK. The tripartite Board is the top decision-making organ in the joint venture and is charged with the responsibility of making policies that guide in the day-to-day operations. Before final decisions are made, issues are first discussed at a nine-member operations committee comprising three representatives from each CMO. The chairing of tripartite meetings is handled on a rotational basis for three months in each quarter of the year. The CEO from each CMO also implement strategy and policy directives by the tripartite Board. The joint license has made it easier for users to comply and lowering license fee due to a reduced joint tariff. It has reduced the cost of revenue collection through sharing of personnel, regional offices, logistics and resources. It has brought harmony and reduced acrimony among the licensed CMOs experienced earlier when each CMO was licensing on their own.

The tripartite arrangement has exposed some noticeable challenges including delays in decision making, interorganizational conflicts, and lack of policy framework to guide operations of KPM, lack of

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21 Kenya Copyright Board, Medium Term Collective Management Organizations (CMOs) Policy Framework (Kenya Copyright Board 2021) 7.
measurement of execution and corrective action at KPM level.

CMOs are further subjected to rigours and exactitudes of other legal and statutory requirements including the provisions of the Companies Act. The Act permits formation of CMOs as private companies limited by guarantees. To this end, each CMO has set of Memorandum and Articles of Association which spell out the relationship between members and directors, governance structures, terms and powers of Board of Directors, decision making process, powers of members as expressed through the annual general meetings and powers of directors. The Act also obligates CMOs to file annual returns showing whether there has been any change on the structure of the company including directors, shareholding among others.

Indeed, the CMOs have strived to comply with provisions of Companies Act\textsuperscript{24} which require them to hold annual general meetings and present the Audited Financial Reports. However, holding of annual general meetings for the CMOs did not take place in 2020 and 2021 due to the COVID-19 pandemic, which precipitated imposition of public health containment measures and protocols. Despite the setback, the CMOs have resorted to using online platforms to hold member meetings and to conduct other business. There has been smooth transition of leadership for the CMOs with elections being held every three years.

2. SNARES AND TRAPS ENTANGLING KENYA’S CMOs

The Copyright sector in the post-independence Kenya got a boost in 1966 when the first Copyright Act was established. This legislation was unsophisticated and failed to introduce any form of regulatory and copyright collective structures for exploitation of copyright. For about 17 years Kenya operated without a CMO. In 1983, the MCSK was born. However, it operated without any form of government regulations, and it has been alleged that MCSK created a monopoly that was marred with lack of transparency and accountability. In 2001, the Copyright Act was enacted and for the first time introduced government regulation and framework of collective management of copyright works. The law allowed for the operationalisation of the KECOBO. It has been argued that for eight years the power of KECOBO was limited and this allowed CMOs to operate unabated. As a result of this Copyright was amended in 2019 and expanded powers of KECOBO over CMOs to improve their integrity, transparency, accountability, good governance, and their responsiveness to artists in terms to royalties’ collection and distribution.

These CMOs in Kenya have attracted criticism for conducting their business without giving much attention to corporate governance principles and for disregarding laid out procedures and best practices\textsuperscript{25}. This has left them reeling from negative publicity, distrust and apathy from creative sector stakeholders. The challenges befuddling copyright sector are commonplace. These challenges include internal and external challenges. One of internal challenge affecting CMOs revolves around allegation of non-adherence to corporate governance.

According to KECOBO, the operational efficacy of the CMOs have been cause of concern to the Board. This concern has seen KECOBO revoke CMOs licenses on several occasions. On 1 April 2011, MCSK was deregistered as a CMO, for functioning inappropriately as a CMO, pursuant to section 46(9) of the Copyright Act, Cap 130. Five years later the same licensed was revoked when KECOBO declined to renew MCSK license for 2017 this time for failing to submit audited accounts, a list of its members and amount received in royalties contrary to Regulation 16 of the Copyright Regulations of 2004.

The Society was ordered to cease collecting royalties until

\textsuperscript{24} The Companies Act, 2015.

\textsuperscript{25} Muendo S, Rot in artiste’s bodies exposed as stakeholders face Senate, the Standard (Nairobi, 7 July 2021).
the application of their license was reviewed. Consequently, KECOBO designated MPAKE as a collecting society for 2017. MCSK license was later reinstated in 2018. In 2021, KECOBO revoked join license incorporating KAMP, PRISK and MCSK for failing to meet licensing conditions. In a press release issued on 24 August 2021, KECOBO noted that decision to revoke the license was arrived at after the three CMOs failed to meet the stringent conditions. The CMOs were unable to hold annual general meetings; allocate 70% of revenue for royalty payment and engage with Kenya Revenue Authority and resolve dispute on tax arrears. Additionally, they were accused of failing to demonstrate evidence of marketing and promotion of the use of ICT collection system, uploading of repertoire to the system under KECOBO supervision and delay in implementing the CMO policy in total.

KECOBO’s decision to revoke the three CMO licenses has impacted negatively on the collections. The public, including CMOs' traditional users have as a result lost trust in the CMOs and have since been withholding payments until the matter, which is in court is resolved. Further as indicated earlier, KECOBO discourages users from making payments to the CMOs hence reducing the compliance rate and in turn result in low collections.

The 2021 license revocation was largely informed by a forensic audit report that largely indicted CMOs operating in Kenya. In pursuant to Section 46E, the KECEBO commissioned a forensic audit to establish causes of underperformance by CMOs in Kenya. The audit revealed certain weaknesses afflicting CMOs. The Audit identified 13 key issues recommended for action. These issues are highlighted as follows: Lack of guidelines on the management of social-cultural funds, which are provided for through MCSK and PRISK Memorandum and Articles of Association. These funds are meant to serve the interests of their respective members. The audit revealed that CMO Board of Directors were conducting their affairs without complying with corporate governance principles. Some of the issues highlighted were unnecessary meetings; missing or unsigned minutes, doubtful board decisions, lack of Board oversight on critical governance areas such as audit, finance and statutory compliance. The audit also indicated that the Board’s lack key skills necessary in the running of the Board Affairs due to their composition.

The Board also lacked continuous in-depth induction and training as well as gender inclusivity. Furthermore, it was noted that Boards have been involved in turf wars with management pointing to micromanagement tendencies. This it was noted, was caused by lack of awareness of Board roles or a structural flow in the CMO structure. The issue of Board continuity was identified owing to lack of retirement by rotation policy. The reported also cited annual general meetings as failing to meet governance standards. This was precipitated by inadequate preparation. In some instances, CMOs failed to present annual financial reports.

It was further noted that CMO Board do not have full control and oversight of budget function resulting in poor budget management, poor debt management and poor financial discipline. Additionally, the Boards lacked work plans, which led to increased board meetings. The report also indicated that CMO did not have standard operating procedures and internal policies such as Board Charter, code of conduct for directors, by-laws, licensing policy, procurement policy among other policy documents which falls within the ambit of respective Board mandates.

It is also apparent that most CMOs have inadequate copyright expertise among the managers and members

of the organizations.\textsuperscript{28} This has continued to haunt their operations a fact that evidenced by poor score on corporate governance parameters.

CMOs were called out for failure of remitting statutory deductions on time. It is a cardinal crime for an organisation to fail remit statutory deductions when they fall due. These statutory deductions that are applicable to CMOs include remission of Pay as You Earn (PAYE), National Hospital Insurance Fund (NHIF), the National Social Security Fund (NSSF), and Higher Education Loans Board (HELB).

The CMOs were put to task for failing to give full disclosures on their operations.\textsuperscript{29} The inability to give full disclosure affects negatively on the quality and quantity of collection and distribution of royalties by CMOs. In addition, the Board committee’s structure did not address adequately the matters that are supposed to be conversed by the Board. Some CMOs did not have audit committees as well as internal audit function. “We note that after the onset of joint operations between KAMP, PRISK and MCSK, this function is yet to be operationalised at a joint level.”\textsuperscript{30}

Failure by CMOs to comply with statutory requirements was also cited. CMOs were unable to comply with KECOBO’s recommended administrative ratio of 30:70, 30% for administrative cost and 70% as royalty eligible for distribution to members\textsuperscript{31}. The forensic audit disclosed that CMOs were owing Kenya Revenue Authority in unpaid VAT taxes running into millions of shillings. The CMOs have been accused of misusing royalties at the expense of member interests. The issue of diversion and misuse of royalties has remained a sticky matter for decades. For instance, in 2019, President Uhuru Kenyatta called out CMOs for paying small amount of royalties to artists. The President informed the nation that, CMOs collected more than KES 200 million but ended up spending 60% on administrative expenses.\textsuperscript{32} The allegations of misappropriation of funds led to suspension of MCSK Chief Executive Officer, Maurice Okoth, and his management team in March 2016. Soon thereafter, Okoth resigned and criminal charges were preferred against them.\textsuperscript{33}

One of cardinal roles of the Board is to manage risks. However, the audit indicated that CMOs lacked risk management policies. This implies that CMOs are not in a position to increase risk awareness and hence enable Secretariat to identify, assess and control risks.

**CMOs RIGHT OF REPLY**

CMOs have not been sitting on their laurels but have been keen on devising means and ways of circumventing governance and administrative barriers plaguing the industry. The issues of governance have remained sticky subject for Kenyan CMOs. Whereas the entities have been accused of flagrantly ignoring the dictates of Corporate Governance, the CMOs have on several occasions defended themselves against these accusations citing external factors that have led to dismal performance. They portend that a requirement for annual license as being disruptive to a CMO’s strategic plan and operations. Concerning joint licensing, CMOs have accused KECOBO of abusing its administrative powers. They alleges that KECOBO is unwilling to issue them with operational license on time\textsuperscript{34}. The Copyright Act provides that CMO licenses should be an annual (12 months) license valid only until 31 December every year, but the last license to be issued to CMOs was in


\textsuperscript{29} Ibid 31.

\textsuperscript{30} Ibid 33.

\textsuperscript{31} Kenya Copyright Board, CMOs Regulations 2018, Clause 3(2)(e).

\textsuperscript{32} Isaya G, ‘Uhuru Unveils Measures to Protect Musicians from Exploitation’ Newsgram (Mumbai, 25 August 2019).


2020. This means that MCSK, KAMP and PRISK operated without a license for failing to meet the terms and conditions for provisional licenses.

The CMOs have termed these licensing conditions as being rigid, impractical, and going against provisions of their Memorandum and Articles of Association. The regulator has also been accused of not exercising good faith, a fact that saw KECOBO revoking CMOs operating license on 23 August 2021. The CMOs are of the view that the Regulator did not avail to them or the public a reasonable justification for withdrawal of their operating license and therefore the move by the regulator was in its entirety unwarranted. They also note that the Regulator failed to renew in writing their operating license for 2021 and that the CMOs have operated on the word of the Regulator since January 2021 until the license was withdrawn. Again, there was no reasonable justification for the Regulator’s failure to issue in writing a renewal of the license. These actions undermine the whole architecture of good governance principles on the part of the regulator.

Dissatisfied with this action, CMOs sought a reprieve from Court where the KECOBO’s decision, to revoke their licenses, was suspended. Today, CMOs are operating at the mercy of a Court Order35. Despite Court ruling in their favour, the CMOs are smarting from effects of negative publicity arising from KECOBO’s action. The public confidence in CMO is at its lowest ebb as evidenced by low collection and compliance levels by users of copyrightable works.

The issue of revocation of licenses has been a perennial occurrence. This has seen MCSK license revoked in 2011, 2017 and 2020. On 10 December 2020, KECOBO informed MCSK that its 2020 CMO license had been revoked, two weeks before it expired. This was done without any justifiable reasons, without giving MCSK an opportunity to be heard on any allegations that would warrant such an action and failing to abide by any of the laid down procedures within the provisions of The Constitution of Kenya, The Copyright Act and Fair Administrative Actions Act, Laws of Kenya36.

These actions, delays, and uncertainties in issuance of a CMO license greatly affects KAMP, PRISK and MCSK in collection of royalties (increases resistance to comply by users), implementation of strategies and general governance. Additionally, the action by the regulator negates ‘going concern accounting principle’, which assumes that CMOs as business entities will remain in business for the foreseeable future and that they will not be compelled to cease their operations. However, Kenyan CMOs, the going concern principle is compromised by actions of the regulator. This in turn has affected CMOs corporate governance, operational structures, and general capabilities.

CMOs while agreeing that they are obligated to comply with statutory requirements of 70:30 ratio, this means that 70% goes to distribution while 30% goes to administrative cost. In order to mitigate the negative impact on this requirement, the KAMP-PRISK-MCSK tripartite Boards resolved and communicated the resolution to KECOBO that they have decided to operate at the ratio of 50:50 for the time being to mitigate the effects of COVID-19 until royalty collections improve. KECOBO responded with disregard and insisted on their preferred 70:30 ratio without any justification(s) and commitment to help the CMOs overcome the challenges they are facing in royalty collection and levels of compliance by big users like telecommunication providers, broadcasters, and hotel and transport sectors. The police directive had big impact on royalty collections. The revenue generated from PSVs has plummeted from KES 40,556,108.50 in 2019 to KES 10,296,621 in 2020 and

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35 Kenya Copyright Board v Music Copyright Society of Kenya & two others (2021) (undecided case).

zero revenue in 2021\textsuperscript{37}.

Furthermore, the requirements have not been met due to low royalty collections which is directly attributed to vicissitudes of COVID-19, withdrawal of police\textsuperscript{38} enforcement in 2019, low compliance by the users of copyrighted works, low tariffs which were sanctioned by the regulator in 2020 and lack of support by other government agencies.

Noncompliance with approved tariffs continues to exact a heavy toll on CMOs. CMOs’ applicable tariffs are published in the Kenya Gazette after a conscientious public participation. Unlike 2019 tariffs which had relatively higher tariffs, the 2020 tariffs\textsuperscript{39} have been decried for adopting flat rate parameters and ignoring previous scientifically based parameters that were largely based on size, dimension of the buildings, lodges, hotels, public utility, and other entertainment spots.

CMOs have been complaining that the current tariffs were imposed on them by the government agencies. The government made a justification that the levels of compliance were bound to rise with reduced and flat rated tariffs. The converse is true, the levels of compliance has considerably gone down with some premises that used to pay over KES one million now being billed for paltry KES 200,000. The flat rate has significantly reduced CMOs revenues since it was a deviation from music licensing principles and standard practice in that the tariffs did not take into consideration the extent to which a premise uses music. Using the 2019 gazette tariff, Intercontinental Hotel in Nairobi’s License fee was KES 1,871,384 and was based on surface area (background use) tariff while the 2020 tariff, the license fee plummeted to KES 133,000.

Over the years, the CMOs have been keen on using ICT systems and infrastructure to aid with collections and distribution in a transparent manner. However, this remains an area of concern for the CMOs due to regular system changes with the current system causing some noticeable challenges. In the year 2016, KAMP and PRISK procured the Distro System for monitoring and distribution purposes, this was later replaced in 2018, by the Suave System. However, the system was shut down in July when the High Court ruled that MPAKE was procedurally and unlawfully licensed by the KECOBO.

CMOs allege that reduced revenues have hamstrung CMOs Board operational efficiency. This has ultimately affected their oversight role in as far as management of resources and meeting statutory compliance requirements are concerned.

CMOs still maintain that 2020 tariffs are laced with some fundamental mistakes of principle, which have led to further market confusion thus undermining streamlined licensing. They hold that while there is consistency in parameter usage in some tariffs and not in others, there is clustering of diverse businesses or non-comparable businesses, and this has affected fair licensing. It has been observed that economic zone principles were not employed throughout retail sector. Additionally, minimum fees per groupings and categories did mot incorporate the disparate economic zones and thus should be reviewed to incorporate economic zone principles.

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Following issuance of a joint licence by KECOBO in 2019 Tenacle Licensing System which was being operated by MCSK was acquired for the KAMP-PRISK-MCSK tripartite collection activities. The system was short-lived given that in 2020, the current ICT system was procured. There


\textsuperscript{38} Ombati C, 'Mutyambai withdraws police escorts from MCSK operations as probe commences’ the Standard (Nairobi, 3 September 2019).


\textsuperscript{40} Kenya Association of Music Producers Annual Reports 2019, 2020 and 2021.
have been debates of how this system, which operates on principle of self-licensing, was forced down the throat of CMOs by government authorities. The cost associated with the current system are relatively higher compared to the previous systems a fact that reduces the amount of money that should be distributed to the rights holders. Further to this, the system is to date still not able to monitor and distribute scientifically as initially expected.

It is instructive to note that CMOs license was revoked in August 2021 due to failure to upload their repertoire on ICT system. According to the CMOs, they have been in consultation with the developer of the ICT system (Liberty Afrika Ltd.) and have provided the necessary metadata for uploading to the ICT system for identification of rights holders within respective CMOs mandate. They complain that the developer is yet complete royalty distribution module, which is still under development phase. CMOs hold that they will upload other details to facilitate scientific royalty distribution subject to the court’s ruling on the ongoing petition between CMOs and the regulator.

Broadcasters have been accused of failing to comply with gazetted tariffs. Most broadcasters, including the government broadcaster KBC, still owe royalties to KAMP dating back to 2014. At the current value of 2020 broadcast radio tariffs for the three CMOs at 100% compliance from the over 180 radio stations licensed by Communications Authority of Kenya is KES 63,650,000; the broadcast compliance for 2019 was KES eight million, KES 11 million in 2020 and KES 29 million in 2021.

Collectively, broadcasters owe right holders KES 1,096,123,200 between January 2017 and December 2019, a period within which broadcast radio collectively made KES 200,373,000,154 (including 2020) and broadcast TV collectively made KES 214,249,876,912 both totaling to KES 414,622,877,066 in advertisement revenue. The fee owed to CMOs (KES 1,096,123,200) is only 0.2% of the total global figure of KES 414,622,877,066.

Regarding marketing activities, CMOs maintain that they have developed animated promotional video clips that demonstrate how to access the online licensing platform via USSD code *553# and web platform www.kpmlicensing.co.ke in both English and Kiswahili. These video clips have been shared on social media platforms before and would continue being shared to promote the online ICT licensing system. Other promotional materials including digital posters have also been developed and have been used for promotional purposes of the ICT licensing system on social media platforms.

Concerning tax arrears disputes, KAMP and PRISK successfully challenged the Kenya Revenue Authority tax assessment before the Tax Objections Tribunal. The matter has since been concluded with the ruling given in CMOs favour. The tribunal held that CMOs are companies limited by guarantee, which fall in the same docket as non-profit companies, clubs, charitable trusts and other similar set, which benefit from the VAT and Income Tax exemptions. The ruling further noted that pursuant to section 21(2) of the Income Tax Cap 470, a trade association can choose or elect, by notice in writing to the Commissioner of Domestic Taxes, to be considered for carrying out business chargeable to tax in respect of any yearly income. However, CMOs have not written to the Commissioner electing that the years under assessment be chargeable to tax.

3. CONCLUSIONS

From the arguments proffered above, it is a clear that CMOs in Kenya and their regulator, the KECEBO, have a case to answer in as far as application of corporate

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41 PwC, Media & Outlook Report (PwC 2019).
governance principles is concerned. It is apparent that the sector has been dogged by controversies as a result of actions of the regulator on the one hand and the actions of the CMOs on the other. It has been demonstrated that CMOs are expected to operate within strictures and exactitudes of corporate governance. Corporate governance cannot be gainsaid. It is a glue that weaves and allows interoperability between different organs in an organization. It allows realization of vision and mission of organization as well as creating value to member-based organizations such as CMOs. It has been established that the concept of corporate governance will suffer injury if there is strained relationship between the administrative regulatory body such as KECEBO and regulated entities in this case CMOs in Kenya. The study shows that a forensic audit has indicted CMOs for failing to adhere to the dictates of corporate governance. In retrospect it has also been established that CMOs are hemorrhaging from the actions of government entities to wit, copyright regulator, police service, and other regulatory bodies. These factors have led to apparent poor performance of CMOs in Kenya with collection going under leaving them with nothing to distribute to the right holders.

4. RECOMMENDATIONS AND WAY FORWARD

It is imperative that KECEBO and CMOs should bury the hatched and identify a formula for working together in an environment devoid of acrimony which has characterised Kenya’s copyright sector for decades now.

To ensure efficient management of royalties, KECEBO should devise strategies on implementing corporate governance management changes envisaged under the Constitution, Company’s Act, Copyright Act, and copyright regulations. Articles 10 and 73 on the national values and principles of governance and Article 232 on values and principles of public service behoove both KECEBO and CMOs to work together in the interest of right owners and consumers of copyrighted works.

It is in this spirit that the KECEBO should enhance existing copyright regulations guidelines, policies and manuals on corporate governance, for CMOs. These corporate governance tools should be anchored on the 2010 Constitution, Copyright Act, specifically corporate governance reforms applicable to CMOs under sections 46E, 46F and 46G of the Copyright Act and all other relevant laws.

To enhance corporate governance, other government agencies should come to the aid of CMOs. To achieve this goal, KECEBO, CMOs, other government agencies such as police, should work in unison to realize constitutional provisions especially Article 40(5) which obligate State to support, promote and protect the IP of the people of Kenya. The regulator should carry out campaigns to ensure that there is top of mind awareness regarding respect of copyright and related rights. KECEBO should continuously create awareness of member rights and organize member seminars and workshops.

To address loopholes identified in the forensic audit, CMOs should continue to improve their systems to ensure they collect and distribute effectively and efficiently. They should also ensure that they afford their members the opportunity for a fair and balanced representation on the Board taking into account the direct economic interest a member has in the functioning of the organization.

The CMO Boards should strive to adhere with the principles of corporate governance. They should deploy strategies for addressing all 13 issues that were identified by the forensic audit report. Board Charter, Code of Conduct and policies, should guide specifically the Board. The Boards should ensure that all necessary policies are put in place. The Boards should also address all structural issues by establishing statutory board committees such as audit and legal committee as well as stabling internal audit at individual CMO level and at KPM level.
To avoid disruption of CMOs operations, the law should be amended to allow for a three-year license instead of one-year license. This will enable CMOs to have realistic and meaningful strategic planning cycles that will allow them to execute planned activities within licensing cycle.

On tariffs, there is a consensus that a flat rate is not sensitive to practical circumstances and leads to dissention or conflict among or between users. New tariffs based on scientific formula should be formulated and implemented.

The systematic leakages in the current copyright regime should be sealed through adoption and operationalization of good governance, entrenchment of transparency and accountability by CMOs. Entrenchment of these values will bequeath to this industry a veritable gain to copyright holders, users of copyrightable works and CMOs in equal measure.

[Through a letter dated 28 August 2019, the Inspector General of National Police Service instructed Police officers to stop supporting the CMOs in enforcing compliance to the Copyright Act. This directive by the IG was based on a misrepresentation of how the CMOs work and KECOBO, the Regulator, did not taken any initiative to address the problem in spite of numerous pleas from CMOs, knowing very well the implications of such a directive on the collection of royalties by CMOs. Unfortunately, the situation in Kenya is that CMOs require the help of National Police for the public to comply with their obligations as provided for in the Copyright Act.

Section 46A of the Copyright Act (2001) provides that the tariffs to be used by the CMOs shall be published in the Kenya Gazette by the Cabinet Secretary.]

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ABSTRACT

The aim of this paper is to evaluate the importance of trademarks and intellectual property (IP) rights as company assets in general. The evaluation is performed through the analysis of the legal framework in the Republic of North Macedonia and assessment of the interface between trademarks and IP rights in general as intangible assets and company law within the country.

This paper firstly analyses trademarks as IP rights, primarily through their essential functions. Afterwards, the paper assesses trademark and IP rights in general through the prism of the company law in the Republic of North Macedonia. In particular, the paper analyses the possibility of investing IP rights in companies as equity – the legal framework and the methods for valuation of the IP rights. The paper further explores methods for IP commercialisation – licensing and franchising as the most suitable and commonly used practices for trademark promotion.

The final part of the paper will analyse some of the world’s most successful companies and how they create value and successful brands using trademarks before addressing the situation with domestic companies, how much they invest in trademarks as a means of building a successful brand, and how much IP rights as intangible assets participate in the overall value of the companies in the Republic of North Macedonia.

Keywords: trademarks, IP rights, company law, brand value, IP commercialisation, intangible assets, Republic of North Macedonia.

1. INTRODUCTION

The purpose of intellectual property (IP) rights is to protect the creations of the human mind. More precisely, IP encompasses rights related to literary, artistic and scientific works; performances of performing artists, phonograms, and broadcasts; inventions in all fields of human endeavour; scientific discoveries; industrial designs; trademarks, service marks, and commercial names and designations; protection against unfair competition and all other rights resulting from intellectual activity in the industrial, scientific, literary or artistic fields. From this broad scope of the definition provided within the World Intellectual Property Organization (WIPO) Convention, it can be concluded that IP rights are deeply rooted in all fields of society.

The trademark has been used in its rudimentary form by traders in the past to mark their products. Today, the trademark has the most widespread use since all businesses use it in their commercial activity as a sign of recognition. In this sense, businesses use trademarks to distinguish their products from the competition and to be more easily identified by the consumers. Trademarks play an important role in building brand image and creating value in the eyes of consumers since they associate trademarks with a particular value of companies.

The paper first defines the trademark as an IP right by analysing its main functions. Afterwards, trademarks and other IP rights are analysed through the prism of company law – firstly, in terms of the possibility of investing IP rights in companies, and secondly, in terms of commercialization of IP rights. Furthermore, the paper
will analyse some of the world’s most successful companies and how they create value and successful brands through the utilization of trademarks. Finally, the paper addresses the situation with domestic companies, how much they invest in trademarks as a means of building a successful brand and how much IP rights participate in their overall asset value.

2. DEFINING TRADEMARK

A trademark is a distinctive sign, word, phrase, or symbol that signifies a given product and thus makes a legal distinction of the same from other products in circulation. According to the Law on Industrial Property of the Republic of North Macedonia, the trademark ‘protects a sign which may be represented graphically, and which is capable for distinguishing goods or services of one undertaking from those of other undertakings.’ The trademark protects signs that can be composed of words and letters in any language or alphabet, numbers, pictures, drawings, colour combinations, three-dimensional shapes, shapes of goods, their packaging, as well as combinations of some or all listed signs. Unlike the Macedonian national legislation, which provides only for the protection of colour combinations, within the European Union (EU), even particular single colours or sounds can be protected as trademarks.

The trademark has been used as a sign to distinguish products since the beginning of trade. In this way, the merchants guarantee that a certain product has particular characteristics. Through the trademark, the customers and clients create expectations for certain qualities which the branded product should possess. The functions of the trademark can be differentiated from the way it is utilized in day-to-day activities. The most important functions of the trademark are the origin function, the distinctive function, the quality function, the advertising function, and the competitive function. The origin function indicates the origin of the product, i.e., it associates the product with a particular company. Similarly, the distinctive function has the purpose of distinguishing particular products from one company from similar products on the market from other companies. One of the most important functions of the trademark is the quality function, which guarantees that the product bearing the trademark has certain characteristics and qualities. Through the advertising function, companies utilize trademarks to promote and build a recognizable brand that will be remembered by the customers. While a brand is a broader concept, trademarks form an integral and indispensable part of the creation of a brand image. Consequently, the terms brand and trademark are at times used interchangeably in this paper. Finally, the competitive function summarizes all the above because the successful use of the trademark differentiates the trademark holder and puts him above the competition in the market.

When discussing trademarks, it is important to note that in addition to the individual trademark that differentiates one product from all others, there are also collective trademarks and certification trademarks (CTM). The collective trademark protects a sign intended for collective designation of the goods or services put on the market by an association of legal and natural right-owners. For example, McDonald’s® is a collective trademark of the McDonald’s Corporation used for the designation of all ranges of products of the company regardless of their characteristics. The CTM, on the other

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3 Ibid., Article 175(2).
4 For example, Deutsche Telekom has registered the ‘magenta’ colour as a trademark [https:// trademarks.justia.com/787/98/n-78798428.html] accessed 28 May 2021.
5 In 2003, the European Court of Justice decided that Beethoven’s melody ‘Fur Elise’ may be protected as a trademark. Case 283/01 Shield Mark BV V. Joost Kist h.o.d.n. Memex (2003) ECR I-14313.
7 Macedonian Law on Industrial Property, (n 2) Article 219.
hand, protects marks that indicate a certain quality, origin, method of production, or other common characteristics of the goods and services of the companies which use them.\(^8\) The use of CTM is conditioned with the possession of the required characteristics, and it is under the supervision of its holder. For example, Woolmark\(^8\) is a CTM that can be put on products made from pure wool which meet quality standards set by The Woolmark Company, regardless of which company produces the wool product.

The trademark falls within the category of IP rights, whose existence and recognition is conditioned by registration. Unlike copyright protection, which is granted to the author from the moment of the creation of the work, trademark protection is acquired only under a previous system of registration by an authorized national agency, which in the case of the Republic of North Macedonia is the state office of industrial property (SOIP).\(^9\) The applicant can be a domestic or foreign natural or legal person.\(^10\) According to the latest report of the SOIP, in 2019, a total of 8488 trademark applications were submitted, out of which 1471 are directly submitted to the SOIP while 7017 are submitted by virtue of the Madrid Protocol\(^11\), i.e., they are submitted to other national registries which are then forwarded to the SOIP.\(^12\) Consequently, more than 89% of the applications are submitted by virtue of the Madrid Protocol, whereas slightly more than 10% are submitted directly to the SOIP. From the 1471 applications submitted directly to the SOIP, 870 are domestic, and 601 are from foreign applicants,\(^13\) i.e., 40.8% are foreign applications, and 59.2% are domestic applications. From the 7017 applications through the Madrid Protocol, 2965 are new applications, and 4052 are applications for extensions. The data indicate that the Republic of North Macedonia is a relatively small but active and diverse market. While there is a significant number of foreign applications, the majority are still submitted by domestic applicants, which indicates that domestic merchants are aware of the importance of trademarks and take necessary steps to secure their protection.

The Macedonian national legislation is in line and complies with the EU acquis as well as with other international instruments in relation to the conditions for copyright protection, as well as the rights and obligations which arise from trademark protection. According to the Law on Industrial Property, the trademark term is 10 years from the date of filling the trademark application\(^14\), and it may be renewed an indefinite number of times for a term of 10 years.\(^15\) This provision is fully in line with the 10-year renewal period from the Madrid Protocol.\(^16\)

**A. TRADEMARKS AND OTHER IP RIGHTS THROUGH THE PRISM OF COMPANY LAW IN THE REPUBLIC OF NORTH MACEDONIA**

As already noted, the trademark was used in a very rudimentary form as a seal distinguishing various products since ancient Greece and Rome. However, that occurred in a period that long preceded trade as we recognize it today. There were no business enterprises, so the trademark was always tied to a natural person – a farmer or a craftsman. However, over the years, as trade and, more importantly, international trade began to develop, and as the idea for profit maximization and costs and risks minimization came into existence, it became necessary to consolidate the economic ventures and create economies of scale, which gave rise to the first companies. Companies are the dominant merchants in

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\(^{8}\) Ibid, Article 223(1).
\(^{10}\) Macedonian Law on Industrial Property, (n 2) Article 179.
\(^{13}\) Ibid.
\(^{14}\) Macedonian Law on Industrial Property, (n 2) Article 211(1).
\(^{15}\) Ibid, Article 211(2).
\(^{16}\) Madrid Protocol, (n 11) Article 7(1).
trade, and as a result, the trademark is more closely associated with companies rather than with natural persons. In this part of the paper, we will review the current legal status of the trademark as an IP right through the prism of company law – first in relation to the possibility of investing trademarks in companies as a contribution, and then in relation to the possibilities for its commercialization.

B. TRADEMARKS AND IP RIGHTS AS SHARE CAPITAL IN COMPANIES

The contribution from the shareholders is the first precondition for the establishment of the company. With this act, the founders of the company transfer a portion of their property to the newly established company. With the constitution of the company, those contributions now become the property of the newly established legal entity. The company as a legal fiction is, in fact, a sum of movable and immovable property. Movable and immovable property as a form of non-monetary contributions, it is rational to consider that IP rights also fall within this category. As a form of non-monetary contribution, IP rights must have an estimated value that is expressed in domestic or foreign currency. Movable and immovable property as a form of non-monetary contribution is more susceptible to trade and turnover. Hence, the assessment of their market value is easier. IP rights, on the other hand, are a specific form of contribution since there are several variable factors on which their value may depend. Hence, it is necessary to have rules and methods for the correct assessment of the value of these rights. In the Republic of North Macedonia, assessments are regulated in the law on appraisals, which stipulates that the competent ministries are obliged to adopt an appraisal methodology in their respective areas. As the competent ministry for the field of industrial property, the Ministry of Economy in 2011 issued the methodology for appraisal of industrial property. The methodology proposes the following

shareholders can have a combination of cash and contributions in kind. However, considering the protective function that the share capital has for the creditors of the company when it comes to non-monetary contributions, it is necessary that they are determined in monetary value. The Macedonian CLA regulates the procedure, form, and manner of subscribing contributions in kind through general provisions that refer to all types of companies, as well as with more specific provisions for different forms of companies.

Since non-monetary contributions, besides movable and immovable property, may also contain the rights of the members or shareholders of the companies, it is rational to consider that IP rights also fall within this category. As a form of non-monetary contribution, IP rights must have an estimated value that is expressed in domestic or foreign currency. Movable and immovable property as a form of non-monetary contribution is more susceptible to trade and turnover. Hence, the assessment of their market value is easier. IP rights, on the other hand, are a specific form of contribution since there are several variable factors on which their value may depend. Hence, it is necessary to have rules and methods for the correct assessment of the value of these rights. In the Republic of North Macedonia, assessments are regulated in the law on appraisals, which stipulates that the competent ministries are obliged to adopt an appraisal methodology in their respective areas. As the competent ministry for the field of industrial property, the Ministry of Economy in 2011 issued the methodology for appraisal of industrial property. The methodology proposes the following

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18 Ibid, Article 3(1)(27).
19 This opportunity is allowed for the partners in general partnerships as well as for the general partners in limited partnership. This approach is justified since the partners in the public company and the general partners in the limited partnership have personal, unlimited and joint and several liability for the obligations of the company. Ibid, Articles 34(2) and 27(2).
20 Ibid, Article 35.
21 Ibid, Article 175 for non-monetary contributions in limited liability companies and Article 291 for non-monetary contributions in stock corporations.
22 Macedonian Law on Appraisals (Official Gazette of Republic of Macedonia No. 115/10, 158/11, 185/11, 64/12, 188/14104/15, 153/15 192/15 and 30/16), Article 47(1).
23 Methodology for appraisal of industrial property, Ministry of Economy of Republic of North Macedonia (Official Gazette of Republic of Macedonia No. 178/11).
method for valuation of industrial property rights, which are listed in hierarchical order:

- Market method;
- Cost method; and
- Income method.\textsuperscript{24}

According to the methodology, the first method which should be applied is the market method – which determines the value based on the prices for the past transactions of the same or similar IP assets. The cost method determines the value of the IP assets based on the costs necessary to replace them with an asset with identical or similar characteristics. Finally, according to the income method, the IP asset is valued based on the total amount of economic income it is expected to generate in the future for the asset’s lifespan. These three methods are also recognized by WIPO as the most common method for an appraisal and valuation of IP rights, although the income method is considered as the most used one.\textsuperscript{25}

When assessing the value of industrial property rights, including trademarks, multiple appraisal methods can be used, as they are largely complementary and do not exclude each other. The choice depends on the objectives of the valuation, the basis of the valuation, market activity and the availability of information on previous transactions.\textsuperscript{26} However, despite the fact that the methodology contains precise parameters and mathematical formulas for determining the value, all calculations are based on the existence of an active market for IP rights or reliance on the companies on IP assets in their business activities, which would serve as a starting point for application of all the listed parameters. However, because in the Republic of North Macedonia, there is no active market for trading IP assets, the application of the methodology and consequently the valuation of IP assets is significantly more difficult.

When discussing trademarks as contributions in companies, the situation is even more unusual due to the nature of trademarks. When establishing a new company, the assumption is that it starts with its business venture from the very beginning and that it still does not have a recognizable product or service. On the other hand, a trademark signifies a product or service that is already to some extent established on the market. Consequently, while trademarks qualify as company assets, the value of a newly registered trademark would be negligible, and because of this, it is uncommon for a trademark to be used as a contribution to a newly established company. In essence, the value of all trademarks is negligible when they are new, but it increases over time with the growth of the company and the product to which it is attached. When discussing an increase of the share capital through new contributions, there are a number of cases where one company acquires another company in order to obtain a trademark or similar IP assets, but such an act does not always mean that there will be an increase in the subscribed share capital of the acquiring company, or that the value of the acquisition will be reflected in the financial statement of the company.\textsuperscript{27} Besides acquisitions, the same holds true for mergers and restructuring of companies.

If it is a trademark that is already established on the market and recognizable in the eyes of consumers, for it to be utilized as a contribution to a newly established company, the holder of the trademark should transfer the ownership through assignment to the newly established company, thereby forfeiting its own benefits. This situation seems unrealistic, as the right is more likely to be transferred by virtue of a licensing or franchise agreement. These agreements as a form of commercialization of the trademark and other IP rights will be considered below.

\textsuperscript{24} Ibid, Article 5(1).
\textsuperscript{26} Methodology for appraisal of industrial property, (n 23) Article 5(2).
\textsuperscript{27} Companies may not wish to increase the subscribed share capital, if it is above the required minimum share capital required in the relevant jurisdiction.
3. COMMERCIALIZATION OF IP RIGHTS

The commercialization of IP assets constitutes the dynamic side of IP law.\(^{28}\) The commercialization of IP rights is the realization of successful intellectual creations. The goal of every company is to make a profit through IP rights, in the same way as with all other resources at its disposal. Profit can be achieved using IP rights to improve the efficiency of own production or service activities (e.g., patents), which will reduce production costs; through the use of IP rights for self-promotion and creating brand image (e.g., trademarks or industrial design); or through the transfer of rights to use an IP asset to third parties.

Below, we take into consideration licensing and franchise agreements as a form of commercialization of IP rights. When it comes to trademarks, these types of agreements are the most important and most often used in practice due to the nature of the trademark as an IP right. Because a trademark is a distinctive sign associated with a particular company, it is rare for ownership of trademarks to be transferred completely through assignation, but rather, if companies decide to allow other companies to use their trademark, it is usually through a licensing or franchise agreement.

The Macedonian Law on Obligations regulates the licensing agreement in section XVIII, Articles 742 through 767.\(^{29}\) According to the Law on Obligations, licensing agreement is an agreement in which the licensor undertakes the obligation to transfer to the licensee in whole or in part the right of use, of the patent, know-how, trademark, sample or model, for which licensor undertakes an obligation to pay the licensor a fee.\(^{30}\) It follows from the definition that with the licensing agreement, the owner of the trademark, i.e., the licensor, may transfer to a third party the right to use the trademark against payment of a fee or royalties. Unlike an assignment agreement, where transfer of ownership of the right occurs and where the assignee becomes a legal successor and owner of the IP right, with the licensing agreement, the licensee has only the right to use the IP right, while the licensor retains ownership. It also follows from the definition that the list of industrial property rights which may be the subject of a license is limited, and it encompasses patents, trademarks, and utility models. From the wording of the definition, it would seem that industrial designs or integrated circuits cannot be the subject of a licensing agreement. However, the list of IP rights is provided within Article 742 of the Law on Obligations should be considered as a non-exhaustive list, especially considering the principle of party autonomy in international commercial contracts.

From a legal point of view, the licensing agreement is characterized by several elements. Firstly, the agreement must identify the parties – the licensor and the licensee. Besides the parties, the most important and essential element in the licensing agreement is the subject of the agreement. The subject of the agreement is the IP right, as well as the extent to which it can be used by the licensee. The license may be exclusive – granting the right to use the IP asset only to the licensee, or non-exclusive, which would allow the licensor to grant that particular right to third parties as well.\(^{31}\) The question which arises is whether the price is considered an essential element of the licensing agreement. It follows from the definition provided within the Macedonian Law on Obligations that without compensation, the licensing agreement would be null and void.\(^{32}\) However, there are situations where the licensing agreement can be concluded without a payment fee, for example, in the situation of licensing agreements without compensation.\(^{33}\) The licensing agreement is characterized by both temporal and territorial dimensions. Namely, the contract must contain a period for which the right is granted, as well as the territory in which the licensee can use it. The Macedonian

\(^{28}\) Anastastovska JD, Pepeljugoski V (n 6) 396.
\(^{30}\) Ibid, Article 742(1).
\(^{31}\) Ibid, Article 745.
\(^{32}\) Ibid, Article 742(1).
\(^{33}\) Anastastovska JD, Pepeljugoski V (n 6) 409.
Law on Obligations stipulates that the duration of the licensing agreement cannot be longer than the period for legal protection of the particular IP right, which is the subject of the agreement. Consequently, the duration of a licensing agreement for a trademark cannot be longer than 10 years, given the fact that legal protection of trademark is given for 10 years (subject to renewal for an unlimited number of times). Regarding the form of the licensing agreement, both the Law on Obligations and the Law on Industrial Property stipulate that the agreement must be concluded in writing.

Trademark licensing agreements are important for the licensor because they generate profits. As already noted, the licensee pays a fee for the use of the trademark. The fee can be in the form of a fixed amount (lump sum), as a percentage of realized sales, or as a combination of both. Besides profit, trademark licensing agreements help companies expand their operations to new geographical or product markets. On the other hand, trademark licensing agreements are also beneficial for the licensees because the familiar and already established trademark stands as a guarantee for certain qualities and characteristics of the products or services, which allows the licensees to generate a guaranteed level of profits.

In addition to the licensing agreement, an important agreement for the commercialisation of IP rights is the franchise agreement. A franchise can be simply defined as a unified method for selling products or services. With the franchise agreement, the franchisor allows the franchisee to use his developed business method against payment of the fee. In the past, the franchising agreement had close links and was often compared to a distribution agreement, but the difference is that in franchising, in addition to the package of IP rights, it is necessary to transfer know-how as well as trade secrets. For this to be done successfully, it is necessary for the franchisor and franchisee to have close and continuous cooperation. From the substance of companies that have a recognizable image and developed operational method to expand into new markets, as well as to generate additional income from borrowing the method to third parties which have enough funds to start a business but may not have enough knowledge and experience to build a successful brand themselves. The subject of the franchising agreement is a package of IP rights that usually include trademarks, industrial designs, copyright and also know-how and trade secrets. The trademark is an integral part of the franchise agreement because it represents the visual part of the business venture, and it helps the consumer to detect certain qualities.

Unlike the licensing agreement, which is regulated in the Macedonian Law on Obligations, there are no provisions that regulate the franchise agreement, and therefore it is considered to belong to the group of so-called agreements of autonomous commercial practice. Since there are no special rules for the franchise agreement within the national legislation, the general contractual provisions of the Law on Obligations will be applicable to this type of agreement. The subject of the franchise agreement is the transfer of the right to use a certain business method and formula, i.e., a uniform way of selling the goods or providing the services, while the goods or services themselves can be considered as a secondary subject of the agreement.

By its nature, the franchise agreement is close to the licensing agreement, but the difference is that in franchising, in addition to the package of IP rights, it is necessary to transfer know-how as well as trade secrets. For this to be done successfully, it is necessary for the franchisor and franchisee to have close and continuous cooperation. From the substance of

34 Macedonian Law on Obligations, (n 29) Article 744.
36 Macedonian Law on Industrial Property, (n 2) Article 272.
38 Anastasovska JD, et al., Dogovori na avtonomnata trgovska praktika (Contracts of Autonomous Commercial Practice) (Justinius Primus Faculty of Law – Skopje 2012) 24.
the franchising agreement, these several characteristics can be observed:

- The agreement is concluded between two independent persons as contracting parties;
- The subject of the contract is the transfer of the right to use a uniform business model and brand image;
- There is a need for close cooperation and trust between the contracting parties – the franchisor is required to provide continuous assistance and training, while the franchisee is required to provide feedback for its performance.\(^40\)

Today, franchising as a method of commercialization is widely used and spread on a global scale. Statistics show that it is most used within the United States (US). In 2019, as many as 773,603 franchises were established.\(^41\) This fact is not surprising given the fact that the franchise as a method has its roots in the US. The number of franchises operating on European territory is significantly lower, and it is estimated that the number is 10,000 franchises operating successfully in more than 20 countries.\(^42\) The leader in Turkey with roughly 1,600 franchises, followed by France with 1,300 and Spain with 900.\(^43\) The least number of franchises are registered in Slovenia – 107, and as much as 48% of these franchises are international, which is the highest percentage of all countries.\(^44\) Unlike the rest of the world, in the Republic of North Macedonia, there is no data on the number of franchises. Some of the franchises of well-known companies such as Domino’s, Coca Cola, Burger King, KFC are easily detectable, but still, the current state of play cannot be successfully determined only through visual observations. Also, the listed examples are international franchises where the franchisors are international companies, whereas the domestic companies are franchisees. There are very few cases where domestic companies are in the role of franchisors, both at home and abroad. The pharmaceutical company Alkaloid is one of the few examples which has successfully franchised some of its products internationally.\(^45\) The data indicates that while the franchise agreement is a powerful tool for the commercialization of IP rights on a global scale, Macedonian companies still have difficulty catching up with these trends. This inactivity inevitably reflects on the value of trademarks of domestic companies.

4. THE TRADEMARK AS AN ASSET FOR SUCCESSFUL COMPANIES

The importance of trademarks is best seen through their use by the world’s most successful companies. The companies that have the highest market value in general also have very high, if not the highest brand values. Successful companies use trademarks to increase their market share as well as to conquer new markets. Unlike in the past when the companies allocated most resources for building production capacities and developing distribution channels, and the investments were directed towards material assets, it is obvious that in recent years this trend is changing. Statistics show that more and more companies from developed countries invest more in intangible rather than tangible assets. This is evident from the data provided in Table 1, where it is clear that US and UK companies invest more in intangibles than in tangible assets.

\(^{40}\) Anastasovska JD, et al. (n 38) 23.
\(^{43}\) Ibid.
\(^{44}\) Ibid.
\(^{45}\) Anastasovska JD (n 37) 720.
Table 1 – Graphic data of tangible and intangible assets of companies based on regions


Investments in intangible assets can be divided into three groups: investments in economic competencies, which include brand investments, investments in computerized information and innovative property. Although it is not possible to determine exactly how much of the investment in intangible assets is invested in promoting and strengthening the brand and image of companies, it is evident that there is a growing trend of these investments, particularly in more developed markets.

In practice, the terms trademark and brand are often used interchangeably. At the academic level, there is a debate whether these terms are synonymous or whether there is a difference. Initially, trademarks and brands were considered to be rough synonyms because they have essentially the same characteristics. Afterwards, authors begin to differentiate them from one another, pointing out that trademark is primarily a legal instrument while the brand is a business tool. The literature in the field of marketing points to a distinction between the two terms, considering the term brand to be a much broader concept than trademark, since it includes, but is not limited to, perceptions, expectations of consumers, reputation and image of the company, and even other IP rights, such as copyright and industrial design rights. However, despite this difference between the two concepts, it is indisputable that a trademark as a distinctive symbol represents the foundation and the core of each brand. Consumer expectations, beliefs and perceptions are of a secondary nature because they are inextricably linked and driven by the trademark of a particular product, service, or company. Hence the brand cannot be analysed separately from the trademark.

When discussing successful companies worldwide and how they use trademarks for successful promotion, it is evident that there is a correlation between the value of the company and the value of the brand of the company. Table 2 contains the list of the top 10 companies with the highest brand value. From this list, seven companies also form the list of the top 10 largest companies in the world by market capitalization. Amazon, Apple, Microsoft, Alphabet (Google), Alibaba Group, Tencent and Facebook are all listed in the top 10 most valuable companies by market capitalization, while Visa is listed at 13, Mastercard at 19, and McDonald’s is listed the lowest – at 63.

Table 2 – List of top 10 companies with highest valued brands

<table>
<thead>
<tr>
<th>#</th>
<th>Company’s name</th>
<th>Brand value (Mil., USD)</th>
<th>Market capitalization (Mil., USD)</th>
<th>Brand value % in market value of the company</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Amazon</td>
<td>415.9</td>
<td>1,711.8</td>
<td>24.29%</td>
</tr>
<tr>
<td>2</td>
<td>Apple</td>
<td>352.2</td>
<td>2, 252.3</td>
<td>15.63%</td>
</tr>
<tr>
<td>3</td>
<td>Microsoft</td>
<td>326.5</td>
<td>1,966.6</td>
<td>16.60%</td>
</tr>
<tr>
<td>4</td>
<td>Alphabet (Google)</td>
<td>323.6</td>
<td>1,538.9</td>
<td>21.02%</td>
</tr>
<tr>
<td>5</td>
<td>Visa</td>
<td>186.8</td>
<td>483.9</td>
<td>38.60%</td>
</tr>
<tr>
<td>6</td>
<td>Alibaba group</td>
<td>152.5</td>
<td>657.5</td>
<td>23.19%</td>
</tr>
<tr>
<td>7</td>
<td>Tencent</td>
<td>151</td>
<td>773.8</td>
<td>19.51%</td>
</tr>
<tr>
<td>8</td>
<td>Facebook</td>
<td>147.2</td>
<td>870.5</td>
<td>16.90%</td>
</tr>
<tr>
<td>9</td>
<td>McDonald’s</td>
<td>129.3</td>
<td>173.8</td>
<td>74.39%</td>
</tr>
</tbody>
</table>

48 Ibid.
49 Ibid.
51 Ibid.
brands, but despite this fact, there are no drastic differences in the final assessment.

While on a global scale, there is a growing trend of investing in companies’ brands and trademarks, the same trend is yet to be reflected in the operations of Macedonian domestic companies. In the next part of the paper, we give an overview of the current state of play in relation to the value of the trademark and other IP rights of domestic companies.

5. TRADEMARKS AND IP ASSETS OF MACEDONIAN COMPANIES

Unlike the rest of the world, where successful companies rely heavily on trademarks and use them to expand their business ventures, in the Republic of North Macedonia, there are not many companies that can position themselves as global brands. As a result, there is a lack of significant data on the value of domestic brands. What is more interesting is that there are cases where established brands that have operated on the domestic market for many years and have had a large number of customers have abandoned the use of trademarks through rebranding.\(^5\) The last example is the merger of the telecommunications operators Vip and One in 2015, after which the company one. Vip was created,\(^5\) which in 2019 was completely rebranded in A1 Macedonia, in accordance with the owner company, the A1 Telekom Austria Group, thereby completely abandoning the use of previous trademarks.

<table>
<thead>
<tr>
<th>10</th>
<th>Mastercard</th>
<th>108.1</th>
<th>383.6</th>
<th>28.18%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average</td>
<td>229.3</td>
<td>1,081.3</td>
<td>21.20%</td>
<td></td>
</tr>
</tbody>
</table>

Source: BrandZ Global Top 100 Report 2020.\(^5\)

What is even more important is the percentage which the brand has in the total market value of companies. From the statistics, it is noticeable that, on average, the value of the brand is roughly 21% of the market value of the companies. This means that through the successful use of the band and trademarks, the companies create value. It is evident from the data that the most valuable asset which successful companies have is the trademark. The company where the value of the brand has the largest percentage share in the market value of the company is McDonald’s with almost 75%, which is almost four times the average. At the same time, McDonald’s is the largest franchisor company, with over 33,000 franchise agreements worldwide.\(^5\) McDonald’s operation is a model for a company’s success through the efficient use and commercialization of the brand.

Unlike measuring a company’s market capitalization, which is a relatively simple process,\(^5\) assessing brand value is a more complex task because there is no uniform valuation method. The data from Table 2 on brand value is measured from BrandZ, as one of the most reputable brand valuation companies. This company uses a complex value calculation formula where the brand value is based on past profits and projected profits in the future.\(^5\) In addition to BrandZ, Brand Finance\(^5\) and Interbrand\(^5\) are also commonly used sources for brand valuation. These companies use different methods to assess the value of

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54 Market capitalization is measured by a simple mathematical formula: market value of the company’s stocks in particular time, multiplied by the total number of stocks issued.


56 More info on the activities related to brand rankings, metrics and research conducted by Brand Finance <https://brandfinance.com/data> accessed 2 June 2021.

57 More info on the activities related to brand rankings, metrics and research conducted by Interbrand <https://interbrand.com> accessed 2 June 2021.

58 This is most evident within the telecommunication sector. For example, the first mobile operator company Mobimak which was established in 1996, was rebranded on several occasions as it changed ownership structure. First in 2006, it was rebranded as T-Mobile Macedonia, when it became part of the T-Mobile group, and in 2015, it merged with Makedonski Telekom and T-Home Macedonia, to create single company under the brand Makedonski Telekom.

59 The brand VIP existed in several countries where the Telecom Austria Group owned telecommunication operators, which have now all been rebranded to A1. The brand One existed only on the Macedonian market and was created with the rebranding of the company COSMOFON after its acquisition by Telekom Slovenia from COSMOTE Greece.
Regarding the valuation of trademarks and brands as companies’ assets, the lack of information is noticeable at the level of the entire Balkan region. Although there are organizations that award certain quality certificates to certain companies, other than basic company data, they do not conduct any in-depth research related to brands and trademarks. As an example, the organization Superbrands Macedonia grants the status of a super brand to certain companies that are significant in their respective fields and industries. However, apart from allowing companies to use the award in their promotion activities, this organization does not provide any data on the value of the brands, nor any established parameters or standards on the basis of which companies could be granted the super brand status. In fact, such organizations themselves have more of an advertising function for companies.

The only company in the whole region that has done brand ranking for the Balkan region so far is the marketing company VALICON from Slovenia. However, even those reports cannot be considered sufficient since the latest report of this company dates to 2015 and is related to the strongest brands that exist in the territory of former Yugoslavia. At the top of the list are Milka and Coca Cola, and the first regional brand is Vegeta in third place. In the list of top 25 brands, 11 are international brands, whereas only 14 are regional brands. Of these 14 brands, six are from Serbia, four from Slovenia, and four from Croatia, and there is not a single brand from the Republic of North Macedonia. There are also no brands from Bosnia and Herzegovina, Montenegro, and Kosovo as members of former Yugoslavia.

Table 4 – Top 25 Brands in former Yugoslavia

<table>
<thead>
<tr>
<th>#</th>
<th>Brand name</th>
<th>#</th>
<th>Brand name</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Milka (CHE)</td>
<td>14</td>
<td>Aquafresh (UK)</td>
</tr>
<tr>
<td>2</td>
<td>Coca Cola (USA)</td>
<td>15</td>
<td>Jaffa Cakes (SRB)</td>
</tr>
<tr>
<td>3</td>
<td>Vegeta (CRO)</td>
<td>16</td>
<td>Fanta (USA)</td>
</tr>
<tr>
<td>4</td>
<td>Argeta (SLO)</td>
<td>17</td>
<td>Donina (CRO)</td>
</tr>
<tr>
<td>5</td>
<td>Cedeveita (CRO)</td>
<td>18</td>
<td>Lenor (USA)</td>
</tr>
<tr>
<td>6</td>
<td>Cokta (SLO)</td>
<td>19</td>
<td>Pepsi (USA)</td>
</tr>
<tr>
<td>7</td>
<td>Orbit (USA)</td>
<td>20</td>
<td>Kiki (SRB)</td>
</tr>
<tr>
<td>8</td>
<td>Nivea (GER)</td>
<td>21</td>
<td>Chipsy (SRB)</td>
</tr>
<tr>
<td>9</td>
<td>Smoki (SRB)</td>
<td>22</td>
<td>Nutella (ITA)</td>
</tr>
<tr>
<td>10</td>
<td>Fructal (SLO)</td>
<td>23</td>
<td>Ariel (UK)</td>
</tr>
<tr>
<td>11</td>
<td>Paloma (SLO)</td>
<td>24</td>
<td>Podravka (CRO)</td>
</tr>
<tr>
<td>12</td>
<td>Nescafe (CHE)</td>
<td>25</td>
<td>Dukat (SRB)</td>
</tr>
<tr>
<td>13</td>
<td>Plazma (SRB)</td>
<td>26</td>
<td>Plazma (SRB)</td>
</tr>
</tbody>
</table>

Source: Valicon TOP 25 Brands

The same company also performs brand ranking on the territory of each of the republics of former Yugoslavia. Figure 1 shows the brand ranking for the Republic of North Macedonia. Again, from the available data, it is evident that half of the listed brands are international, two are regional, and only three are domestic.

Figure 1 – List of top 10 brands in the Republic of North Macedonia

<table>
<thead>
<tr>
<th>#</th>
<th>Brand name</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Argeta (SLO)</td>
</tr>
<tr>
<td>2</td>
<td>Milka (CHE)</td>
</tr>
<tr>
<td>3</td>
<td>Stobi Flips (MKD)</td>
</tr>
<tr>
<td>4</td>
<td>Vegeta (CRO)</td>
</tr>
<tr>
<td>5</td>
<td>Coca Cola (USA)</td>
</tr>
<tr>
<td>6</td>
<td>Orbit (USA)</td>
</tr>
<tr>
<td>7</td>
<td>Bitolski Jogurt (MKD)</td>
</tr>
<tr>
<td>8</td>
<td>Pelisterka (MKD)</td>
</tr>
<tr>
<td>9</td>
<td>Nescafe (CHE)</td>
</tr>
<tr>
<td>10</td>
<td>Pepsi (USA)</td>
</tr>
</tbody>
</table>

Source: <www.marketing365.mk>


Even though this is the single comprehensive research on trademarks within the region, it still has drawbacks. The research ranks brands based on an online survey and field survey conducted on a sample of 1,000 to 1,500 respondents from each country. This research gives us an insight into what the perception of the consumers is about the brands, but it does not contain a financial aspect or financial formula, and consequently, there is no determination of the value of the brands. In addition, although not stated explicitly in the research, it is evident that the ranking is only in relation to trademarks for goods, and companies providing service activities are not taken into consideration.

In the absence of sufficient data on the value of domestic brands, we analysed the values of trademarks and IP rights of companies through their financial statements. As a sample, we included the companies listed on the Macedonian Stock Exchange. Due to the large number of companies listed on the stock exchange and the relatively low level of activities, only companies forming the index MBI10 were taken as a sample.

Table 5 – List of MBI10 companies as of the latest date of revision (15 December 2020)

<table>
<thead>
<tr>
<th>#</th>
<th>Company’s name</th>
<th>MSE Symbol</th>
<th>Number of stocks</th>
<th>Market capitalization (EUR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>9</td>
<td>NLB Banka Skopje</td>
<td>TNB</td>
<td>854,061</td>
<td>32,932,870</td>
</tr>
<tr>
<td>10</td>
<td>Stopanska Banka Bitola</td>
<td>SBT</td>
<td>390,977</td>
<td>14,934,578</td>
</tr>
</tbody>
</table>

Source: <www.mse.mk>

We consider the MBI10 index companies primarily for several reasons. Firstly, all publicly listed companies have an ongoing obligation to publish quarterly and yearly consolidated financial reports, which enables access to intangible and IP assets of these companies. While there are other large companies in the market that would be relevant to this research since they are established as limited liability companies or are not listed on the stock exchange, access to their financial statements is limited, and consequently, they cannot be analysed. Secondly, the MBI10 index companies are the most liquid companies on the Stock Exchange Market. This means that people find these companies attractive for investment due to their successful business strategies. Considering this, the assumption is that the more successful the company is, the higher the brand value and trademark value are. These companies are also among the companies with the highest market value. It is noteworthy that half of the companies are banks, three are service companies in the field of telecommunications, tourism, and construction, and only two are companies dealing with concrete products which are in the petroleum and pharmaceutical industries.

Since it is not possible to calculate the ratio of the market value of the company to the value of the brand of the company, we will focus on calculating the ratio of total assets of companies and IP rights on getting some basic idea of their role and significance for some of the domestic companies.

The financial statements for the listed companies that are published on the website of the Macedonian Stock Exchange are prepared in accordance with International Accounting Standards (IAS) and International Financial Reporting Standards (IFRS). (Macedonian Stock Exchange)
Accounting Standards.\textsuperscript{66} International Accounting Standard 38 refers to intangible assets.\textsuperscript{67} According to this standard, trademarks, licensing agreements, and franchise agreements are cited as examples of intangible assets, among others.\textsuperscript{68} From the financial statements, only the aggregate value that the companies have recorded as intangible assets is available, without specifying the individual sections dedicated for IP rights. In any case, intangible assets represent value for the company arising directly or indirectly from IP rights. The second column of Table 6 shows the total assets from the 2020 financial statements of the companies that are part of the MBI10 index. The column next to it shows the intangible assets from the same financial statements. In the last column, the percentage of intangible assets in relation to the total assets of the companies is presented.

Table 6 – Comparison of total asset value and intangible asset value of MBI10 Companies for 2020

<table>
<thead>
<tr>
<th>#</th>
<th>Company’s name</th>
<th>Total assets value (MKD)</th>
<th>Intangible assets value (MKD)</th>
<th>% of intangible assets in total asset value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Alkaloid Skopje</td>
<td>15,015,534</td>
<td>1,892,421</td>
<td>12.6%</td>
</tr>
<tr>
<td>2</td>
<td>Stopanska Banka Skopje</td>
<td>105,984,156</td>
<td>127,670</td>
<td>0.12%</td>
</tr>
<tr>
<td>3</td>
<td>Granit Skopje</td>
<td>3,607,243</td>
<td>21,549</td>
<td>0.59%</td>
</tr>
<tr>
<td>4</td>
<td>Komercijalna Banka Skopje</td>
<td>132,600,677</td>
<td>71,561</td>
<td>0.05%</td>
</tr>
<tr>
<td>5</td>
<td>Makepterol Skopje</td>
<td>8,207,759</td>
<td>5,805</td>
<td>0.07%</td>
</tr>
<tr>
<td>6</td>
<td>TTK Banka Skopje</td>
<td>8,844,455</td>
<td>16,63</td>
<td>0.18%</td>
</tr>
<tr>
<td>7</td>
<td>Makedonski Telekom</td>
<td>19,900,296</td>
<td>2,366,029</td>
<td>11.8%</td>
</tr>
<tr>
<td>8</td>
<td>Makedonijaturist Skopje</td>
<td>2,532,932</td>
<td>342</td>
<td>0.01%</td>
</tr>
<tr>
<td>9</td>
<td>NLB Banka Skopje</td>
<td>96,545,213</td>
<td>278,154</td>
<td>0.28%</td>
</tr>
<tr>
<td>10</td>
<td>Stopanska Banka Bitola</td>
<td>11,015,113</td>
<td>71,467</td>
<td>0.64%</td>
</tr>
</tbody>
</table>

Source: calculated from consolidated financial reports\textsuperscript{69}

There are several points that can be drawn from the table. Firstly, it is more than obvious that domestic companies invest more in tangible than intangible assets. Secondly, it is evident that in absolute numbers, almost half of the companies have recorded intangible assets that are even lower than the average Macedonian salary. Perhaps to some extent expected, Alkaloid and Telecom have the highest value of intangible assets. These are the only companies in which the percentage of intangible assets are reflected as more than 1% of the total assets – in Alkaloid the intangible assets are 12.6% of the total assets of the company, while in Telecom, 11.89%. These companies are the most internationalized because, in addition to the domestic markets, they are present in several foreign markets. Makedonski Telekom, as part of the Deutsche Telekom Group, is present in more than 30 countries, covering most of the significant markets throughout the world.\textsuperscript{70} The Alkaloid, through its nineteen subsidiaries, is present in the entire Balkan region, in some EU countries, as well as Russia and the US.\textsuperscript{71} In Makedonijaturist, the intangible assets have the lowest value, representing only 0.01% of the total asset value.

Although the statistics refer to values taken from accounting and financial statements, and intangible assets cover more than just trademarks, it is obvious that domestic companies are lagging not only in comparison with the most successful companies on a global scale but also with companies from the region. The main disadvantage is, of course, the fact that most of the domestic companies, no matter how powerful they are nationally, operate only on the domestic market, or at most at, the regional Balkan market. Globally, these are very small markets, and consequently, the funds allocated for brand promotion are minor. It remains to be seen in the future whether some of the domestic

\textsuperscript{66}International Accounting Standards (Official Gazette of Republic of North Macedonia No. 79/2010).


\textsuperscript{68}Ibid.

\textsuperscript{69}<www.mse.mk>.


companies will expand to other regional or global markets and whether that would lead to an increase of investments in intangible assets such as trademark and other IP assets.

6. CONCLUSIONS

Today, trademarks have significant value for companies’ worldwide success. In today’s globalized world, conquering new commercialization of trademark and IP rights, in general, opens new opportunities for companies as a source of revenue. A significant part of the strategy for the growth and development of successful companies focuses on the strengthening and promotion of the company’s brand and trademarks.

Today, there is an increasing trend of investment in intangible assets, and in certain markets, investment in intangible assets is greater than investment in tangible assets. Statistics show that the value of the brand of many of the world’s most successful companies represents between 20-40% of the company’s value. Unlike the rest of the world, Macedonian companies still devote insignificant resources in terms of intangible assets, traditionally relying on tangible assets such as production facilities, plants, equipment etc. Evidence for this is the fact that only in a small number of companies the value of intangible assets is more than 10% of the value of total assets of the company. This setup stems from the fact that many of these companies are established and operate mainly in the domestic market. As a recognizable domestic brand, most of the funds are directed to the production process to reduce costs and optimize production. Another reason for this might be that since these companies are embedded in the domestic market, they are not incentivized to reflect the true value of IP in their accounting and financial statements, or they lack interest and understanding of the strategic value of IP.

Those companies that are focused on conquering new markets, inevitably, must invest in promotion and strengthening of the brand, and consequently, investments in intangible assets would have to be significantly higher. In light of the EU integration process occurring within the country, it is recommended that domestic companies, and in particular successful companies already established on the domestic market, orient themselves to new markets and increase investments in intangible assets and IP rights, thus creating recognizable brands which will be able to compete on the internal market of EU.

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11. CREATIVELY DISRUPTING AND DIGITAL COPYRIGHT REGIME OF AN AFRICAN FILM INDUSTRY: NOLLYWOOD'S PRESENT CONTINUOUS PATH

Samuel Samiai Andrews*

ABSTRACT

This paper analyses how creativity and inventions during the digital era have influenced the Nigerian film industry. Although, the Nigerian copyright jurisprudence has not significantly adapted to digital interventions, the global nature of audio-visual-cinematographic business practices will quicken such adaptation. Nollywood represents the Nigerian film industry, which mostly consists of the audio-visual production systems. Nollywood is now the third largest film industry globally by production metrics. Digital era cinematic productions are changing the Nigerian film industry's creative structures in significant ways under a weak copyright enforcement regime. Digital technology has become part of Nollywood's strategic method of eradicating film piracy. Digital era interventions influenced the Nigerian film industry to adapt its distribution systems of creations after technology interrupted the former global intellectual property (IP) regulatory Order. In this instance, this old Order recognized only non-technological creative works. This new distribution system carries tremendous advantages beyond combating piracy, including overcoming the negative impact of a pandemic. This paper explores how the disruptions of digital technology, laws, local economic inequities, and film piracy created the enabling environment for Nollywood's emergence while setting it on an ingenious growth. It analyses the tension between digital technology's normative trends and copyright ownership regimes created by the Beijing Treaty on Audio-visual Performances (Beijing Treaty). It concludes with certain prescriptions towards a sustainable film industry.

Keywords: Nollywood, intellectual property, digital copyright, African films, creative disruption, fourth industrial revolution, artificial intelligence.

1. INTRODUCTION

The core legal regime for protecting the film and audio-visual industries are copyright and related neighbouring rights, for example, performers of live music, dances and broadcasting of creations within platforms that are not tangible.1 However, other intellectual property (IP) regimes like patent, trademark, and unfair competition laws still play significant legal protective roles in the audio-visual industries.2 The World Intellectual Property Organization (WIPO) led the charge in the late 1990s to reconceptualize global copyright regimes to recognize technological enhanced and supported creations.3 The changes in copyright laws by most developed economies encourage new businesses, which these new laws fundamentally support.4 For example, in the music industry, the iTunes business model from Apple Corporation was one of the early businesses that

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1 Okediji RG, ‘Copyright and Public Welfare in Global Perspective’ (1999) 7 Ind J Global Legal Stud 117, 118-19; The Copyright Act (Laws of the Federation of Nigeria) (2004), Cap 28, § 26 (describing neighbouring rights as performer’s rights, which include performing, recording, broadcasting live, dramatic performance, dance, mime, musical performance and reading/recitation of literary act as far as it is a live performance given by one or more individuals).

2 Ibid.


leveraged the new 1990s copyright regime.\textsuperscript{5} In the film and audio-visual industry, video on demand business enterprises represent the new model of consuming visual contents enhanced by digital technology and jurisprudence.\textsuperscript{6} Nollywood in its original and current format, as this paper will analyze later, is a direct outcome of the digital era enhanced productive capabilities.\textsuperscript{7} Copyright ownership is loosening due to new distribution channels powered by digital technology.\textsuperscript{8} Therefore, the digital era creative jurisprudence will impact its production ecosystem.

The contemporary digital legal regimes have further liberalized and democratized copyright ownership exclusivity.\textsuperscript{9} Copyright sustains international trade through regimes like the Trade-related Aspects of Intellectual Property Rights (TRIPS) and the World Trade Organization (WTO) guidance.\textsuperscript{10} Members of these Treaties have made efforts to comply with the unobstructed trade goals and multilateral engagements of these instruments.\textsuperscript{11} Nollywood’s creative ownership and performance rights’ regime has evolved from its checked history to present day technology-enhanced creations.\textsuperscript{12} Its growth continues with the body of astounding works available for public consumption.\textsuperscript{13}

Nollywood has grown to be Africa’s most successful film industry and the third largest, globally after Hollywood and Bollywood.\textsuperscript{14} By 2013, most economists considered Nollywood as a formal sector in Nigeria’s developmental growth.\textsuperscript{15} In 2014, Nollywood was a USD 5.1 billion industry and added more than 5% value to Nigeria’s GDP.\textsuperscript{16} At the turn of the 20th century, digital technologies enabled creative industries with humongous internal revenue and income generation capacity.\textsuperscript{17} Digital technologies changed the methods by which audio-visual content and creative works reached the public.\textsuperscript{18} Therefore, digital creations are disruptive technologies.\textsuperscript{19}

A disruptive technology is one that displaces an established creative orthodoxy and builds a new business method in an industry.\textsuperscript{20} Often, technological disruptions influence industrial legal regimes. The existing legal regime lags behind the trending technology, leaving the courts to perform gatekeeping functions of husbanding the new technologies.\textsuperscript{21} For example, in the United States (US), Sony Corp. of America v Universal City

\begin{itemize}
\item Haynes J, et al., ‘Evolving Popular Media’ in Nigerian Video Films (2000) 51 (Nollywood emerged from the new inventions of digital technology. At that time, VHS cassettes became the main source of contents production and distribution in the films or audio-visual industry. In its later years, Nollywood depends principally on digital streaming, an invention of the digital era to produce, distribute and even fight illegal use of its content-
\item Reidenberg (n 9).
\item Carroll (n 9).
\item Tushnet R, ‘Performance Anxiety: Copyright Embodied and Disembodied’ (2013) 60 Journal Copyright Society USA 209-248.
\item Ku (n 18).
\item Spar DL, Ruling Waves: From the Compass to The Internet, A History of Business and Politics Along the Technological Frontiers (2001) 15.
\item ibid.
\end{itemize}
Studies, Inc., illustrates how a new technology enabled the practice of ‘time shifting,’ which is recording of television shows for private viewing later. The video cassette recorder (VCR) created by Sony Corporation disrupted the ways in which movie studios distributed movies to its consumers. Movie studios in the lawsuit claimed that the VCR contributed to the infringement of their copyright by allowing unauthorized recording of the contents. The US Supreme Court held that ‘time shifting’ was a permissible fair use and that the VCR system was legal because the technology was capable of ‘substantial non-infringing uses.’ This US Supreme Court decision validated disruptive technology like VCR. It set a precedent for US courts, affirming that new technologies could balance the objectives of copyright with their utilitarian purposes. However, so far the Nigerian courts have not given guidance on the digital era IP jurisprudences in a fundamental way.

2. ARTICLE ROAD MAP

This article evolves in three Parts. Part one examines the historical factors that influenced the emergence of a new film ecosystem and Nollywood. It critically examines the intersections of culture and a new technology in the birth of the contemporary Nigerian film industry. Part two analyzes how the digital era laws like the Beijing Treaty have expanded the moral and economic rights of cinematic creatives, especially actors and performers, and its legal impact on Nollywood. Part three further explores the devolution of the new rights for creatives in Nollywood, especially ownership, authorship and the responsibilities of their collective societies. It concludes with the postscript of the legal landscape of Nollywood.

A. PART ONE: DIGITAL INTERVENTION AND THE EMERGENCE OF A NEW FILM INDUSTRY

The Birth of Nollywood

At the beginning of the 1990s, the Nigerian film creatives introduced a new genre of film production, which solely depended on audio-visual production systems. Other African countries copied the Nollywood genre and production system, which was more economically feasible than celluloid film production. The audio-visual mode of film production was popularized by a Nigerian filmmaker, Kenneth Nnebue, in the early 1990s. As opposed to the celluloid type films, it captured the yearning taste for cinematic entertainment and filled the gap that cinema theatres left open.

In the early 1990s, Kenneth Nnebue, Chris Obi Rapu and Okechukwu Ogunjiofor scripted, produced, and directed ‘Living in Bondage’, the film that began the Nollywood era in Nigeria. Kenneth Nnebue imported empty caches of video home system (VHS) tapes from Asia for purposes unrelated to filmmaking but creatively changed the purposes of the goods by recording Living in Bondage on them. He took advantage of the digital technology available at that time to primarily make an income during a period of dire national economic meltdown. He has stated that his primary reason for engaging in filmmaking was commercial. Apart from starting a new creative

23 Id 441-442.
24 Ibid.
31 Esonwanne (n 31) at 24.
32 Ibid at 26-27.
33 Ibid.
industry, Nnebue deliberately set the stage for Nigerian creatives to become artistic and literary entrepreneurs that would later change the income earning power of Nollywood actors.\(^{35}\) This singular innovation of Nnebue created a film genre peculiar to Sub-Saharan Africa.\(^{36}\) The history of Nollywood has been widely recorded in legal and non-legal literature.\(^{37}\) Therefore, this paper would not expand on the historical background of the industry.

The seamy side of the VCR devices, which is a typology of the digital era technology, was that it enabled easy duplication of audio-visual content leading to widespread film piracy.\(^ {38}\) The straight to video (STV) production system became the weak link in the Nollywood distribution chain because the digital versatile disc (DVD), videotapes, and VHS cassettes had no protection against illegal duplication. Nollywood lost around USD two million yearly during its early years to film piracy and artists earned less income for their creative works.\(^ {39}\) Film piracy became Nollywood’s Achilles’ heel because digital technology that enabled the rapid production of films by authentic filmmakers, had become the method of replicating illicit copies of Nollywood films.\(^ {40}\) The illicit film replication continues in large volumes and is unregulated.\(^ {41}\) A quarter century after the first Nollywood films emerged, the industry is now at a crossroad that requires enhanced copyright protection.\(^ {42}\)

The digital era technology has made the production of non-celluloid films less expensive.\(^ {43}\) For example, a STV content using a VHS, compact disc (CD), or DVD in Nollywood can take a period between one week to two months for less than a two-hour movie.\(^ {44}\) Film production on celluloid systems takes much longer and costs more to deliver compared to digitally produced movies.\(^ {45}\) Nollywood had no formal distribution system for its films, but resorted to street vendors and the existing market distribution hubs of Onitsha, Alaba, and Idumota markets.\(^ {46}\) These commercial centers were renowned markets for electronics and general merchandise.\(^ {47}\) Without regulation of the distribution of Nollywood films, it was easy for filmmakers and non-filmmakers to seize the opportunity and create an informal distribution network.\(^ {48}\)

**B. THE DEMOCRATIZATION OF A CREATIVE SPACE**

Digital technologies democratized the cinematic creative and productive space with its attendant changes to laws.\(^ {49}\) Filmmakers did not require big budgets or expensive sophisticated equipment to make movies anymore.\(^ {50}\) The pre-existing Nigerian film industry processes and practices followed the traditional studio formalized production systems.\(^ {51}\) Few filmmakers and

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\(^{35}\) Esonwanne (n 31).

\(^{36}\) Arewa [n 32].

\(^{37}\) Onuzulike; Arewa; Haynes; Olayiwola (n 33).


\(^{39}\) ibid.


\(^{41}\) ibid.


\(^{45}\) Olayiwolal (n 32).

\(^{46}\) Uzoatu (n 44) (Onitsha is in the eastern region of Nigerian and a popular trading center. Idumota and Alaba are popular market centers in Lagos in the western region of Nigeria. Idumota and Alaba market mostly serve Nigerians living in Lagos, the commercial nerve center of Nigeria and major cities in western Nigeria. Onitsha market caters for Nigerians living in the eastern and southern region. The marketers had inside knowledge of the consumption pattern for indigenous Nigerian cultural goods and maximized these traits for effective promotion of Nollywood movies. The established network of these marketers enhanced the outreach of Nollywood’s publicity among consumers. The early publicity by Onitsha, Idumota and Alaba marketers gave Nollywood’s genre the notoriety, which spurred its ascendancy as a global movie industry).


\(^{48}\) ibid.


film production entrepreneurs dominated the Nigerian film industry during the period after independence in 1960 until the early 1990s.\(^{52}\) Ola Balogun, Eddie Ugboroh, and Hubert Ogunde were the pioneer filmmakers in Nigeria during the celluloid era of filmmaking, immediately post Nigerian Independence.\(^{53}\) Ola Balogun produced the first Yoruba and Igbo speaking Nigerian film.\(^{54}\) The 1990s opened up the creative space for new works and creative entrepreneurs.\(^{55}\)

The Outer Reach

In the aftermath of diversifying Nigerian telecommunication systems, mobile phones and devices quickly became vital distribution channels for Nollywood films.\(^{56}\) In late 2011, private telecommunication service providers acquired the capacity to stream video films to Nigerians through mobile devices and wireless means.\(^{57}\) Digital technology introduced the system of streaming music and films which influenced the rise of the video-on-demand (VOD) business.\(^{58}\) At the same time, a new crop of Nollywood filmmakers revisited the celluloid format of making films with a big budget.\(^{59}\) Nollywood filmmakers revived the showing of films in cinema theatres, preceded with elaborate premiering events. The hybrid distribution and production systems of celluloid and digital formats coupled with the revival of film showings in multiplexes and cinema theatres makes up the ‘New Nollywood’.\(^{60}\)

The phrase ‘New Nollywood’ distinguishes the creative texture and business model of the Nigerian indigenous film industry that evolved in the early 1990s (the classic Nollywood) and the production systems that began in the latter half of 2000.\(^{61}\) In the COVID-19 pandemic era, Nollywood filmmakers were able to stay afloat during the restrictions associated with the pandemic by relying on income streams from the digital distribution of their content.\(^{62}\) Digital technology enhanced the home entertainment experience during the lockdown and other restrictions put in place to safeguard public health.\(^{63}\)

C. PART TWO: DISRUPTIVE AND CREATIVE JURISPRUDENCE

a) Nollywood and Digital Copyright

Legal scholars introduced the concept of ‘digital copyright’ at the beginning of this millennium to emphasize the recognition of the interface of digital technology and copyright laws in the protection of creative rights.\(^{64}\) The consequence of the Internet Treaties of the mid 1990s initiated by WIPO, was the

53 Ibid.
54 Id at 141 (Amadi the first Igbo language film was produced in 1975; It is a story of a man who could not cope with city life in Lagos. He had to move back to his village to restart his life. While in the village he used the skills learnt in the city to develop an agricultural entrepreneurial business).
56 Ryan (n 51).
57 Ibid.
59 Jedlowski (n 30) at 37-38 (In 2006, Jeta Amata, was one of the early Nigerian filmmakers to use digital era production systems and techniques with the movie Amazing Grace, which came with premiering style distribution and high budget film productions).
63 The Economist (n 63).
The Nigerian creative industries have experienced three phases of technological disruption that significantly influenced its mode of production. The first phase was the digital duplication of visual content, which created a movie industry entirely on VHS, CD-ROM, VCD, and later DVD.

Kenneth Nnebue’s ‘Living in Bondage’ film is a product of the first phase of technological disruption with his then novel idea of using empty VHS cassettes he imported from Japan for duplicating his film and marketing them in that format.

The second phase was the User Generated Content (UGC) phase where third parties either created original contents or derivatively created contents from pre-existing original works. Social media like YouTube distributes most of these UGC. The third phase of technology disruption is the practice of uploading and streaming Nollywood films on the Internet. For example, YouTube, IROKOtv, Netflix and other VOD platforms enable uploading of copyrighted video films. Most of the time, these social media platforms are channels for uploading unauthorized films. Such new distribution methods for Nollywood films implicate a creator's copyright and other IP rights.

Innovators on new platforms like the Internet and software-driven sites began to rely on new legal regimes to protect their creative content both online and offline. The Nigerian legal systems have not yet recognized regimes like licenses, torts and contracts. The Nigerian copyright law and policies, especially in the distribution...
of audio-visual content, lags behind technology.79 However, in 2015, the Nigerian Copyright Commission (NCC) began the process of amending its copyright laws to include the digital means of film production. The NCC proposed law covered creative rights associated with emerging new technologies.80 In the global IP space, WIPO and other international creatives are working to adapt cinematographic industries to effective legal and policy outcomes of the digital era.

b) The Beijing Treaty Regime and the Nigerian Film Industry

The Beijing Treaty grants a Nollywood actor the economic rights of reproduction, distribution, rent and making available her work.81 Nollywood actors invariably would have the right to authorize the fixation and communication of their performances on an audio-visual format and on the Internet.82 The Treaty grants contracting State parties the option of stipulating in their national laws that actors may exchange the right of authorization for equitable entitlements.83 The equitable entitlements are for the direct or indirect use of their works in audio-visual format made available to the public.84 The Beijing Treaty jurisprudence may democratize creative right ownership of performers and actors the same way digital era technologies did for cinematic productions.85 Contracting Parties may also stipulate in their national laws that once an actor consents to the audio-visual fixation of a performance, the exclusive rights of authorization transfers to the producer of the film.86 This right of transfer would not deny the actor any right to royalty or equitable remuneration in the performance.87 For Nollywood actors to enjoy the benefits of the equitable remuneration provision of the Beijing Treaty, Nigeria must domesticate it in its laws. Comparatively, the US’ protection of performances under the Beijing Treaty has raised questions about the legality of granting copyright protection to audio-visual performers.88 The Beijing Treaty has granted performers and actors codified moral and economic rights with a global scope.89 Some US legal scholars claim that the Beijing Treaty would introduce moral rights concepts into the US through a back door and affect the public domain exception for copyright works.90 These scholars have raised concerns about the broad ramification of the Beijing Treaty provisions as having a chilling effect on fair use of copyrighted works.91 They assert that performers

82 Beijing Treaty, Article 12(3) (‘independent of the transfer of exclusive rights described above, national laws or individual, collective or other agreements may provide the performer with the right to receive royalties or equitable remuneration for any use of the performance, as provided this Treaty including as regards Articles 10 and 11’); Beijing Treaty, Articles 7-11 (setting out exclusive rights of authorization for performers, exclusive rights of making available fixed performances and exclusive rights to establish remuneration for secondary uses of fixed audio-visual performances); WIPO, ‘The Beijing Treaty’ <https://www.wipo.int/beijing_treaty/en/> accessed 18 April 2021 (emphasizing the economic and moral rights of performers like actors in the digital era).
83 Beijing Treaty, Article 12 (‘1) A Contracting Party may provide in its national law that once a performer has consented to fixation of his or her performance in an audio-visual fixation, the exclusive rights of authorization provided for in Articles 7 to 11 of this Treaty shall be owned or exercised by or transferred to the producer of such audio-visual fixation subject to any contract to the contrary between the performer and the producer of the audio-visual fixation as determined by the national law.’); Copyright Act (Laws of the Federation of Nigeria) (2004), Cap. 28 § 10(4) (‘in the case of a cinematograph film or sound recording the author shall be obliged to conclude, prior to making of the work, contracts in writing with all those whose works are to be used in the making of the work’).
84 Beijing Treaty (n 83 and 84).
85 ibid.
86 ibid.
87 ibid.
89 WIPO (n 82).
90 Travis (n 89) at 61-67.
91 Rossini (n 89).
may abuse the exclusive powers granted by the Treaty to prevent others from benefiting from their works even when its use is within fair use.\textsuperscript{92} However, this paper avers that Member States may use the legal exceptions of fair use or fair dealing within its national legislations to check a performer’s overbearing use of her exclusive rights (performer’s rights abuse).\textsuperscript{93} For example, in Nigeria the proposed Copyright Amendment Bill has certain exceptions or exemption provisions that may allay the fears of industry stakeholders on performer’s rights abuse.\textsuperscript{94}

c) Amending the Laws Regulating Nollywood

The digital era cinematic production systems have significantly shifted copyright ownership and authorship holdings from its nuclear control to a diverse holding system.\textsuperscript{95} In response to the changing legal regimes of the 21\textsuperscript{st} century digital era, the NCC completed the Nigerian Copyright Act amendment project in 2015.\textsuperscript{96} The NCC submitted the proposed law to the Federal Government of Nigeria for further legislative and executive processes needed to give Nigeria a new copyright law that fulfills the exigencies of the digital era productive methods.\textsuperscript{97} Unfortunately, the process of amending the Nigerian copyright law is suffering delay, without official reasons from the Nigerian regulatory authorities.

d) Defining Nollywood Actor’s Copyright

The current Nigerian Copyright Law and the proposed amendment does not explicitly define a movie actor’s copyright. However, the current Copyright Law and the proposed amendments have given direction on the scope of Nollywood filmmakers’ and actors’ copyright.\textsuperscript{98} Films, including audio-visual works like Nollywood creations are literary works.\textsuperscript{99} The current Nigerian Copyright Law assigns screenplay and the screenwriter with protection because this category of creation belongs to the traditional class of authors.\textsuperscript{100} The director of a film generally derives copyright protection from their artistry and creative application of skills.\textsuperscript{101} These directing skills and their application in the filmmaking process should be original.\textsuperscript{102} For example, originality may emerge from how a film director manoeuvres the angle of a camera and applies lighting techniques in making a movie, which would attract copyright protection.\textsuperscript{103} However, for producers of Nollywood films, copyright arises mostly from industry traditions, contractual arrangement and the existing Copyright Law.\textsuperscript{104}

\textsuperscript{92}Travis (n 89) at 80–81.


\textsuperscript{94}The Copyright Act (Laws of the Federation of Nigeria) (2004), Cap. 28, §§ 6, 7, and 8, Second Schedule (Repeal & Re-enactment) Bill (2021) (SB. 688). This Law is sponsored by Senator Tokunbo Abiru. It finally got its first Reading on 4 May 2021 and has now gone through the second legislative reading.


\textsuperscript{97}Ibid.

\textsuperscript{98}Draft Copyright Bill (2015) § 55(2) (Nigeria) (stating, ‘In this part, – performers – includes actors, singers, musicians, dancers, and other persons who act, sing, deliver, declaim, play in, interpret, or otherwise perform literary or artistic works or expressions of folklore irrespective of whether the work was fixed or only fixed during performance’); The Copyright Act (Laws of the Federation of Nigeria) (LFN) (2004), Cap. 28 § 10(4) (‘in the case of a cinematograph film or sound recording the author shall be obliged to conclude, prior to making of the work, contracts in writing with all those whose works are to be used in the making of the work’); (meaning that the author, the one who makes, financial, logistic and fundamental investments and arrangements for the making of the film is mandatorily required to enter a written contract with all those whose works, including performances, are to be used in the making of the film); The Copyright Act (LFN) (2004), §§ 26-28 (Nigeria).


\textsuperscript{102}Hughes (n 101); Dougherty (n 102).

\textsuperscript{103}Dougherty (n 102).

\textsuperscript{104}The Copyright Act (LFN) (2004), Cap. 28 § 10(1) (copyright conferred by sections 2 and 3 of this Act, shall vest initially in the author), § 51(f) (‘author’ in the case of cinematograph film, means the person by whom the arrangement for making of the film were made, unless the parties to the making of the film provide otherwise by contract between
e) Copyright Owner or Author? Which is which in Nollywood?

The current Nigerian Copyright Law joins other common law jurisdictions like the US and Canada in emphasizing a single author as one creative genius and the central pillar of creativity. An author in the Nollywood industry would be ‘...the person by whom the arrangements for making of the film were made...’ The ‘making-arrangement’ definition seems suited for the corporate or deep pocket financiers of cinematographic works. Unfortunately, the definition of a film author under the current law is not helpful and inclusive of the audio-visual collaborative process. The first two sections of the law indicate the preference for an author as the foundation of creativity. These two sections use the word ‘author’ to refer to creators of copyright works. However, it grants ownership of copyright during assignment and licensing to the assignee or licensee. If the Nigerian law had intended a copyright author and owner to have the same meaning, the law should have expressly stipulated the need to seek license or authorization from the author of a film, as it had done all along in cases of written contracts. The Nigerian Copyright Law perhaps intended a copyright author and owner to possess the capacity of exercising non-exclusive rights despite its clear provisions in Section 6. The convoluted scenario of copyright authorship and ownership regime seems a case of poor legislative drafting which the impending amendment has attempted to cure.

f) Copyright Author and Owner under the Impending Nigerian Copyright Law

Section 24 of the Draft Copyright Bill (2015) vests copyright ownership initially in an author. The use of the word ‘initially’ connotes the transferable nature of copyright ownership. The drafting language of the Draft Copyright Bill uses the words ‘copyright owner’ and ‘author’ interchangeability. However, the same law has shown that one must first become a copyright author before ownership of the same. The Draft Copyright Bill has shown that you can be a copyright owner but not an author. The signalling phrase showing this distinction in the impending law states that:

[...] an author or other owner." The proposed amendment to the copyright law further attempts to differentiate the incidents of ownership, stating that owning a material that embodies a copyrighted work does not transfer or assign such copyright, nor does owning a copyright that is embedded in a material, confer ownership of the material.
D. PART THREE: THE FORMAL NOLLYWOOD

In a filmmaking project, traditionally, creativity spreads across various stages of film production.121 Proprietary creation begins from the conceptualization of the film story to the screenplay stage of filmmaking and continues to the editing of the finished shoot.122 The allocation of the Nigerian copyright focuses on rewarding the source of funding a film project.123 Establishing Nollywood formal internal norms and culture could set standards for efficient creative practices.

a) Creating Nollywood Norms

i) Effectuating Institutions

Creating institutions in the Nollywood industry through idea-submissions, recognition of electronic contracts and metrics systems may reduce creative and legal

copyright or to have granted a license for the exploitation of the work, unless otherwise provided by a written agreement. (9) …unless otherwise provided by agreement, an author or other owner of the copyright who has transferred his copyright or granted a license for the exploitation of a work shall not be deemed to have transferred the right of ownership in the material object in which the work is embodied”.

121 Raustiala, Sprigman (n 9).

122 ibid.

123 The Copyright Act (n 105) § 51(f).


125 Gong Jj, Young SM, ‘Financial and Nonfinancial Performance Measures for managing Revenue Streams of Intellectual Property Products: The Case of Motion Pictures’ (2016) <https://srm.com/abstract/3459849> accessed 4 May 2021 (exploring an empirical study on product life cycle revenue management using IP products as case study on the significant role financial and non-financial performance measures play in managing and keeping revenue and metrics derived from the film and audio-visual content industry); Edde H, ‘FG Partners French Development Agency to Grow Economy through Copyright Protection’ (BusinessDay, 26 November 2020) <https://businessdayng/news/article/fg-partners-french-development-agency-to-grow-economy-through-copyright-protection/> accessed 22 February 2022 (reporting on the survey and report conducted by Price Waterhouse Cooper (PwC) and KPMG consultants for Agence Française de Développement (AFD), where old data that were already in public domain was cited as current metrics on the state of the growth of Nigeria’s Creative Cultural Industries); This author avers that Nigeria lacks ascertainable and reliable data to scale its creative industrial output.


In the Nigerian music industry, a CMO called the Musical Copyright Society of Nigeria (MCSN) has led the charge in aggregating creative data, controlling its member’s creative rights and royalties online. The MCSN’s GoCreate Apps for monitoring the distribution and publication to the public of musical works of its members within Nigeria indicates its adaptability to digital era tools. Perhaps, this technology will also create data for the music industry’s planning and production purposes. The Chairman of the Audio-visual Rights Society of Nigeria (AVRSN), the only recognized CMO for the Nigerian film industry, lamented recently in a presentation that the industry has limited capacity to capture royalties from the digital platforms. The AVRSN should tap into the digital era technological advantages, which is long overdue for an industry that is more than two decades old. The ubiquitous nature of downstream uses of streamed cinematic contents especially within cyberspace and other remote places make relying entirely on human monitoring an impossible task. Therefore, digital management assets eases royalty management and license enforcement.

Digital era copyright regimes like Technical Protection Measures (TPM), Rights Management Information (RMI), and Copyright Management Information (CMI) which looks like the equivalent of the Nigerian RMI, would be available to Nollywood if the Copyright Bill of 2015 becomes law. The current Nigerian Copyright Law has no provisions for digital copyright legal issues except the recognition of computer programs as literary works. Computer software and programs form the foundation of the digital era creations in the film and the entertainment industry at large. The Draft Copyright Bill recognizes the significance of the intersection of digital technology and copyright management. Some of the legally acceptable technical protection measures in the digital content spaces are geolocks, checkers (by Google) and passwords as keys for access to content. These TPMs are software or programs, which copyright protects as long as they ‘... prevents, restricts, or otherwise limits access to the work.

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132 Draft Copyright Bill (2015), §§ 44-54 (Nigeria) (stating as used in this section – RMI means information which identifies the work, the author of the work, the owner of any right in the work, or information about the terms and conditions of use of the work, and any numbers or codes that represent such information, when any of these items of information is attached to a copy of a work or appears in connection with the communication of a work to the public).
133 17 USC § 1202 (US) (stating that ‘No person shall knowingly and with the intent to induce, enable, facilitate, or conceal infringement’ and defining CMI as used in this section, to mean any of the following information conveyed in connection with copies or phonorecords of a work or performances or displays of a work, including in digital form, except that such term does not include any personally identifying information about a user of a work or of a copy, phonorecord, performance, or display of a work; The title and other information identifying the work, including the information set forth on a notice of copyright; The name of, and other identifying information about, the author of a work; The name of, and other identifying information about, the copyright owner of the work, including the information set forth in a notice of copyright; With the exception of public performances of works by radio and television broadcast stations, the name of, and other identifying information about, a performer whose performance is fixed in a work other than an audio-visual work; With the exception of public performances of works by radio and television broadcast stations, in the case of an audio-visual work, the name of, and other identifying information about, a writer, performer, or director who is credited in the audio-visual work; Terms and conditions for use of the work; Identifying numbers or symbols referring to such information or links to such information; Such other information as the Register of Copyright may prescribe by regulation, except that the Register of Copyright may not require the provision of any information concerning the user of a copyrighted work).
134 Microsoft Corporation v Franke Associate Limited (2012) 3 NWLR (Pt. 1287) 301 (Nigeria); Copyright Act (LFN) (2004), Cap. 28 §§ 11(1)(a); 51(1)(f).
136 Draft Copyright Bill (2015), §§ 44-54 (Nigeria) (highlighting the digital copyright provisions, which stipulates how technological measures and law regulates creativity).
iii) Moderating Copyright with Takedowns and Putbacks

In the Draft Copyright Bill, one of the vital tools now available to the Nollywood copyright owner is the ability to moderate the online performance and display of her films. The law regulates the Takedown of unauthorized films on any digital platform. The Nollywood copyright owner could demand the takedown of a film online. However, the fair use or fair dealing defence under the Draft Copyright Bill triggers a ‘Putback’ of any film taken down. The NCC on its own could cause the takedown of offending or infringing films on a digital platform. Worrisome is the NCC’s unilateral power to block an online user accused of uploading infringing content access to an Internet site without due process. This unchecked power of the NCC ought to be subjected to judicial review before becoming effective. The Putback provisions moderates the excesses that may occur on the part of copyright owners in their attempt to abuse their rights. This paper recommends the application of the fair use doctrine in adjudicating takedown notices before the Nigerian courts and the NCC. The impending law frowns consequentially at online copyright infringement as shown in the severe penalty applied to repeat offenders whose suspension from Internet activities is ‘[...] at least one month.’

iv) Standardizing Idea-Submissions

Legal literature has inundated the IP field with the theory that copyright does not protect ideas but expressions of ideas. In Nollywood like most cinematographic industries, films start with someone conceiving an idea of a story for interpretative performance on the big screen or digital platform, an idea purveyor. The owner of this idea either puts it down in the form of a screenplay or conveys this idea to an established professional. IP scholars refer to this phase of film creation as the ‘idea-submission’ phase. Copyright seems the improper regime to protect an idea-purveyor. However, like in the US, contract law looks like the proper regime to resolve disputes arising from these transactions. Some screenwriters may not be the owners of the idea of the film which becomes a screenplay. The idea-submission process often creates litigation, especially where business culture and norms are non-existent. In Nigeria, copyright does not pre-empt contract law even where creative regimes are operational. The federal...
The Draft Copyright Bill has recognized the concept of implied contract in resolving copyright ownership issues.\textsuperscript{158} Although the Nigerian Copyright Law recognizes the contractual intent of parties generally in assigning and licensing copyright cases, the court should adopt the general doctrine of contract formation in resolving idea-submission disputes when it arises in Nollywood.\textsuperscript{159} The central issues should be the breach of contract or breach of implied contract of passing off a film idea.\textsuperscript{160} Additionally, trade secrets, non-disclosure agreements (NDA), and unfair competition laws are regimes that Nollywood could deploy especially at the conceptual stages of literary and artistic works.

Apart from the adverse publicity created by a pre- and post-production litigious tensions for the Nollywood investment environment, it could inflate the cost of film production.\textsuperscript{161} In addition to the high cost of hiring professionals to conduct due diligence of creative authorships in a film, aspiring collaborators may demand oppressive financial indemnities and copyright clearance schemes before taking on creative projects from budding Nigerian film creatives. Most budding Nollywood filmmakers lack the knowledge of digital era jurisprudence. On the other hand, the wealthy film producers or investors have the advantages of retaining professional advisors who will most often give them a head-start in pre-production negotiations. For example, Netflix would have access to the best lawyers, business analysts and advisors because they can pay for their services during license-contract negotiations. This paper does not conclude that an efficient idea-submission system in Nollywood will eradicate copyright infringement disputes and lawsuits. However, having a standardized and robust creative system at this developmental stage would establish certain levels of business certainty. Certainty in business norms commands investors’ confidence, especially those seeking good returns on their investment rather than engaging in distractions like lawsuits.\textsuperscript{162} Therefore, an industry promoted idea-submission system will set norms that will guide all parties.

b) Nigerian Film Industry Online Piracy Issues

We have earlier discussed in Part two how New Nollywood distribution systems, which includes streaming and uploading of contents by VODs or independent filmmakers on the Internet, fundamentally changed the Nigerian movie consumption experience. Technological advancement particularly in this millennium has created an intriguing online film piracy problem.\textsuperscript{163} Existing Nigerian Copyright Law is incapable of redressing the evolving online film piracy systems.\textsuperscript{164} Nollywood already had an acute film piracy problem before the advent of streaming technology.\textsuperscript{165} The borderless nature of cyberspace and increased anonymity for rapid illicit distribution of audiovisual contents confounded creative right enforcement.
The current Nigerian Copyright Law stipulates the use of traditional remedies to restrain film pirates, which includes classic forms of injunctions like Mareva, Anton pillar, interim, perpetual and ex parte injunctions. Unfortunately, these forms of reliefs fail to cater to the fast pace of content infringements on platforms with streaming capacities. The copyright owner would have suffered irreparable damages beyond restoration for injury in situations that a film pirate streamed her content illegally. The multiplier nature of digital contents and the economic advantages that arise immediately from their consumption means that the actual copyright owner would lose humongous financial returns in the work. To redress this problem, in France, sport broadcast copyright owners use a special injunction known as ‘dynamic injunction’ to block the streaming of illegal sports broadcasts in real time. Dynamic injunction is platform specific injunction that stops the broadcasting of sport activities on the motion of the copyright owner without recourse to traditional eligibility rule of ex parte injunctions.

The French law recently recognized the innovative nature of streaming technology and grants a copyright owner this unique relief adapted to the digital nature of the infringement. Nollywood stakeholders should advocate for amending injunctive reliefs to suit exigencies of the online digital infringement. Nigeria currently has a robust application of criminal law to enforce copyright infringement. It may have to reinvigorate its criminal legal capacities to fight online piracy and prohibit illicit digital transmission of Nollywood copyrighted contents. Even the US Congress recently amended its copyright laws to enhance the prohibition of illicit digital transmission of copyrighted works with enhanced criminal prosecution.


168 ibid.

169 ibid.

170 ibid.


172 ibid.

173 The Copyright Act (2004), Cap. 28, § 38(1) (creating copyright inspectors with similar powers like the Nigerian Police of criminal seizure of illicit copyrighted goods and entering of a place to conduct search and seizures); the following cases are few of the criminal law enforcement action for copyright infringement by the Nigerian Regulatory authority, Nigerian Copyright Commission v. Bassey & Ors FHC/CA/31C/2003 (protecting broadcasting rights by convicting a pirate broadcast organization infringing on copyright broadcasting rights of the Broadcasting industry); Musical Copyright Society of Nigeria v. Nigerian Copyright Commission (FHC/L/C/786/2010); Compact Disc Technologies V. Nigeria Copyright Commission (CA/L/L/____/2010); Anazia D, ‘Appeal Court Favors MCSN’s Right to Sue for Infringement of Works’ (The Guardian (Nigeria), July 2015) <http://guardian.ng/saturday-magazine/appeal-court-favours-mcsns-right-to-sue-for-infringement-of-works/> accessed 30 April 2021 (reporting that MCSN on behalf of its members sued a copyright infringer, and as at 2015, the NCC has commenced more than 150 criminal cases against accused copyright infringers).

174 18 USC § 2319 C (4) ‘(4) the term ‘work being prepared for commercial public performance’ means – (A) a computer program, a musical work, a motion picture or other audio-visual work, or a sound recording, if, at the time of unauthorized public performance – (i) the copyright owner has a reasonable expectation of commercial public performance; and (ii) the copies or phonorecords of the work have not been commercially publicly performed in the US by or with the authorization of the copyright owner; (B) a motion picture, if, at the time of 10 unauthorized public performance, the motion picture—(i) (I) has been made available for viewing in a motion picture exhibition facility; and (ii) has not been made available in copies for sale to the general public in the US by or with the authorization of the copyright owner in a format intended to permit
3. CONCLUSIONS

Nollywood is an industry that emerged as an economic reality but has metamorphosed into a global creative and impactful presence. Digital technology disrupted the methods and means of filmmaking particularly its distribution and quick turnaround processes in production. This disruption has national and international significance because copyright subject matter is highly transnational. The creative industries like film, music traditional culture, audio-visual content creations and performances have adapted to the ecosystem evolving from the intervention of the digital era. Nigeria is in the process of updating its Copyright Law to recognize the emerging digital copyright and innovative legal rights. Although the Nigerian political legislative processes seem lethargic and lags behind, the NCC continues to spur the Nigerian creative stakeholders to keep the process afloat. In amending its laws, Nigeria has proposed to recognize new copyright regimes particularly in the neighbouring rights sector of performer’s rights. There seems to be a possibility of the economic benefits of copyright may cater for actors in the film industry, unlike the current tradition where a single corporate executive producer or producer holds copyright to a film and most of the economic benefits inuring to a film project.

The disruptive nature of digital technology impacts the conceptualization of copyright regimes. In Nigeria, the impending law should clarify and simplify the concepts of copyright originality, ownership, and authorship. The law should clarify or discontinue the introduction of copyright registrations as evidence of authorship and ownership. The NCC is spearheading the introduction of copyright registration regime into Nigeria, which may muddy the judicial and practical enforcement of creativity.

The transformation of Nollywood from a pedestrian low budget industry to its status of global recognition involved creative and legal evolution powered by digital technology. Currently, Nigeria lacks laws that recognize the creative disruptive capacities of technology, digital copyright, contract and other regimes for protection of the film industry creativity. Nollywood stakeholders like the CMOs and film producers should rethink the current unfair revenue sharing arrangement through transactional dialogue. I have suggested elsewhere that Nollywood stakeholders must have a better understanding of the digital era transactional regimes especially as it concerns copyrighted contents online. A formalized creative environment for Nollywood with institutions capable of implementing best business practices will spur a sustainable growth path.

The Beijing Treaty makes a performer’s (Nollywood actors’) right a personal right that is inseparable from the performer. The international recognition of audio-visual performance right supports Nollywood’s growth objectives. It will translate in practical terms to increase revenue for the Nigerian film industry. Beijing Treaty has created personal economic rights for Nollywood actors and creatives. Nollywood perhaps will continue to produce more socially and economically upward mobile Nigerians. Socially, a new class of Nigerians, whose talents can be monetized and now gainfully employed with reward of authorial rights for creativity will join the upwardly mobile economic cadre of society. Digital era creative disruptions birthed Nollywood and most likely more genres will evolve from it in the entertainment industry.


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17 United States Code §§ 512, 1201, 1202

12. FOUNDATIONS THAT JUSTIFY THE USE OF DISTINCTIVE SIGNS TO GENERATE CONFIDENCE AND TRANSPARENCY IN ELECTRONIC CONTRACTING IN THE CONTEXT OF THE COVID-19 PANDEMIC IN PERU

Fernando Augusto Chávez Rosero*

ABSTRACT

This paper aims to identify the foundations that justify the use of distinctive signs (certification marks) to generate confidence and transparency in the electronic contracting in the context of the Coronavirus (COVID-19) pandemic, specifically in Peru. In this regard, this paper reflects on the importance of legal certainty in contracts and the trust that electronic contractual systems should generate, in such a way that they provide sufficient efficiency under reduced transaction costs in matters of contractual predictability. Therefore, it is urgent that distinctive signs enter the scene to promote efficient and safe economic transactions so the expectations of consumers and suppliers in the market are satisfied. Well, the distinctive signs (certification marks) granted by a certification entity authorized by the National Institute for the Defense of Competition and Intellectual Property (INDECOPI) in Peru, will allow us to identify the supplier that will comply with the terms and conditions agreed in the contract and with it the confidence and security necessary in the framework of electronic contracting.

Keywords: distinctive signs, electronic procurement, legal security, procurement efficiency, contractual balance, national, and international public policies.

1. INTRODUCTION

Currently, lack of trust is a problem in electronic contracts in Peru. This in relation to the different stages of electronic contracting. For example, aspects related to the suitability of the product received by the final consumer and compliance with the terms and conditions during the execution of the contract.

For this reason, it is important, given the adverse circumstances created by the pandemic, which has replaced face-to-face contracts with electronic contracts, which has limited, for example, contact between the parties for direct negotiation of the terms and conditions of the contract, to promote security and transparency in electronic contracting.

Faced with this reality, we can ask ourselves: What are the fundamentals that justify the use of distinctive signs to generate trust and transparency in electronic contracting in the context of the COVID-19 pandemic in Peru? Do we have the regulatory framework and the institutions that promote intellectual rights in Peru? How is ecommerce carried out in Peru and how has it spread? How can we promote legal certainty, efficiency and contractual balance in electronic contracting? How could signs contribute to generating security and reliability in achieved? Through a private insurance system that will allow the provider to respond to the consumer in case of non-compliance with the agreed terms and conditions and because it is essential to insure the consumer against a possible non-conformity of the product or service provided by the supplier in the market.

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Fernando Augusto Chávez Rosero, Foundations that Justify the Use of Distinctive Signs to Generate Confidence and Transparency in Electronic Contracting in the Context of the COVID-19 Pandemic in Peru

Electronic contracting in Peru? And in the international context, what is the role of Member States of the World Trade Organization (WTO) and World Intellectual Property Organization (WIPO) to promote secure and reliable electronic contracting?

Answering these questions is necessary and essential in order to justify the use of distinctive signs to generate trust and transparency in electronic contracting in the context of the COVID-19 pandemic in Peru, since distinctive signs will allow us to identify economic agents in the market.

In this way, we will provide electronic contracting with legal security mechanisms that mitigate the impact of mistrust generated by the use of information and communication technologies (ICT) and overcome clearly evident legal security problems. In this direction, the use of distinctive signs that allow us to identify economic agents in the market is certainly essential.

Finally, we believe that in this effort both the WTO and WIPO should play a very important role in promoting through the Member States the use of distinctive signs that allow us to contract safely and efficiently.

2. FOUNDATIONS THAT JUSTIFY THE USE OF DISTINCTIVE SIGNS TO GENERATE CONFIDENCE AND TRANSPARENCY IN ELECTRONIC CONTRACTING IN THE CONTEXT OF THE COVID-19 PANDEMIC IN PERÚ

A. LEGAL PROTECTION OF DISTINCTIVE SIGNS AND THE CONSUMER IN THE 1993 PERUVIAN POLITICAL CONSTITUTION AND SPECIAL LAWS

The Political Constitution of Peru, 1993 (Peruvian Constitution), has established in Sub-section 8 of Article 2 that the State defends intellectual property (IP) rights by establishing that everyone has the right to ‘freedom of intellectual, artistic, technical and scientific creation, as well as to ownership of such creations and to any benefits derived from them. The State fosters access to culture and encourages its development and dissemination’.

In this order, Legislative Decree 1075\(^1\) Which Approves Supplementary Provisions of Legislative Decree 486 of the Commission of the Andean Community that Establishes the Common Regime on Industrial Property (Legislative Decree 1075) regulates the aspects related to the legal protection of the distinctive signs and refers to specific procedures as provided in the Single Text of Administrative Procedures of the National Institute for the Defense of Competition and Protection of Intellectual Property (INDECOPI).\(^2\)

Thus, if we consider Article 80 – Certification Mark: ‘Without prejudice to Article 185 of Decision 486, a certification mark may consist of any element identifying the product to which it applies as originating in a particular geographical place, where a given quality, reputation, or other characteristics of the product is essentially attributable to its geographical origin’. Here is the possibility of using certification marks in electronic contracting.

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Likewise, it has been established in Article 65 of the Peruvian Constitution that the legal protection of consumers and users constitutes the cornerstone on which the Peruvian consumer protection system has been built. This normative provision has institutionalized this defense and provides that the State protect the rights of consumers and users and guarantee the right to information goods and services available to them on the market and security.

One of the manifestations and materialization of the said protection is found in special legislations. In this particular case, reference is made to the Consumer Protection and Defense Code (CPDC) contained in Law 29571⁴ which includes as one of the fundamental rights, the right to information (specifically in Articles 2 and 5).

It should also be noted that another of the pillars on which the consumer protection system in Peru is based is the legal protection of expectations, which is often linked to the duty of suitability of suppliers in relation to consumers. This protection is contained in Articles 18 and 19 of the CPDC⁵.

B. INSTITUTIONS THAT PROTECT DISTINCTIVE SIGNS AND CONSUMERS IN PERU

From its institution to date, INDECOPI has served as the decisive actor in consumer protection in Peru. As stated in Article 1 of the Legislative Decree 1033 that Approves the Law of Organization and Functions of the National Institute for the Defense of Competition and the Protection of Intellectual Property (Legislative Decree 1033), INDECOPI ‘is a specialized public body with legal status under internal public law, which enjoys functional, technical, economic, budgetary, and administrative autonomy. It is attached to the Presidency of the Council of Ministers and governs its operation in accordance with the provisions contained in this Law and its complementary and regulatory norms’.⁶

We are, therefore, before an administrative body, which is functionally attached to the Presidency of the Council of Ministers in the field of the Executive Power of the Peruvian public administration.

In line with this, by virtue of the provisions of Subsection d) of Section 2.1 of Article 2 of Legislative Decree 1033, its function is ‘to protect the rights of consumers, ensuring that the information in the markets is correct, ensuring the suitability of goods and services based on the information provided and avoiding discrimination in consumer relationships.’⁷

Likewise, it has been specified in Section 2.2. of Article 2 of Legislative Decree 1033 that ‘For the fulfillment of its functions, INDECOPI is empowered to issue directives with general effects, supervise and supervise economic activities, impose sanctions, order preventive and precautionary measures, issue mandates and corrective measures, resolve controversies, as well as the other powers provided for in this Law’.⁸

Within the framework of the Legislative Decree 1033, INDECOPI is organized and structured mainly at the level of administrative decision-making bodies through Directorates, Commissions, and Chambers, with Technical Secretaries attached to each of them. This organization is outlined in accordance with the provisions stated earlier as well as the Supreme Decree 099-2017-PCM that modifies the Regulation of Organization and Functions of the National Institute for the Defense of Competition and the Protection of Intellectual Property – INDECOPI in which it describes its organizational structure.⁹

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⁵ ibid.
⁷ ibid.
Thus, depending on its organizational structure and the provisions of Article 2 of Legislative Decree 1033, INDECOPI has the following functions:

1) Monitor free private initiative and freedom of business through subsequent control and elimination of illegal and irrational bureaucratic barriers that affect citizens and companies, as well as ensuring compliance with the rules and principles of administrative simplification;

2) Defend free and fair competition, sanctioning anti-competitive and unfair behavior, preventing the anti-competitive effects of business concentration operations and ensuring that there is effective competition in the markets;\(^1\)

3) Correct distortions in the market caused by the damage derived from dumping practices and subsidies;

4) Protect the rights of consumers, ensuring that the information in the markets is correct, ensuring the suitability of goods and services based on the information provided and avoiding discrimination in consumer relations;

5) Monitor the process of facilitation of foreign trade through the elimination of non-tariff trade barriers in accordance with the legislation on the matter;

6) Protect credit by conducting a bankruptcy system that reduces transaction costs and promotes the efficient allocation of resources;

7) Establish standardization, accreditation and metrology policies\(^1\);

8) Manage the system of granting and protection of IP rights in all its manifestations, in administrative headquarters, in accordance with the provisions of this Law; and,

9) Guarantee other rights and guiding principles whose supervision is assigned, in accordance with current legislation.\(^1\)

In this way, INDECOPI legally protects free private initiative and freedom of business. It also promotes free competition in the internal and external market through the facilitation of international trade to national economic agents, the legal protection of consumers, protection of creditors’ credit, as well as IP rights.

C. ELECTRONIC PROCUREMENT

In the economic growth in Peru and the new forms of contracting products and services, electronic contracts have become vitally important. In this sense, Mr. Cáceda, President of the Chamber of Electronic Commerce (CAPECE), explains, ‘Ecommerce in Peru in 2019 registered a growth of 30%, one of the highest rates in the region. However, we still rank sixth in Latin America in terms of ecommerce volume’. Additionally, he explains, ‘e-commerce already exceeded the USD 4,000 million at the end of 2019, 30% more than last year’.\(^1\)

Similarly, Mr. Blacksip explained the annual growth rates by saying:

[...] the fact that Peru has good annual growth rates is mainly due to the fact that the value of categories in Internet retailing, such as consumer electronics (technology), multimedia products, and clothing and footwear, the three largest in

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\(^{1}\) Literal b) was modified by the Sole Supplementary Modifying Provision of Emergency Decree No. 013-2019, published on 19 November 2019 which will enter into force within a period of nine months, counted from the day after its publication, and will remain in force for a period of five years. Subsequently, the aforementioned validity was modified by Article 2 of Legislative Decree No. 1510, published on 11 May 2020, entering into force on 1 March 2021, and remains in force for a period of five years, the text of which is provided in the next paragraph.

\(^{10}\) The Sub-section was repealed by Sub-section 4 of the Sole Repeal Complementary Provision of Law No. 30224, published on 11 July 2014, effective after the end of the period of 270 calendar days of the validity of cited Law.
the nation, they have made the annual value go from 611.6 million soles to 2,339 million in less than seven years, between 2013 and 2019, this being just the beginning.\textsuperscript{14}

In this way, statistics show a very favorable outlook for electronic contracts. According to the Official Report of the Electronic Commerce Industry in Peru. Impact of COVID-19 on ecommerce in Peru and prospects for 2021, the figures of ecommerce 2020, are:

(i) Penetration of ecommerce in consumption through cards, from 12.5% in January 2020, it increased to 45% in July 2020; total at the end of 2020 of 35%;
(ii) Ecommerce growth (YTY), from 43% in January 2020, increased to 160% in July 2020; total at the end of 2020 of 50%;
(iii) Online shoppers, from six million in January 2020, increased to 8.9 million in July 2020; total at the end of 2020 of 11.8 million. [...] ;
(iv) Penetration of ecommerce over total commerce, from 1.5% in January 2020, increased to 3.5% in July 2020; total at the end of 2020 of 5%.\textsuperscript{15}

The same panorama is evident in investments. According to Pacheco, ‘[Thanks to digitization], more and more Peruvians are opting for digital channels to acquire and market different goods and services’.\textsuperscript{16} This has been explained in a news article as follows:

As Peruvians become familiar with digital channels and a more varied offer, they also adopt certain attitudes. For IPSOS Peru, the connection reaches 41% of the national urban population (72% in Lima), which is equivalent to 13 million inhabitants who connect to the internet at least six times a week, and cell phone use has also increased to unthinkable levels due to wide post-paid offers from various local telephone companies which allows brand campaigns and strategies to reach the consumer more directly. Cell phones allow the user to be always active. In this way, we can affirm that as in Peru, Latin America is in the midst of a fast-moving technological revolution. It is estimated that by 2020 there will be 171 million new smartphone users in the region, according to Facebook IQ.\textsuperscript{17}

In this sense, it can be pointed out that ecommerce, at different levels of contracting (for example, at the business-to-business (B2B) level), has allowed companies to organize themselves horizontally and vertically to enable supply and meet the requirements of the end consumers. At the business-to-consumer (B2C) level, ecommerce has improved with the use of technological platforms to bring products and services closer to final consumers. At the consumer-to-consumer (C2C) level, the exchange of goods and services has been attempted using the consumer-product experience itself to reach more consumers. And finally, at the business-to-government (B2G) level, public procurement has been improved.

Thus, it should be noted that electronic contracts involve all economic agents in the market and contribute to improving the experience of the final consumer, such as

\textsuperscript{14} Ibid.
the service implemented in Real Plaza Go, as detailed by the Commerce:

Real Plaza Go "is the proposal of the firm with which it seeks to reach its customers through digital channels, thus giving way to electronic commerce. Real Plaza Go is much more than a marketplace; it is the extension of our 21 shopping centers.

With this platform, we seek to transfer our purpose of happiness to the digital world, in open space 365 days a year and 24 hours a day, which will allow our customers to buy without having to leave home and choose the way they want to receive their products, either through traditional delivery or another of the options we offer", said Daniel Duharte, CEO of Real Plaza’ 18, above all because it contributes decisively to the reduction of transaction costs.

On this line of thought, Blacksip also stated that:

In the last five years, Internet retail in Peru has evolved remarkably. If we analyze the numbers of this type of commerce in 2013 and compare them with current figures, it is evident that Peruvians each year bet much more on digital channels to supply their needs, be it goods or services. 19

This progress has been made, thanks to the support of multilateral organizations such as the United Nations Commission for International Trade Law (UNCITRAL) in reducing obstacles to trade. As has been explained, the UNCITRAL was established by the General Assembly in 1966. 20 The General Assembly, in establishing the Commission, recognized that disparities between national laws governing international trade created obstacles to that trade, and considered that, through the UNCITRAL, the United Nations (UN) could play a more active role in reducing or eliminating of those obstacles. 21

This has ultimately allowed progress in the legislative field of digital signature and certificates, based on the sustainable development goals (SDGs): ‘UNCITRAL supports the SDGs. In the Addis Ababa Action Agenda, the States supported the efforts and initiatives of the UNCITRAL, as the central legal body of the UN system in the field of international trade law, aimed at increasing coordination and cooperation in the legal activities of international and regional organizations operating in the field of international trade law and promoting the rule of law at the national and international levels in this field. 22

At this point, two normative laws of the UNCITRAL must be mentioned:

(i) Model Law on Electronic Commerce (1996) (together with its new Article 5 approved in 1998) which aims to [...] enable and facilitate ecommerce by offering legislators a set of internationally acceptable rules aimed at removing legal obstacles and making ecommerce more predictable; 23 and

(ii) UNCITRAL Model Law on Electronic Signatures (2001), which aims to [...] enable and facilitate the use of electronic signatures by establishing technical reliability criteria for the equivalence between electronic and handwritten signatures. 24 Both Model laws have contributed

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19 Blacksip (n 13).
in an outstanding way to the regulation of electronic commerce in Peru.

It should be noted that these Model texts have been reflected in Law 27269 – Law of Digital Signatures and Certificates of Peru, thanks to the support of the Competent Administrative Authority within the framework of the Official Infrastructure of Electronic Signature for Peru, and the support of the Commission for the Standardization and Inspection of Non-Tariff and Non-Tariff Trade Barriers (CNB), the INDECOPI, in accordance with Article 57 of Supreme Decree 052-2008-PCM Regulation of the Law on Digital Signatures and Certificates. The abovementioned rules approve the Certification Policies, Registration or Verification and Added Value, Certification Practice Statements, Registration or Verification and Added Value, the Security Policies, and the Privacy Policies and Plans of the Certification Entities, Registration or Verification and Added Value, of both public and private Certification Service Providers, and other policies.

In the case of the Law of Digital Signatures and Certificates, it promotes electronic contracting in a reliable and secure manner. The norm regulates the use of the electronic signature, granting it the same validity and legal effectiveness as the use of a handwritten signature or another analogous one that implies a manifestation of will.

Thanks to the Official Electronic Signature Infrastructure, public policies are aimed at providing greater legal certainty in electronic contracting. Here we can find the promotion of the use of distinctive signs for reliable and safe hiring harmonized with international policies and regulations.

Likewise, due to inter-institutional coordination between the National Registry of Identification and Civil Status (RENEC) and the National Superintendency of Customs and Tax Administration (SUNAT), pilot projects have been developed for personal identification through the use of the DNI – E or Electronic DNI. Additionally, progress in issues of digital certification of electronic signatures will allow greater legal certainty in electronic contracts. In this direction, these projects seek to improve the tax determination, collection, and inspection system from the issuance of electronic payment vouchers.

In this sense, due to the availability of sufficient legal platforms and the necessary legal protection in relation to personal identification issues, electronic contracting in general and consumer contracting is opening, one that involves the interaction of the final consumer of goods and services with the suppliers. And that has seen an unprecedented advance in the history of ecommerce in Peru.

In this context, the government of Peru, through INDECOPI, the Consumer Protection Commission must guarantee the right to information in relation to the products and services marketed in the digital-physical market, making it important to identify the products and services in a safe and reliable way both in the national and international market using distinctive signs. It should also be noted that in electronic consumer contracts, aspects related to commercial advertising and guaranteeing the veracity of the information transmitted to the consumer, the customer experience and aspects related to industrial property are important to guarantee security and trust when hiring.

30 Blacksip (n 13).
Let us remember in relation to the latter that in the Peruvian geographical space, there is a propensity for marketing products that may not be authorized by the holders of distinctive signs and/or marketing the products as simply defective, which has an unfavorable impact on the consumer experience. As Bravo explains, efforts such as those of the CAPECE have been made in this direction, which has sent a proposal that includes the formalization, banking, inclusion, and respect for IP. It is summarized as follows:

1. Allow the entry of 100% formal MYPES – Micro, Small and Medium Enterprises (MSMEs) through marketplaces, who undertake to safeguard the formality and IP of the products;
2. Guarantee the use of biosafety protocols, dispatching their products through a certified logistics operator, who are committed to safeguarding health and social distancing; and,
3. No MYPE should carry out its own dispatches but outsource it to a company specialized in it.  

An important aspect in consumer relations is the solution of controversies, within the forms of solution we find the private or public ones; however, one of the ways to prevent conflicts and solutions could be to generate trust and security in consumer relationships in the market through the use of distinctive signs, because as Bravo has pointed out:

Although online mistrust is one of the heels of Achilles in ecommerce. However, it has started to gain ground in 2019, as 33% of Peruvians feel more confident when buying than last year, according to a study carried out by Ipsos Peru.  

It is necessary to emphasize that when a private solution is not possible, the intervention of the State through INDECOPI will be necessary and indispensable, specifically the Consumer Protection Commission, the Regional Office Commissions, or the Executive Summary Procedures Bodies. There is also an urgent need to strengthen the online dispute resolution (ODR) mechanisms in this field and expand the institutional basis for the legal protection of consumers on equal terms with regard to economic agents in the market as forms of dispute resolution in contracts.

D. LEGAL SECURITY IN ELECTRONIC PROCUREMENT

Legal security, as Rosas explains to us, is defined as follows:

Legal security within the legal framework translates into the "certainty" of the permanence of the legal framework, as well as protection against an anomalous situation, in case of inconveniences in the execution of the contract, without the possibility of unexpected legislative modifications, which violate the principle of trust.

In this way, it is important to ask the following question: How do we guarantee legal certainty in terms of predictability and create a more efficient market in which consumer rights are protected? To answer, this task could be achieved to the extent the consumer knows they have suitable mechanisms that allow them to prevail their rights against the suppliers of goods and services.

For this reason, legal certainty in the framework of consumer contracts is essential. In this sense, at the contractual level in the case of written contracts, adhesion contracts, contracts with general contracting clauses approved administratively or not, verbal

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contracts, it is necessary to incorporate within the contractual forms certain mechanisms that would allow consumers to access the resolution of disputes immediately, easily, free of charge.

In this way, we will guarantee, in terms of legal certainty, sufficient predictability for the parties involved in the contracting of consumption and users. As Hernandez explains:

> Predictability can be explained as the situation in which the subjects can know what the current rules of the game are, and, with some certainty, they can trust that these will not be modified between the time of decision making and that of execution. These rules of the game are provided by the law and that predictability is provided by legal certainty.34

In this manner, efficiencies are generated within the market to the extent that the consumer knows and knows they have suitable mechanisms allowing them to defend their rights.

A more efficient market in terms of predictability will provide greater economic growth as it will provide us with the necessary platform to generate confidence in the consumer at the time of contracting, since consumers will know how to materialize their rights in case they have been violated.

Likewise, providers will be provided with the possibility of resolving disputes in less time, effort, and with reduced transaction costs, which will provide them with greater sustainability over time in relation to the economic activity they carry out in the market, allowing them to improve the consumer experience.

E. EFFICIENCY IN ELECTRONIC PROCUREMENT

In the framework of electronic contracting, one aspect that would improve contractual efficiency is predictability where both the supplier and the consumer are aware of the favorable and unfavorable aspects to which they are subjected when contracting in the different stages of recruitment; that is, in the pre-contractual, contractual and post-contractual stage.

They can also verify the aspects related to the identity of the parties with whom they are contracting, the object and content of the contracts they enter into, the forms of dispute resolution, and in the face of inefficiencies that may exist, clearly have alternative mechanisms dispute resolution solutions could be useful for its prompt resolution.

In this way, it will be essential that the economic agents providing suitable goods and services in the market can be properly identified, and in that direction, it is urgent to have the means that allow users to fully identify them. In this direction, distinctive signs enter the scene, whether at a private or public level, using which consumers will be able to find properly identified suppliers through certification marks in electronic contracts.

F. THE CONTRACTUAL BALANCE IN ELECTRONIC PROCUREMENT

If we can identify suppliers in the market through distinctive signs informing us that our purchase of product or service is safe and reliable, we could ask the question: Is it possible to generate the contractual balance between the subjects that intervene in the framework of consumer contracting?

In this regard, we could answer in the affirmative since consumers will have the information regarding the

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34 Hernández J, ‘Seguridad Jurídica y Costos de Transacción: Algunas distorsiones en el Código Civil’ (Revista Derecho y Sociedad, 1997)
provider’s profile and the type of product that it sells in the market. Furthermore, the consumer will know that regarding the possible risks involved in contracting the good or service, even if, for example, during the different stages of contracting he is protected by an insurance system, which will allow greater reliability at the time to make the purchase.

Likewise, we can point out that the contractual balance between the intervening parties would also be reestablished when we empower the consumer vis-à-vis the provider by providing them with sufficient tools to enforce their rights, while reducing the existing asymmetry in the contractual legal relationship between the provider and the consumer.

G. THE CONTRIBUTION OF DISTINCTIVE SIGNS IN SAFE AND RELIABLE ELECTRONIC CONTRACTING IN PERU

As indicated above, the use of distinctive signs in Peru can favor the identification of suppliers in the market that are committed to improving the experience of the final consumer. Even in case of failures and distortions that may be generated in electronic contracts, the same suppliers could implement an insurance system that allows the reimbursement of money in case the consumer exercises their right of restitution and/or the possible risks and damages that may be generated as a result of the contracting of the goods and services in the market.

In this context, the promoting role of the State is important through INDECOPI and the private sector that may be empowered to carry out the certification of suppliers in the market.

What is the distinctive sign that we propose and what elements could it incorporate?

The distinctive sign that we propose the supplier to exhibit is the distinctive sign with the name ‘E-Commerce – 100% Reliable and Safe’ which can be granted by a private or public certification body and that could involve a distinctive sign at a global level. The design would be under construction, but the following graphic can be taken as a reference:

![Distinctive Sign](image)

The distinctive sign would enable consumers to identify that the purchase on the Internet is reliable and safe and that there is an insurance system providing compensation for any aspect that could emerge in electronic contracts, whether of a consumer nature or linked to international trade in which ICT are involved, since the idea is to guarantee the execution of the contract while safeguarding the interests of the parties.

Likewise, in the adverse context that humanity is going through, it will allow us to identify suppliers that comply with sufficient biosafety and hygiene protocols to safeguard the interests of the end consumer by significantly improving their experience with the product or service put into operation and available to the consumer.

H. PROMOTING RELIABLE AND SECURE ELECTRONIC CONTRACTING AT THE INTERNATIONAL LEVEL

Finally, from this perspective, Member States of the WTO and WIPO can make efforts to harmonize public policies aimed at promoting reliable and secure electronic contracting, which allows the expansion of the economy of Member States at the national and international level.
Additionally, we consider that this aspect can be incorporated into the Model Law of Electronic Procurement and establish the incorporation of aspects related to the use of distinctive signs for the promotion of Reliable and Secure Electronic Procurement.

The use of distinctive signs and certification marks in the current context of electronic contracting cannot be implemented at the Member State level because it is an aspect not specifically contemplated. However, it can be included within the Model Law on Electronic Commerce.

The regulation in the Model Law on Electronic Commerce will allow us to harmonize the legislation of the Member States at the national and international levels and to identify suppliers that offer reliable and safe products. In this way, the markets will be strengthened. Let us remember that, in the international normative field, we are always faced with flexible solutions against the rigidity that on some occasions means the laws of each of the Member States.

In this way, we will have a sufficient platform to contract reliably and securely, something highly anticipated by all consumers globally.

3. CONCLUSIONS

(i) The legal foundations which justify the use of distinctive signs in the electronic contracting in the context of the COVID-19 pandemic, for the Peruvian case, are the Peruvian Political Constitution of 1993, Legislative Decree 1075 at the level of special legislation on distinctive signs, and the Regulation of the Peruvian Consumer Protection System. For the particular case, we refer to the CPDC, contained in Law 29571, counting for this with institutions such as INDECOPI.

(ii) The economic foundations which justify the use of distinctive signs in the electronic contracting in the context of the COVID-19 pandemic, for the Peruvian case, are economic growth for the new forms of contracting of products and services, which presents positive annual growth rates. Latin America is in the midst of a technological revolution that is advancing rapidly at the different levels of electronic contracting.

(iii) Within the framework of electronic contracting in Peru, progress has been made in the legislative field of digital signatures and certificates, based on the sustainable development objectives based on the Model Law, thanks to UNCTAR Model Law on Electronic Commerce (1996); and the UNCTAR Model Law on Electronic Signatures (2001). However, it is necessary to incorporate public policies at the national and international level that allow us to promote the use of distinctive signs to generate trust and security in digital contracting and face-to-face contracting, based on the identification of suppliers offering standards in the commercialization of reliable and safe products and services.

(iv) Legal certainty in the framework of consumer contracts is essential. In this sense, it is necessary to incorporate into the contractual forms the mechanisms that allow us to access conflict resolution immediately, easily, and free of charge. It is possible that the distinctive signs offer us the possibility of contracting in a reliable and secure manner, since we could identify suppliers that comply with the contracts and resolve disputes with consumers.

(v) In terms of contracting efficiency, it will be essential to adequately identify the economic agents that provide suitable products and services in the market, and in this sense, it is urgent to have distinctive signs, such as certification marks, which allow us to verify said conditions.

(vi) Distinctive signs, particularly at the level of the Member States, can favor the identification of providers in the market that are committed to
improving the experience of the final consumer. Even in the face of failures and distortions that may be generated in the field of electronic contracting, the same providers could implement an insurance system that allows money to be reimbursed if the consumer exercises his right of restitution and/or the possible risks and damages that may be generated as a result of contracting the products and services in the market.

(vii) It is possible can make efforts to harmonize public policies aimed at promoting reliable and secure electronic contracting based on the incorporation into the Model Law on Electronic Commerce of aspects related to the use of distinctive signs for Reliable Electronic Contracting.

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13. VACCINE PATENTS IN TIMES OF CRISIS: TIME TO RE-EVALUATE THE PATENT BARGAIN?

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ABSTRACT

While the global race for COVID-19 vaccines and related patents have resulted in many forerunners (Pfizer, Moderna and AstraZeneca), the equal accessibility of these has created further challenges. The forerunners’ ability to develop an effective COVID-19 vaccine with unprecedented swiftness may be due to a multiplicity of factors, including the critical need to control a global pandemic, significant pumping of finances through public funds, and direct donations by private individuals and companies. In order to make vaccines urgently available, the standard approval processes needed to be expedited while granting liability exemptions for pharmaceutical companies, as demanded. Indemnifying Big Pharma is a significant factor that hinders access to COVID-19 vaccines (in addition to price, patent restrictions, and cold chains) as for many low and middle-income countries; this may not be a viable option. Moreover, the patent bargain that is commonly relied on to support the patenting of inventions seems to have taken a new turn, under the current pandemic conditions where the public is expected to trade-off more than usual, making the forerunners more potent than ever, making access to lifesaving medicine even more difficult. This paper aims to examine to what extent the pandemic situation has shed new light on the traditional patent bargain. It further proposes the re-evaluation of the patent bargain through the introduction of appropriate responsibilities for Big Pharma as the private monopoly holders for the vaccines to achieve an expected and appropriate balance in the patent bargain between the public and Big Pharma.

Keywords: patents, COVID-19 vaccine, patent, bargain, justification, quid pro quo.

1. INTRODUCTION

Since the COVID-19 outbreak was reported in late 2019, one of the biggest, if not the most significant, issues the world faced was to find a vaccine to prevent the wider spread of this highly contagious disease. While the race for a COVID-19 vaccine began soon after that and many successful and efficient COVID-19 vaccine development became a reality, and its progress was unfolding daily across the world, another complex set of issues surrounding the COVID-19 vaccines emerged. These varied from maintaining equal access to vaccines, limiting vaccine nationalism, improving vaccine confidence in the general public to minimise vaccine hesitancy.

Many initiatives locally and internationally were introduced and implemented to address some of these concerns to no avail. One of the most potent international initiatives suggested is by India and South Africa, commonly known as the TRIPS Waiver, currently being discussed, although at a snail’s pace since late 2020, at the World Trade Organization (WTO) to minimise the access issues through relaxing the vaccine patent restrictions. Big Pharma is firmly blocking this initiative through the powerful countries of the Global North. Another promising initiative, COVAX, aimed to create unparalleled equal access to the vaccine, but that...
too was not a success due to the Global North bypassing COVAX and entering into bilateral agreements with Big Pharma. The lack of success in both the above initiatives is a consequence of the Pharma-Industrial Complex, a phenomenon where a substantial pharmaceutical industry has acquired great economic and political power, enough to influence public policy concerning life-saving medicines. Expectedly or unexpectedly, the current patent law, based on an illusory patent bargain, is a significant contributory factor in facilitating the engendering and the sustaining of the pharma-industrial complex. In the current COVID-19 climate, the consequence is the prediction that Big Pharma is to achieve a significant financial gain from the biggest disaster of the century, while millions of avoidable human deaths are left to happen – a hallmark of disaster capitalism.

Against this backdrop, this paper argues that a renegotiation of the patent bargain could be considered an alternative mechanism to address some of the issues surrounding COVID-19 vaccines where the onus of addressing such issues is shared with Big Pharma. Firstly, this paper aims to add to the existing literature around the illusory nature of the concept of Patent Bargain that courts and intellectual property (IP) proponents continue to rely on by using COVID-19 vaccines as a case study. Moreover, the paper suggests ways in which the patent bargain could be renegotiated where the appropriate balance that the patent law promises could be achieved.

2. PATENT BARGAIN

Granting exclusive property rights to innovations under the patent law has been most commonly justified under the ‘reward theory’ and ‘contract theory’, which often complement each other. While the former justifies the private monopoly rights as a reward for the innovative contribution made, the latter, under the metaphorical patent bargain, justifies granting such rights as an exchange for the disclosure of the recipe of the invention. The patent bargain is expected to justify the granting of exclusivity for an invention in return for disclosing the said invention’s recipe. The exclusivity is also a reward here since there is the assumption that the inventor may not disclose such innovations if not for the promised exclusivity, which may hamper the social and technical progression as a consequence. Thus, the bargain narrative has been seen as an appealing ground to support the granting of patents.

This section of the paper will attempt to dissect this contract theory-based patent bargain as a foundation for the later discussion concerning how the patent bargain functions in relation to the COVID-19 vaccines and whether a new patent deal is required where public health and access to medicine play an integral role in such negotiations.

Often referred to as ‘quid pro quo’ in patent law cases, the bargain analogy provides an illusion of consensual agreement between the two contracting parties, i.e., the inventor (often a private company) and the public (executed through the State), where exclusivity is traded for disclosure. Thus, the quid pro quo has been viewed by courts as ‘disclosure in sufficient detail to enable one skilled in the art to practice the invention’ and at times as ‘the benefit derived by the public from an invention with substantial utility’ in return for temporal and exclusive rights. However, the reality, more often, falls short of demonstrating a mutually beneficial contract between the two parties. This paper argues that such lack of balance is due to the many assumptions made when relying on a quid pro quo approach for patenting generally and patenting COVID-19 vaccines more specifically.

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8 Ibid.
The first assumption made within a patent bargain narrative is to assume that the patentee always discloses the full recipe for the invention, enabling a person skilled in that specific field to recreate it in return for exclusivity. However, such disclosures have proven to be hardly enabling due to them being delayed, inadequate or opaque preventing the very aim of knowledge sharing that the patent bargain proposes. Secondly, the bargain analogy seems to believe that the patentees prioritise their inventions to address societal needs. Such an assumption can be deduced from the often-made argument that the patents are utilitarian or have substantial utility to society. However, such views fail to explain the lack of cure available for Dengue when there is a cure for erectile dysfunction. Perhaps the utilitarian objectives need to be supported by their potentiality for financial benefit when prioritising investment in specific innovations. Thirdly, the patent bargain assumes that the patentee would use appropriate pricing for their products so the society could afford to benefit from them. But instead, the pricing seems to be based on the ground ‘whatever price the [Western] market will bear, with no obligation for the industry to price their products at an affordable rate. Thus, the patent system and the illusory bargain that it relies on seems to support granting a private monopoly without responsibility to patent-holding companies.

Often the proponents of patent exclusivity for vaccines would argue that the existing TRIPS flexibilities around compulsory licensing (CL) schemes adequately serve the purpose of maintaining the appropriate balance in the patent bargain. However, much ink has been split in highlighting the limits of TRIPS flexibilities due to the cumbersome nature of relying on CLs. These have resurfaced during the COVID-19 pandemic, particularly around the ‘TRIPS Waiver’ discourse. Being only applicable on an individual product and individual country basis, the potential for further restriction being imposed at the national level often leading to bureaucratic hurdles, regulatory obstacles such as data exclusivity and etc. do not make CLs a viable or appropriate method to maintain a patent bargain in a time of crisis. Thus this paper does not attempt to repeat such arguments but instead makes an effort to focus on the manner in which vaccines as specific innovation would work within the metaphorical patent bargain in times of crisis.

The paper will revisit the patent bargain metaphor to understand how it is performed concerning COVID-19 vaccines later, but firstly, the following section will examine vaccines as a particular patentable innovation more specifically to ascertain how the patent-reliant Big Pharma has perceived them.

3. Vaccines as a Poor Contender for Market-based Patent Innovation

Since its introduction in the early 20th century, vaccines have played a crucial role in disease control, elimination, and eradication, resulting in the significant reduction of human morbidity and mortality. Thus, it is not an

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12 Due to legal loopholes in publication requirements allowing postponement of disclosing the invention fully.
13 Deliberately withholding information and know-how to prevent efficient recreation of the invention.
14 Disclosing the information in a manner that is difficult for another to understand and thus, limiting the possibility of its recreation by a third party.
17 Ibid 3.
exaggeration to identify vaccines as the most effective public health intervention. Nevertheless, the distinctive characteristics of vaccine innovation seem to be threatening its continued use and development in an era where medicinal innovation seems to be controlled based on the financial gain by Big Pharma as gatekeepers, and the rest of the world is constantly kept at their mercy.

The multifaceted benefits of vaccinations have been identified beyond controlling targeted infectious diseases worldwide to include a more comprehensive societal advantage. They have proven to be helpful in preventing related diseases to the targeted disease as well as preventing the development of cancer. Reduction of infant deaths through perinatal and early infancy inoculations further empowers women as they need to have many children in case some may not reach adulthood reduced, which has further social, educational, and economic benefits. While inoculation programmes have contributed to the reduction of morbidity and mortality rates in the world population, what often goes less regarded is the economic efficacy of such methods and their contribution towards the achievement of health equity in a society where the financially able and the financially vulnerable can both be equally protected.

Regardless of these multiple benefits of vaccines, they have become less enticing for Big Pharma and their research and development (R&D) priorities. The specific characteristics of vaccines, their market economies coupled with the patent-driven innovation systems relied on by Big Pharma, seemed to have made vaccines unattractive as a biotechnological investment. Such factors include the inability or difficulty to quantify the overall economic savings that vaccines provide by preventing the broader dissemination of an infectious disease than medicines that cure disease. Thus, the successful outcome of the former is considered a non-event. However, the successful outcome of the latter is considered a tangible benefit. The long-term immunity that most vaccines can provide with a single dose also makes them unattractive as they are therefore less profitable for Big Pharma compared with other medicines that require lifelong use in the long run. The barriers to maintaining a cold chain when delivering vaccines to remote parts of a country/the world while sustaining its efficacy compared to the ease of distributing conventional drugs also make vaccines to be seen as a less attractive investment. Such difficulties often mean the target market could get significantly reduced, or the high cost of delivery would drastically increase the price, making them unaffordable for some populations and particularly people in the Global South. This has become visible during the current COVID-19 crisis, where Moderna and Pfizer vaccines require cold chain

22 For Example, Measles vaccination can protect from multiple complications such as dysentery, bacterial pneumonia, keratomalacia and malnutrition, as mentioned in Strebel PM, Papania MJ, Halsey NA, ‘Measles vaccine’ in Plotkin SA, Orenstein WA, (eds) Vaccines, 4th ed. (WB Saunders 2004) 389.
23 For example, reduction of cervical cancer with the use of HPV vaccine against stereotype 16 and 18, as per Harper DM, Franco EL, Wheeler CM, Moscicki AB, Romanowski B, Roteli-Martins CM, et al., HPV Vaccine Study Group. ‘Sustained efficacy up to 4.5 years of a bivalent L1 virus-like particle vaccine against human papillomavirus types 16 and 18: follow-up from a randomised control trial’ 15 April 2006, Lancet 367.
25 See Andre FE, et al. (n 21) and Shearley AE (n 21).
29 Rappuoli R, et al. (n 17).
distribution.\textsuperscript{33} Thus, regardless of the more comprehensive public health benefits and health equity vaccines could deliver, they are generally considered unappealing within a patents-based pharma-industrial complex.

Since vaccines are generally considered a non-lucrative form of innovation, the following section will explore whether the COVID-19 vaccine innovation was considered similarly or differently and the reasons for such considerations.

4. THE RACE FOR A VACCINE, LIKE NO OTHER

Since the World Health Organization (WHO) declared COVID-19 as a public health emergency of international concern in January 2020,\textsuperscript{34} the race for a COVID-19 vaccine was in full force, providing the first few efficient vaccines available much earlier than anticipated. Currently, more than a dozen vaccines have started to be rolled out across the world.\textsuperscript{35} While it was a welcome outcome to have such vaccines available in an expedient manner to control this highly infectious disease when reflecting on the vaccine development in other recent infectious disease outbreaks and the delay in developing an effective vaccine for them, some contributing factors for such disparity is vital to be identified for this paper.

As discussed in the previous section, although vaccine development is generally underfunded (for the reasons considered therein) with COVID-19, substantial financial donations were awarded to Big Pharma by private philanthropists,\textsuperscript{36} as well as by the public\textsuperscript{37} through various governments in the Global North. All three forerunners of COVID-19 vaccines benefited from generous financial contributions. For Moderna vaccine, while the country singer Dolly Parton donated USD one million to Vanderbilt University,\textsuperscript{38} significant donations appear to have been made by the US government as direct financial support and indirectly through the National Institute of Health with whom Moderna Inc. developed this vaccine, coined as ‘people’s vaccine’ by public interest groups due to this very reason.\textsuperscript{39} More than 97% of research funding that went into the development of the AstraZeneca vaccine too is attributable to public funding,\textsuperscript{40} while Pfizer vaccine development benefited from direct funding of USD 445 million from the German government.\textsuperscript{41} Thus, it is no secret that COVID-19 vaccines, unlike other vaccines generally, have received significant funding for their R&D.

While the public money is being pumped towards Big Pharma from one end, they also demanded exemption from any public liability claims for any vaccine-related injuries.\textsuperscript{42} While Pfizer vaccine was provided with such statutory indemnity by the UK government in


\textsuperscript{39} Safi, (n 34).

\textsuperscript{40} Griffin, Armstrong (n 34).

December 2020,43 AstraZeneca44 and Moderna,45 too, have included such indemnity clauses in their vaccine contracts. Such indemnity provision for Big Pharma has compelled the respective governments to absorb or address such potential civil liability claims.46 For example, in the UK, COVID-19 is added to the Vaccine Damages Payment Act, which grants a meagre amount of GBP 120,000 if one were to suffer severe disability as a consequence of taking a listed vaccine in the said Act.47 Any lesser level of harm would not make one eligible for any damages. While vaccine indemnity provision is not necessarily limited to COVID-19 vaccines, given the significant public funding received by Big Pharma for its development, it is questionable whether the public should also absorb the subsequent costs relating to the COVID-19 vaccines. It seems that Big Pharma is socialising the risks but privatising the profits.48

Expeditious approval of COVID-19 vaccines is another significant difference compared with other vaccine approvals. For example, it has been reported that the European Medicine Agency (EMA) approved a COVID-19 vaccine within 70 days compared to the average approval time of 210 days.49 When compared with another recent infectious disease crisis of Ebola, where the vaccine against it had been developed and awaiting clinical trials more than 10 years before its outbreak in 2014-2016,50 and only approved by the FDA in December 2019,51 one can see the rate of rapidity at which COVID-19 vaccines have been approved at. While the nature of the current crises meant that an accelerated approval process was a necessity for the benefit of the public, it is also worth noting that Big Pharma, too, benefit from such expedited approval as a swifter approval can contribute towards their brand promotion.

Due to the pandemic, governments bid for many hundreds of millions of COVID-19 vaccines, even during their development stage. For example, as Kate Bingham, the Chair of the UK’s Vaccine Task Force, confirms, the UK has not only supported the clinical trials and development of specific vaccines but had secured 400 million doses52 of vaccines.53 Similarly, the US had offered to buy 600 million doses of Pfizer vaccine alone,54 another 500 million doses from Moderna55, and 300 million doses of AstraZeneca.56 This level of guaranteed sales for the vaccines at such early stages of their development is also a unique position that COVID-19 vaccine developers benefited from. While the Global North hoarded COVID-19 vaccines multiple times of the required amount, the Global South countries struggled to have access to any.57 Such nationalistic

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45 While governments of the Global North may consider this option with limited occasions for such damages being granted, the Global South governments may not, creating vaccine inequity during a pandemic.
47 Lentich P, Hertig G (n 3).
51 When the UK population is less than 70,000,000, i.e., more than five times of the country’s population.
53 Griffin, Armstrong (n 34).
56 Bhutto F, ‘The world’s richest countries are hoarding vaccines. This is morally indefensible’ The Guardian (17 March 2021)
approaches to an international crisis that led to vaccine nationalism, which further contributed to the failure of initiatives such as COVAX and delaying the TRIPS Waiver, may have contributed to millions of preventable human deaths in the Global South.

As clearly evaluated in this section, the unprecedented support Big Pharma received in developing a COVID-19 vaccine, the accelerated approval from regulatory bodies, guaranteed sales even before the approval stages were completed meant that they were in a far better position financially with COVID-19 vaccines. As predicted in January 2021 by some WTO Members\(^\text{58}\) and confirmed by subsequent reports, the forerunners of the COVID-19 vaccines have reaped\(^\text{59}\) or are expected to gain\(^\text{60}\) significant financial returns even before the pandemic has ended. When the public has provided extensive support towards the development of COVID-19 vaccines while having to purchase such vaccines back, Big Pharma is only accountable for a (limited) disclosure for enjoying exclusive monopoly rights to these vaccines and gaining significant financial benefit does not, this paper argues, even provide a semblance of an appropriate bargain between the Big Pharma and the public.

5. **BALANCING THE SCALE: A NEW PATENT DEAL?**

As discussed previously, the public, from their side of the bargain, provided substantial financial contribution for COVID-19 vaccine development, facilitated accelerated vaccine approval, granted private monopoly rights over such vaccines with no limitation on pricing, and subsequently not only bought back such vaccines from Big Pharma but also indemnified them from potential injury claims. In return, the public is only expected to receive the disclosure of the vaccine recipe, which is not timely, adequate or proper disclosure, making such disclosure irrelevant or almost non-existent.

It is no secret then that the patent bargain needs re-evaluating, and there is no time like the present pandemic to understand this need clearly and lobby for necessary changes in finding a new, better patent deal. A deal where the bargain is based on the interests of the public rather than Big Pharma and strengthening the pharma-industrial complex further. A proper *quid pro quo*. This section of the paper will hint at how the patent bargain could be renegotiated so that the public is not worse off when granting exclusive monopoly rights to big pharma.

The experiences of the COVID-19 crisis made it clear that the ‘private monopoly without responsibility’ approach in patenting does not work for the benefit of the public, highlighting the terrible nature of the illusory patent bargain. This position becomes apparent when examining the current COVID-19 vaccine crisis closely. Thus, this paper proposes that introducing some responsibilities into the patent bargain could be assistive in balancing the scale to an appropriate level.

Such responsibilities that ought to be added to this new patent deal could commence by restoring the disclosure responsibility as envisaged when the patent bargain was first relied on. The need for a disclosure that is timely, adequate, and clear. Disclosure of the full recipe. Moreover, it is reasonable to expect that big pharma needs to play an active role in improving vaccine confidence in the public, given that their demand for indemnity and lack of transparency can often be seen as contributory factors to vaccine hesitancy. Finally, some accountability levels in maintaining equal access to vaccines and limiting vaccine nationalism need to be built at the international level.

\(^{58}\) TRIPS Waiver communication IP/C/W/672 (n 39).


into the bargain with appropriate sanctions for failing to do so since no one is safe until everyone is safe during a pandemic. Incorporating the above as primary responsibilities in return for a private monopoly may provide a glimpse of a balanced patent bargain.

6. CONCLUSIONS

This paper closely examined the patent bargain justification in vaccines generally and COVID-19 vaccines more specifically to highlight the lack of balance in this bargain between the public and Big Pharma. While the public seemed to have borne much of the onus of COVID-19 vaccine innovation by making considerable financial contributions, providing efficient and accelerated approval for vaccines, purchasing them back, and even offering indemnity for Big Pharma, it seemed to suggest that the time has undoubtedly come to renegotiate the patent deal.

In that regard, this paper proposes firstly to identify and confront the various assumptions made when relying on this contract-theory justification where expected disclosure is hardly provided, financial gain rather than public or societal needs being central to innovation schemes and pricing based on ‘what the market can bear’ rather than what the public can afford. In essence, a private monopoly is given with no responsibility expected from Big Pharma in return.

Thus, in making the patent bargain a more balanced one, this paper proposes the re-evaluation of it by relying on COVID-19 vaccines as a case study and reflecting on potential and reasonable responsibilities that could be built into the patent bargain to work towards achieving an appropriate quid pro quo between the public and the Big Pharma.

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ABSTRACT

Along with the continuous development of the Internet, cyberspace is increasingly expanding and spreading from one country to another. As a result, nations are connected more closely; people have become closer and economic transactions, cultural and social exchanges have become more convenient. All these factors bring great benefits in terms of economic and social development to many countries. However, the enormous growth of cyberspace and the digital environment also pose certain threats to a number of socio-economic fields, including the field of copyright protection. While revolutionizing the way through which individuals, communities, and countries can communicate and exchange information, the digital environment also provides a very convenient basis for copy and use activities without the consent of the author. The digital environment indeed creates significant legal challenges to copyright protection.

This article shows an interest in learning about the legal aspects of copyright protection in the digital environment and thereby finding effective solutions for protecting this right in the new context.

Keywords: copyright, digital environment, literary and artistic works, Vietnamese law.
property rights (economic rights). Infringement of copyright is considered a violation of law and may be subject to remedial sanctions according to the provisions of the law.

The recognition and protection of copyright, like the recognition and protection of other IP rights, serves two purposes. Copyright protection is primarily intended to encourage creative activities of creators, in other words, to encourage creativity in the community. When the law can offer holders the right to exploit material benefits from the work and no one else can exploit it without the consent of the author then everyone in society will feel secure in creating. Consequently, people are motivated to create and thereby encourage the whole community. On the other hand, copyright protection aims to facilitate proper public access to works. The protection itself gives the author the ability to exclusively exploit material benefits from the work, which indirectly encourages the author to put the work in circulation to the public, through which the public can access the work. The provision of a certain term of protection for a work also has a two-sided effect. In addition to guaranteeing creators exclusive control of their work during the protected period, the public also has free access to the work after the protection period ends.

B. THE DIGITAL ENVIRONMENT AND CHALLENGES TO COPYRIGHT PROTECTION

a) History of Copyright Protection and the Emergence of the Digital Era

Literary and artistic works have appeared for a long time, right from the early days of civilization when numerous masterpieces of poetry, painting, and literature were created. However, it was not until the middle of the 15th century – when printing technology was created and flourished in Europe – that reproduction of literary works became easier. At that time, the need for copyright protection for literary works was first expressed. From the end of the 19th century to the 20th century, the application of analogue technology brought tremendous changes to the printing and entertainment industries. Many new literary and artistic products were created such as photographs, cinematographs, sound recordings, media films and television, satellite images, architectural works, sculptures, etc. The copyright scope was no longer limited to works on paper. Analog technology also made copying literary and artistic works much easier than before. In response to this situation, many countries began to expand copyright protection regulations, mainly on increasing the number of material rights. Copyright protection was also extended to 50 years after the author’s death. Furthermore, international copyright treaties, such as the Berne Convention for the Protection of Literary and Artistic Works (1886), were concluded among countries to ensure international copyright protection.

From the end of the 20th century to the 21st century, a technology wave developed – the digital technology wave with the appearance and popularity of personal computers and the Internet. The digital environment has been bringing about fundamental alterations in the way of copying, using, exchanging, circulating and disseminating literary and artistic works. Despite only being created in the past few decades, the digital environment has quickly become essential for living and working. Every day we use smartphones, connect to the Internet to consult, search, and read a huge amount of information on-screen. Moreover, we can use desktop computers, laptops for working, emailing, watching

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2 Intellectual Property Law (2005, amended and supplemented in 2009) uses the terms 'moral rights' and 'property rights'. The Berne Convention (1886) uses the terms 'spiritual rights' and 'economic rights' respectively.


5 Jie Hua J, Toward a more balanced approach: rethinking and readjusting copyright systems in the digital network era (Springer 2014) 3.
movies, listening to music and entertainment regardless of the location. Digital environments are constituted by two principal elements which are the personal computer and the Internet⁴.

Appeared and popularized through commercialization in the 1980s, the personal computer was the beginning of the formation of the digital environment⁷. With personal computers, people had a new interactive environment with a new interactive interface. Humans wrote documents, drew designs, composed music, and made movies with unprecedented efficiency and speed. Along with the personal computer was a vast system of software that helped people perform tasks, especially compositional works, more efficiently. Writers could compose their work in a shorter time and with less physical effort, and architects could create their own designs with little attempt to erase, eliminate or tear up faulty drawings. Personal computers are becoming more modern and more professional, with many forms and variants such as desktop computers, laptops, and tablets that people can use almost anywhere and, in any situation, to cater to their diverse needs. The software is also getting more complex, helping users to perform increasingly difficult operations with higher quality. An immense system of software that can meet almost all human needs, from work to entertainment, from communication and information exchange to disseminating information, ideas, and personal viewpoints.

The other, more important, and more prominent part of the digital environment is the Internet. The Internet consists of a number of different networks that are interconnected and together link hundreds of millions of computers worldwide. Another name for the Internet is the Information Superhighway. The Internet was started in 1969 by a United States (US) government project, ARPANET, designed to support communications during a nuclear disaster in the US⁵. Since 1980, the ARPANET network has connected to a number of other networks and extended the range of users by TCP/IP method⁶. In 1993-1994, the World Wide Web (WWW) was officially established together with the organizations operating the Internet.

In the 1970s, there were only three networks operating on the Internet, but that number increased to 50,000 in 1996. Today, that number has become uncountable. No private organization has complete control over the Internet, and the Internet does not have a single centralized database. Therefore, no one can control the data as well as the content of information on the Internet¹⁰.

Normally, the Internet is known as a cyberspace where people can search for and exchange information, send letters, watch movies, listen to music, express personal opinions, and so on. However, the function of the Internet is far greater than what can be listed. From the very first years when the Internet became ubiquitous, the European Union (EU) assessed the Internet as a source to provide revolutionary services, including all features of information technology, telecommunications, and television technology. The Internet can promote basic features such as¹¹ store huge amounts of data, including both traditional and non-traditional works (e.g., software). Data may also include multimedia products, that is, a combination of different literary and artistic forms such as paintings, pictures, music, etc. The range of services that can be provided from the Internet is extremely diverse, from remote work, online banking,

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⁹ TCP/IP stands for Transmission Control Protocol/Internet Protocol. TCP/IP controls communication between all computers on the Internet. More specifically, TCP/IP specifies how information is encapsulated (also known as packets), sent and received by computers that are connected to each other. TCP/IP was developed in 1978 by Bob Kahn and Vint Cerf.
¹¹ Ibid.
online shopping, electronic journalism, entertainment, libraries, distance education programs, online betting, distance travel, etc. The areas in which the Internet can be used are very diverse, including most areas in which people participate in daily life, for example work, information and training, online shopping, monitoring, healthcare, and entertainment.

Now, services from the Internet can be delivered interactively, meaning that each end-to-end service user can receive different service content. This is different from the traditional TV service delivery method, which means fixed service content from the centre and all end-to-end users receive the same service content.

b) Challenges to Copyright Protection in the Digital Age or Environment

With such characteristics, the digital environment has been having a profound impact on the field of copyright protection. On the positive side, it can be stated that the digital environment has contributed to the promotion of literary and artistic works more widely and directly to the public. With the significant features of the Internet and computer software, literary and artistic works can also be adapted in a convenient and creative way, thereby bringing more benefits to the creators. However, besides the positive points, the digital environment also poses many challenges from many dimensions and aspects to the specific copyright protection issue mentioned below.

National and international laws on copyright protection are built on a separate set of concepts, for example, work, author, term of protection, moral rights, property rights, etc. The presence of the digital environment is unlikely to change the perception of the nature of these concepts. The European Commission indicated in the early years of the new global network that the digital environment could have significant impacts on the interpretation of such concepts\textsuperscript{12}.

First, the concept of 'author' can be interpreted more broadly in the digital environment. In the traditional approach, creators are often understood as natural persons, for example, a painter making a painting, a writer writing a novel, a musician composing a song. If the 'author' is a group of people, it is also a collection of natural persons. In the digital environment, it is possible that works are created by many people and follow a chain, a complex process presided over by a legal person. In the production process of a software, it will be difficult to determine how far the efforts of individuals are, and the final product can hardly be created without the organizational efforts of the legal persons, or multimedia products, or works created by the efforts and organization of legal persons. Therefore, legal persons can also become authors of literary and artistic compositions.

Second, the concept of 'originality' is often defined quite easily for traditional literary and artistic works. A novel, a painting or a song is associated with the author's name, and it is easy to determine whether the author is really the person who created the work, or in other words, the entire work is due to the author's name whether the author created it or not. However, a multimedia work may be created on the basis of a composite of works or parts of other works. In that case, it would be a matter of clarifying to what extent the assemblage would be considered original. Thus, the characteristics of a digital work 'make it difficult' to determine its originality.

Third, the concept of first-time publication is also difficult to specify in a digital environment. Usually, a work that is made available to the public in a certain country, even a location in a certain country will be considered a work published in that country. However, the digital environment is borderless and not the usual physical environment. The boundary between private and public space in a digital environment is also tough to distinguish. Therefore, it is hard to use traditional methods to identify a digital work that is first-time published in the digital

\textsuperscript{12} Id, pg. 25.
environment.

With the development of analogue technology, there were new types of literary and artistic works that needed copyright protection, for example, recorded songs, radio and television programs, works of photography, cinematographic products, etc. Similarly, in the digital era, a number of fresh and unprecedented works, such as multimedia products and computer software, have appeared. These products are clearly intellectual, inventive, and original; therefore, they must be subjected to IP protection. However, the classification of these objects into literary or artistic works to be protected by copyright, or creative technical products to be protected by inventions or utility solutions, is complicated.

In the digital environment, all IP rights are more susceptible to infringement than in the conventional environment. But copyright is the most vulnerable right. Therefore, one of the biggest challenges for copyright protection in the digital age lies in the issue of infringement.

The history of the establishment and development of copyright as presented above shows that every time science and technology develop, they pose new challenges to the issue of copyright protection, and copyright protection law must change to meet these difficulties. With the adoption of digital technology and the advent of the Internet, the challenges of copyright protection have been raised with an unprecedented degree of concern. Copyright infringement can now be done easily over a large scale making it difficult to detect. The Internet now has billions of users and with just one click, countless users can access copies on the net. Copy operation can be done quickly and secretly without anyone being able to detect and prevent it.

In addition to allowing the exact reproduction of the original, digital technology also allows users to edit and adapt works, making it difficult to distinguish between original works and edited ones as they circulate freely on the Internet. Therefore, it is very challenging for authors to ensure the integrity of their creations. Moreover, the widespread presence of the Internet and digital technology also makes it troublesome for authors and copyright holders to control the use and storage of other subjects’ works.

In particular, in the digital environment, there are also acts of copyright infringement that have never existed before, thereby making it difficult to develop laws to regulate, detect and handle violations. If a network company creates a website that allows users to share music and movie files themselves, would that be a copyright violation? Or suppose that an Internet service company has an online newspaper as a client with its own server. That online newspaper, without permission, translates an article of another online newspaper abroad and saves it on its own server. However, every time a user reads an article in the online newspaper, the article must be uploaded to the Random Access Memory (RAM) cache provided by the Internet service company. So, is the act of temporarily storing that article on the RAM of the Internet service company considered a copyright infringement? These are just two of many examples of new forms of copyright infringement emerging in the digital environment.

It is clear that the digital environment presents enormous and multidimensional challenges to copyright protection. These matters have been occurring with the popularity and rapid growth of the digital life. International laws, as well as national laws, have made certain efforts to compete with these challenges in recent times. The introduction of new international treaties on copyright protection, such as the WIPO Copyright Treaty (WCT) or the WIPO Performance and Phonogram Treaty (WPPT), along with new laws in the countries, is a sign of such efforts.

\[\text{Kaplan (n 3).}\]
2. CURRENT VIETNAMESE LAW ON COPYRIGHT PROTECTION IN THE DIGITAL ENVIRONMENT

Faced with the great challenges that the digital environment poses in the field of copyright, it is necessary to have new perspectives and methods in copyright protection, so that it is suitable for the continuous development of science and technology and still ensures the traditional legal values. Recognizing this issue, Viet Nam's copyright law in recent years has always had additional amendments to effectively protect copyright in general, and copyright in the digital environment in particular. However, unlike some countries in the world, Viet Nam does not have its legal documents to protect copyright in the digital environment. This means that copyright protection documents are generally applied to protect copyright in the digital environment, typically the following documents:

- Decree 22/2018/ND-CP of the government issued on 23 February 2018 detailing a number of articles and measures to implement the 2005 Intellectual Property Law and the 2009 Law Amending and Supplementing a Number of Articles of the Intellectual Property in terms of copyright and related rights;
- Decree 100/2006/ND-CP of the government issued on 21 September 2006 detailing and guiding the implementation of a number of articles of the Civil Code and the Intellectual Property Law regarding copyright and related rights;
- Decree 131/2013/ND-CP of the government issued on 16 October 2013 on sanctioning of administrative violations of copyright and related rights;
- Decree 28/2017/ND-CP of the government issued on 20 March 2017 amending and supplementing a number of articles of the government's Decree 131/2013/ND-CP dated 16 October 2013 on handling penalties for administrative violations of copyright and related rights and the government's Decree 158/2013/ND-CP dated 12 November 2013 on sanctioning of administrative violations in the field of culture and sports, tourism and advertising;
- Joint Circular No. 07/2012/TTLT-BTTTT-BVHTTDL dated 19 June 2012 of the Ministry of Information and Communications and the Ministry of Culture, Sports and Tourism stipulating the responsibilities of intermediary enterprises in the protection of copyright and related rights in the Internet network environment and telecommunications network;

A. OBJECTS OF COPYRIGHT PROTECTION IN THE DIGITAL ENVIRONMENT

According to Article 14 of the 2005 Intellectual Property Law, objects entitled to copyright protection in the digital environment are: literary works, science, textbooks, curriculums, and other works shown in writing or other

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14 In France, it is “Creation and Internet Law” of 2010; in Europe, it is “Directive on the coordination of certain aspects of copyright and related rights in 2001”; in the US, it is “Act on the digital millennium copyright in 1998”.  

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characters; lectures, speeches, and other talks; press
works; musical works; theatre works; cinematographic
works and works created by a similar method; visual and
applied art works; photographic works; architectural
works; plans, diagrams, maps, drawings related to
topography, scientific works; literary and folk art works;
computer programs, data collections; a derivative work is
protected provided it does not prejudice the copyright in
the work used to make the derivative work.

B. COPYRIGHT HOLDER IN THE DIGITAL
ENVIRONMENT

In principle, all copyright holders in the traditional
environment are also in the digital environment,
including authors and copyright holders. An author is a
person who directly creates literary works, art and
science with intellectual labour and creativity through the
use of supporting tools to express works such as
drawings, images, sounds, language, shape movement,
colour. The work bears the author’s personal imprint,
most clearly expressing the thoughts, ideas, and purposes
that the author wants to convey to people through his
works. Article 8 of Decree 100/2006/ND-CP, Article 6 of
Decree 22/2018/ND-CP states:

An author is a person who directly creates part or
the whole of a literary work, art, science.

According to Article 36 of the 2005 Intellectual Property
Law, a copyright owner is:

An organization or individual holding one, several
or all of the property rights specified in Article 20
of this Law.

On that basis, the people who is the owner of the
copyright for works in the digital environment will be in
the cases specified in Articles 36 to 42 of the

2005 Intellectual Property Law, specifically: The one is
individuals and organizations that use their time, finance,
material and technical facilities to create works\(^{15}\); Copyright holders is an individual or organization that
concludes a contract or assigns tasks to the author of the
work\(^{16}\); Copyright holders are individuals or organizations
that inherit property according to the law on
inheritance\(^{17}\); Copyright holders are individuals or
organizations that are consigned copyright\(^{18}\); Copyright
holder is the State\(^{19}\).

C. CONTENTS OF COPYRIGHT IN THE DIGITAL
ENVIRONMENT

Copyright in the digital environment includes two groups:
moral rights and property rights. These are the exclusive
rights on the procedures and conditions of exploitation
and use of the work in different forms and methods
prescribed by law. In Viet Nam, the moral rights and
property rights of authors are recognized in Articles 19
and 20 of the 2005 Intellectual Property Law. This
contains many specific provisions of copyright in the
digital environment. Accordingly, many rights of authors
have been expanded by Vietnamese law in both scope
and content to suit the development of science and
technology such as the right to publish works, the right to
copy, the right to communicate works to the public, and
the right to lease both copies and originals of the works
and others.

a) Moral rights: Moral rights are very personal, so
they become associated permanently with the
author (indefinitely protected) and cannot be
transferred (except for some exceptions)\(^{20}\),
including the right to name the author, right to
put his name on the work, right to publish or
permit others to publish, right to protect the
entire work, right to not allow other users to
modify, mutilate, or deform it in any way
undesirable to the author’s honour and

\(^{15}\) Intellectual Property Law, Articles 21(2) and 38.

\(^{16}\) Id, Article 39.

\(^{17}\) Id, Article 40.

\(^{18}\) Id, Article 41.

\(^{19}\) Id, Article 42.

\(^{20}\) Id, Article 19.
reputation. Among the above rights, the right to publish a work is a right that is permitted by law to be transferred. Publication of a work is understood as the release of copies of a work to the public, in a quantity sufficient to meet the reasonable needs of the public, depending on the nature of the work, with the consent of the copyright owner. When the work is created, it will be brought to the public, through which the public knows the author and the work. As a result, publishing the work on the Internet without the agreement of the author is an infringement of the moral rights of the author. On the other hand, the author’s permission to publish his work does not mean that the author allows publication on the Internet. In the digital environment, the right of publication, which is one of the rights of an author, is most susceptible to infringement. Because once it is allowed to publish works on the Internet, the spread and dissemination of works via the Internet will be beyond the author’s control.

b) Property rights: Property rights offer authors and copyright holders the exclusive right to exploit, permit or forbid others to exploit, and obtain material benefits from the exploitation of their works. Property rights are transferable and protected in a certain period depending on the type of work. According to Article 20 of the 2005 Intellectual Property Law, the group of property rights includes the following specific ones:

i. The right to make derivative works: The right to create works from other people’s works, including works translated from one language into another, works adapted, compiled, annotated, and selected. The creator of a derivative work is the author of that work and is protected only in accordance with the law if it does not prejudice the copyright of the work used to make the derivative work.

ii. The right to perform works in public: The right granted by the copyright owner to exclusively exercise or permit others to perform the performance of the work directly or indirectly through phonogram, recording programs, image, or any other technical means accessible to the public including the performance of the work anywhere except at home. With this provision, the right to perform includes live performance in front of the public (such as musical performances at the theatre, storytelling, poem-reciting on radio, television, etc.) or indirect performances through audio and video recordings that are played through compatible devices at public locations (such as airplanes, discos, supermarkets, hotels, restaurants, karaoke services, etc.). In the digital environment, performance rights are mainly exercised indirectly, so the recognition of this content in Vietnamese law also shows the specificity of copyright in the digital environment.

iii. The right to copy works: The right to copy is the most important right in the group of property rights (economic rights) of the author. Compared to other copyright, the right to copy is among the most vulnerable to infringement in the digital environment. According to Clause 10, Article 4 of the 2005 Intellectual Property Law, the ‘copying’ of a work means making one or more copies of the work or

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22 Decree 100/2006 Detailing and guiding the implementation of a number of articles of the Civil Code and the Intellectual Property Law regarding copyright and related rights, Article 23.
23 Intellectual Property Law (n 13), Article 14(2).
24 For literary works is the lifetime of the author, plus 50 years after the author’s death, cinematic works are 50 years from publication, photography is 25 years since publication.
the phonogram, the recording of the work by any means and in any form, including electronic form. Thus, the act of copying a work in the digital environment no longer stops at tangible copying (by photocopying technique) but extends to electronic forms by any means, regardless of whether it is permanent or temporary storage. Thus, a 'copy of a work' is a direct or indirect reproduction of a part or all of the work. Therefore, the creation of an important part or the entire work in the computer cache or in the process of transmission over the Internet constitutes an act of copying the work and is subject to the exclusive permission of the copyright holder. Clause 2, Article 23 of Decree 100/2006/ND-CP concretizes this content as follows:

Copying is the right of the copyright holder to have the exclusive right to perform or permit others to make copies of the work by any means or form, including permanent or temporary storage of the work in electronic form.

This regulation shows the specificity of the right to copy in the digital environment. However, this provision has been amended by Article 5 of Decree 85/2011/ND-CP. The amended provision is as follows:

The right to copy is one of the property rights belonging to the author’s exclusive right, which the owner performs or allows others to make copies of the work by any means or form, including making copies in electronic form.

The amendment in Decree 85/2011/ND-CP, omits the temporary copy, which means that the temporary copy is not under the exclusive control of the copyright holder.

Decree 22/2018/ND-CP continued the provisions of Clause 2, Article 21 as follows:

The right to copy a work specified at Point c, Clause 1, Article 20 of the 2005 Intellectual Property Law is the right of the copyright owner to exclusively perform or permit others to make copies of the work by any means by any forms, including making copies in electronic form.

This is an issue that currently has many different viewpoints, with split opinions among scholars in the world as well as in Viet Nam.

iv. The right to distribute and import copies and original works: It is the exclusive right of the copyright holder to distribute works or to allow third parties to perform the distribution of authors' works by any forms or technical means accessible to the public for sale, rental or other transfer of the original or a copy of the work, including the transmission of copies of the work on the Internet.

v. The right to communicate works to the public by wireline, radio, electronic information networks or any other technical means: It is the exclusive right of the copyright holder to perform or to allow others to make the work or copies of the work accessible to the public at a place and time of their own selection. The act of communicating work may or may not accompany copying of the work, so a right of transmission is a right that may include a right to copy and a right to distribute or publish work in the digital

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25 Point d, Clause 1, Article 20 of the 2005 Intellectual Property Law; Clause 3, Article 23 of Decree 100/2006; Clause 3, Article 21 of Decree 22/2018/ND-CP.

26 Point d, Clause 1, Article 20 of the 2005 Intellectual Property Law; Clause 4, Article 23 of Decree 100/2006/ND-CP; Clause 3, Article 21 of Decree 22/2018/ND-CP.
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environment. This regulation is important for copyright protection in the digital environment, whereby a work that is communicated to the public without the consent of the copyright owner will be considered a copyright infringement, even if the work is communicated via the internet or similar networks.

vi. **The right to lease the original, or copies of works, computer programs:**
Accordingly, the right to lease the original or copies of the work will be made exclusively by the copyright holder or authorized by others for limited use. Before the advent of the Internet, copying became extremely easy. The provisions of Vietnamese law aim at expanding the rights of copyright holders. Accordingly, the copyright owner has the right to lease not only the original, but also its copies. However, the right to lease does not apply to a computer program when the program itself is not the principal object of the lease, such as a computer program associated with the normal operation of vehicles as well as other machinery and technical equipment. The lessee is responsible for applying for permission and making payments to the copyright owner in accordance with Clause 3, Article 20 of the 2005 Intellectual Property Law.

The abovementioned property rights and moral rights automatically arise as soon as the work is formed in a certain material form. Organizations and individuals that exploit and use works must fulfill their legal obligations towards authors and copyright holders. Copyright holders are entitled to royalties, remuneration and other material benefits arising from allowing other organizations and individuals to exploit and use their works. However, in order to balance the interests between the author/copyright holder and the community’s interests, Article 25 of the 2005 Intellectual Property Law stipulates the cases in which the subjects are allowed to use the work but do not have to apply for it and without paying remuneration to the author or copyright holder, particularly:

- Self-reproducing a copy for the purpose of personal research and teaching;
- Reasonably citing the work without misrepresenting the author’s intention to comment or illustrate in his work;
- Quoting works without falsifying the author’s intention to write newspapers, use in periodical publications, in radio and television programs, documentaries;
- Quoting works for teaching in schools without distorting the author’s intention, not for commercial purposes;
- Importing copies of other people’s work for private use.

**D. COPYRIGHT INFRINGEMENT IN THE DIGITAL ENVIRONMENT**

In the digital environment, copyright infringement acts are performed simply and smoothly in many different ways. According to Article 28 of the 2005 Intellectual Property Law and Article 7 of Decree 105/2006/ND-CP, the acts of copyright infringement are regulated rather specifically and include many different acts. As a result, there are acts of copyright infringement in general and acts that are considered characteristic of copyright infringement in the digital environment.

- **Acts of copyright infringement in general:** Appropriating copyright; Impersonating the author; Publishing and distributing works without

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27 Point e, Clause 1, Article 20 of the 2005 Intellectual Property Law; Clause 5, Article 23 of Decree 100/2006/ND-CP; Clause 5, Article 21 of Decree 22/2018/ND-CP.
the author’s permission; Publishing and distributing works with co-authors without permission of such co-authors; Modifying, mutilating or misrepresenting the work in any way that is prejudicial to the honour and reputation of the author; Releasing the work without the permission of the author, the copyright owner; Copying more than one copy of a work without the purpose of teaching or scientific research; Using the work without the permission of the copyright owner, without paying royalties, remuneration or other material benefits as prescribed by law; Leasing the work without paying royalties, remuneration and other material benefits to the author or copyright holder; and Exporting, importing, distributing copies of works without the permission of the copyright owner.

Typical acts of copyright infringement in the digital environment: Duplicating, reproducing, distributing, displaying or communicating works to the public through communication networks and digital media without the permission of the copyright owner; Attempting to cancel or disable technical measures taken by the author to protect the copyright of his work; Attempting to delete, change the right to manage information in electronic form; and Manufacturing, assembling, transforming, distributing, importing, exporting, selling or leasing equipment despite knowing or having grounds to know that such equipment invalidates technical measures taken by the author to protect the copyright.

Thus, compared with the traditional environment, copyright infringement acts in the digital environment are often associated with the use of high-tech measures. These acts not only originate from individuals or groups intentionally or unintentionally infringing, but intermediary service providers are also directly responsible for copyright infringement in the digital environment.

E. MEASURES TO PROTECT COPYRIGHT IN THE DIGITAL ENVIRONMENT

Vietnamese law provides various measures to protect the legitimate rights and interests of authors in the traditional environment as well as in the digital environment. These measures can be divided into two groups:

a) Application of technological measures on the services, digital information storage space rental services, including storage space to rent website hosting.

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28 Intermediary services include telecommunications services, Internet services, online social networking services, digital information search
part of the author and the right holder

This is a typical way to protect copyright in the digital environment. Clause 1, Article 198 of 2005 Intellectual Property Law stipulates that authors and copyright holders have the right to apply technological measures to prevent acts of infringement of their IP rights. The application of technological measures as specified in Article 43 of Decree 100/2006/ND-CP and Clause 2, Article 21 of Decree 105/2006/ND-CP means that authors who hold the copyright in work have the right to include the rights management information associated with the original or the copy of the work to identify the author’s own imprint. Such as, the author’s full name, the copyright owner of the work; personal address, email address of the author; the author’s distinctive symbols such as drawings, codes, symbols, logos, completion time of work, full names of other individuals and organizations participating in the creation of the work etc.

Rights management information appears with the publication and communication of a work to the public in order to identify the work, the author of the work, the holder of the rights, information on the terms and conditions of use of the work, and any figures or codes or symbols representing such information for copyright protection. At the same time, right holders can apply high-tech measures (such as COP-Illegal content obstruction program) to prevent unlawful acts of accessing works or illegally exploitation of copyright under the law.

Thus, according to Vietnamese law, through advanced technical methods, authors and copyright holders can update and disseminate information related to themselves on the work to affirm that it is their work and is protected by copyright. Technological measures and rights management information shall be freely chosen by the author and the copyright holder as appropriate for each type of work.

b) Legal measures taken by competent state agencies

- Civil remedies: Civil remedies are applied both in the traditional environment and the digital one. Article 202 of the 2005 Intellectual Property Law stipulates that the court shall apply civil measures to handle organizations and individuals that commit acts of copyright infringement, including:

  i) Forced termination of infringing acts:
Authors and copyright holders can either themselves or through the Court request the infringer to stop their infringing acts as soon as they discover the infringing acts. The request to stop infringing acts in the digital environment is manifested with a request to remove the work from the web or not to make the work public. Nevertheless, specific procedures for removing infringing work from the website have not been specified, such as how long does the request take? Or if there is a delay in removing infringing work, who will be responsible for it?

  ii) Forced public apology and rectification:
Similar to the right to request an end to infringement, authors and copyright holders can themselves request an apology and rectification from the infringer publicly or through the court to issue a legally binding judgment against the infringer. The person who commits the infringing act must apologize and rectify it through public means of media such as newspapers, online newspapers, television and radio channels, or on personal websites, websites where the infringing acts are performed.

  iii) Compulsory performance of a civil obligation: When an infringer uses a protected work without asking the
copyright owner’s permission, the owner has the right to request this person to perform the obligation to pay a sum for the use of the work from the time of use. In the traditional environment, a copyright owner can require the infringer to pay royalties for distributing his or her work. Additionally, if the work is not removed from the infringing website, the copyright owner will negotiate through the copyright collective management organizations (CMOs) and ask them to fulfil the obligation to pay royalties.

iv) Forced compensation for damages:
Claims for damages caused by copyright infringement in general and in the digital environment are only applied in practice when the author or copyright owner proves the infringement and that there is a cause-effect relationship between the infringement and the damage occurred. Accordingly, when infringers commit such acts, intentionally or unintentionally, as specified in Article 28 of the 2005 Intellectual Property Law and cause damage to the copyright holders, they are obliged to pay compensation. However, proving physical and mental damage caused in the digital environment is challenging for authors and copyright holders. In addition, Vietnamese law does not have specific provisions for determining the level of physical and mental damage to authors in the digital environment, so it will be hard to give appropriate compensation to deter subjects from committing acts of copyright infringement in the digital environment.

v) Administrative measures: Copyright infringement (in the traditional or digital environment) is essentially a violation of the law on State management in the field of IP and affects the interests of copyright holders, the interests of consumers and creates negative effects on the social community, so this action can be sanctioned for administrative violations according to the provisions of Vietnamese law.

Decree 131/2013/ND-CP and Decree 174/2013/ND-CP, dated 13 November 2013, regulating 'Sanctions for administrative violations in the field of post and telecommunications, information technology and radio frequencies', are two legal documents specifying administrative measures applied to copyright infringement acts, including ones in the digital environment. Faced with the fact that copyright infringement acts in the digital environment are being carried out quite easily, the above legal documents have increased the level of penalties for copyright infringement acts. Accordingly, for individuals who commit acts of copyright infringement, two main forms of sanction can be applied: warning and fine. As for the fine, the maximum amount is VND 500,000,000 depending on the nature and seriousness of the violation. This shows the seriousness and deterrence of Vietnamese law against acts of copyright infringement. In addition, violators may also be subjected to additional sanctions and other remedial measures in the digital environment (such as requests to remove the unauthorized works in electronic form). However, like civil remedies, currently Vietnamese law does not have specific provisions in sanctioning acts of copyright infringement in the digital environment.

- Criminal remedies: Acts of copyright infringement on the Internet are common and diverse and, in many cases, cause great physical and mental damage to the authors and copyright holders, which administrative measures and civil
remedies are not strong enough to deter and punish. The 2015 Penal Code has new regulations with severe penalties to deter and punish those who commit acts of copyright infringement in the digital environment. In addition to increasing the fine level for copyright infringement acts, another new point of the 2015 Penal Code is clearly stipulating the measures taken by commercial legal entities when handling infringement of copyright and other related rights. In fact, commercial legal entities are one of the subjects that disseminate direct or indirect acts of copyright infringement in the digital environment and have full conditions to enforce property sanctions. Therefore, it is completely reasonable to apply strict sanctions on commercial legal entities.\(^3\)

- Measures to control goods at the border:
  Despite not being directly related to dealing with copyright infringement acts in the digital environment, border control measures have practical implications for preventing copyright-infringing products circulated on the market (such as illegally reproduced tapes and discs, published piracy publications, etc.). In fact, among the products infringing copyright circulating on the market, a few products are caused by copyright infringement acts in the digital environment (such as publishing books downloaded from the internet without the author’s permission; the release of tapes and discs of music programs downloaded from the internet, etc.).

The main tenor of border control measures is associated with the temporary suspension of customs procedures for goods suspected of infringing upon copyright by customs authorities. Procedures for applying the measure of temporary suspension of customs procedures are specified in Article 218 of the 2005 Intellectual Property Law and the 2015 Customs Law. When the requester suspends customs procedures, the customs authority shall issue a decision to suspend customs procedures for the shipment. When it is proved that imported and exported goods infringe copyright, the customs authorities have the right to destroy, without compensation, the whole of such goods. This is an effective measure to prevent goods infringing on IP rights from circulating on the Vietnamese market.

3. THE ACTUALITY OF COPYRIGHT PROTECTION IN THE DIGITAL ENVIRONMENT IN VIET NAM

The main feature of copyright infringement is that it is very easy to do but has great benefits, especially in today’s digital environment. From that fact, the measures for handling copyright infringement acts in the digital environment according to the provisions of current Vietnamese law are tougher and stronger than before. For example, the fine level is higher, and the sanctions are also more severe. However, this is not enough to effectively prevent copyright infringement acts in the digital environment in Viet Nam today. This actuality can be summarized in two main characteristics:

Firstly, copyright infringement acts in the digital environment are very common in most fields and difficult to control.

In the digital environment, acts of copyright infringement are very typical in all types of works that are subject to copyright. For example, some specific areas are as follows:

A. IN TERMS OF THE FILM INDUSTRY

It is shown that with just a few simple steps, subjects with basic information technology knowledge can build their own website and provide direct links that lead to other online movie sites or upload it to the website to watch movies for free. Users who do not need to register as a member of the website can still watch movies online.
without having to pay and choose the quality of SD, HD, Full HD, or 3D movies. To go to cinemas today, it will cost about VND 50,000 to VND 150,000 for a movie ticket/person with international standard sound quality, screen and blockbuster movies released in Viet Nam for the first time. However, just sitting at home with an Internet-connected computer or a ‘smartphone’ with an Internet connection, just a few days after the movie was shown in theatres, users are able to enjoy those movies. Thus, consumers benefit from watching movies online for free on websites, and the creators of websites also reap huge profits thanks to the increasing views. At the seminar, protecting film and television copyright, held in June 2015 in Ho Chi Minh City, within the framework of the international exhibition, Vietnamese film and television technology, 2015 statistics show that: ‘30%-40% of movies are now distributed online right after their release’.

According to the inspection report of the Ministry of Culture, Sports and Tourism, from 2007 to now, the situation of copyright infringement for cinematic works on the Internet has taken place on an increasingly large scale, focusing on the type of movies shown in theatres and foreign movies.

B. IN THE FIELD OF PUBLICATIONS

If making pirated books needs to go through many time-consuming stages such as copying, printing, or publishing, then for works that spread on the internet, copying out many versions is extremely simple and hardly takes much effort and time. E-book sharing websites with famous names such as, thuvienebook.com, vnthuquan.com, songhuong.com.vn, ebook4u.vn, sahara.vn, and others regularly upload useful books on the Internet, thereby attracting numerous domestic customers. These illegal electronic publications are often available on the internet only a few days after their print release. The number of literary works fully published on these websites is fairly large.

C. IN RESPECT OF COMPUTER SOFTWARE

According to the statistics of Microsoft and Vietnamese software companies, pirated computer software in Vietnam accounts for more than 98% – an overwhelming number compared to the world average rate of approximately 50% of computer software is pirated.

The current state of copyright infringement on computer software in Viet Nam mainly focuses on the following forms:

a) Softlifting

’Softlifting’ is the term used when a person purchases a licensed copy for one person’s use only of a program but that person uploads it to multiple machines for multiple users. In today’s digital environment, softlifting is the most common type of intrusion and probably the easiest way to implement.

b) No Restrictions on Client Access

The infringement by not restricting client access occurs when a copy of a software program is copied to an organization’s server and that organization’s client system is allowed to freely access that software. This violates the owner’s IP rights in the software. Additionally, violations occur when an organization has a single license that allows the installation of software to a single machine, but the organization allows the clients to access the software freely, free of charge, without the permission of the owner.

c) Preload in Hard Drive

Preload in hard drive occurs when an individual or company selling the computers installs on the computers handling of copyright infringement with computer programs in Viet Nam today.

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33 Copyright infringement with computer programs in Viet Nam and
34 Prof. Dr. Vu Thi Hai Yen, Textbook of Hanoi Law University 2021, p. 53.
Le Thi Bich Thuy, Protection of Copyright in the Digital Environment in Viet Nam

permission. This violation is very commonly done by the selling-computer company to encourage buyers.

Secondly, the authorities face many difficulties in detecting and handling copyright infringement acts in the digital environment.

In the digital environment, copyright infringement cases are accomplished by several new methods and tricks such as applying high technology, using modern equipment to edit, distort and change the content of the original script, creating many different works that make it challenging for the public to distinguish which is the original one. This phenomenon causes physical and mental damage to the author or owners of the work – people who have to spend a large amount of money to create works to send to the public. In fact, it is not that the authorities are unaware of the rampant status as well as the harmful effects of piracy in the digital environment. However, this is a new form of violation, the area of violation is virtual and wide. In addition, the sanctions are not kept up with reality and are not deterrent enough, making violations become increasingly public and blatant.

There are a number of reasons why authorities have difficulty in detecting and handling copyright infringement acts in the digital environment, which are:

(i) It is difficult to prove copyright infringement in the digital environment; it is hard to determine the damage because usually the information and content of works put on the digital environment is not intended to collect fees for readers and viewers, but mainly to attract advertising and collect money from advertising.

(ii) Upon detecting copyright infringement, website administrators can easily and quickly remove and destroy infringing information.

(iii) The authorities do not have high expertise and depth in the field of copyright protection, especially copyright protection in the digital environment.

(iv) The person who has been infringed or infringed upon copyright has not requested the proper competent authority to settle to protect his/her interests.

(v) There are no specific sanctions in handling copyright infringement acts in the digital environment.

4. PROPOSING SOLUTIONS TO IMPROVE VIETNAMESE LAW ON COPYRIGHT PROTECTION IN THE DIGITAL ENVIRONMENT

From the overview of the law and the current situation of copyright infringement in the digital environment in Viet Nam, the author finds that it is necessary to improve the Vietnamese law on the following points:

A. ENACTING NEW LEGISLATION OR AMENDING EXISTING LEGISLATION ON COPYRIGHT PROTECTION IN THE DIGITAL ENVIRONMENT.

Currently, regulations on copyright protection in general and regulations on copyright protection in the digital environment, in particular, are generally stipulated in the 2005 Intellectual Property Law together with the adjustment of other relations on IP rights (industrial property rights and rights to plant varieties). This leads to the fact that it is very difficult to consult the provisions of the law, especially those specific to copyright protection in the digital environment. The regulations intertwined with the provisions on copyright protection, in general, make the regulations on copyright protection in the digital environment in Viet Nam currently quite faint. The need to issue separate and independent regulations on copyright protection in the digital environment not only is a problem of form and technique but also shows the specificity and difference in copyright protection between traditional and digital environments. This is corresponding to the general trend of the world in this field. However, this is a long-term solution because when

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the copyright protection in the traditional environment in Viet Nam is still quite inadequate, the implementation of this solution is rather early, and not feasible.

The advent and rapid development of technology, or the birth and development of the Internet in detail, leads to the lack of a number of specific provisions in copyright protection in the digital environment in Viet Nam that are currently causing certain difficulties in copyright protection in the digital environment. These are the provisions that Vietnamese law needs to amend and supplement in the near future. Specifically, some of the provisions are as follows:

B. REGARDING TEMPORARY COPYRIGHT

Provisions on temporary copying are recorded in Clause 10, Article 4 of the 2015 Intellectual Property Law; Clause 2, Article 23 of Decree 100/2006/ND-CP, whereby the right to temporary reproduction belongs exclusively to the author and copyright holder. However, according to Decree 85/2011/ND-CP, the creation of temporary copies was not under the exclusive control of the author/copyright holder. However, according to Decree 85/2011/ND-CP, the creation of temporary copies was not under the exclusive control of the author/copyright holder. In Decree 22/2018/ND-CP, temporary copies were not mentioned, more specifically, Clause 2, Article 21 of this Decree stipulates:

> The right to copy works provided at Point c, Clause 1, Article 20 of the 2015 Intellectual Property Law is the right of the copyright holder to exclusively perform or permit others to make copies of the work by any means or form, including making copies in electronic form.

This shows the ambiguity in the provisions of Vietnamese law on temporary copyright. This is a huge obstacle to identify copyright infringements in the digital environment.

In terms of technology, it is shown that in the digital environment, any object of copyright can be shaped by a ‘file’, so based on that, the protected object can be identified, copied and communicated to the public. The transmission of data in the current digital environment is carried out by technology called ‘packet chaining’, using the TCP/IP Internet protocol suite. The consequence of using the above technology is that a ‘temporary copy’ of data must always be created in the computer’s RAM at an intermediate node on the network or in the RAM of the device performing a similar function in the data transfer process.

In the traditional environment, the right to copy is always associated with tangible copies, and there is a clear line between the use of reproduction-related and non-reproduction-related protected objects. However, in the digital environment, the line between using a protected work attached to a copy and not attached to a copy is blurred because almost every use of a work is always accompanied by copying a protected subject, at least temporarily copy.

The question arises, whether a temporary copy in the digital environment is considered an object of copyright protection? The scope of copyright protection for authors and right holders in the digital environment will be much wider than in the traditional environment if it is protected. Similarly, the restrictions on author rights (allowing to use the work whether the rights holder agree or disagree) will be narrower than in the traditional environment.

In order to determine which temporary copies are subject to copyright protection and which “temporary copies” are not, Vietnamese law should provide the basis for the lifetime of the data in ‘RAM’. If the lifetime in ‘RAM’ is too short, the copy is considered ‘transitional’ only, and then when the computer is powered off and the ‘temporary copy’ is completely lost, it is not an object protected by copyright. Therefore, the subjects making temporary copies in this situation do not infringe
C. ADD PARTICULAR SANCTIONS TO APPLY TO COPYRIGHT INFRINGEMENT ACTS IN THE DIGITAL ENVIRONMENT

Specifically, the application of compensation for damage and sanction measures for copyright infringement acts in the digital environment needs to show particularity compared to the traditional environment. Compared to the traditional environment, the same violation (for example, illegal copying) in the digital environment brings much greater damage to the right holder. Therefore, the way to determine the damage as well as the calculation of the level of compensation must also clearly show the differences so that it corresponds to the physical and spiritual damage that the right holder may lose due to the act of copyright infringement in the digital environment. Correspondingly, sanctions should be specific to each copyright infringement in the digital environment and be strong enough not only to punish but also to deter subjects performing these acts. Clearly define the responsibilities of individuals and organizations providing Internet services in case the subject of copyright is infringed in the digital environment.

The law needs to clearly define the role of Internet service providers being most important in the distribution of copyright infringing objects in the digital environment. This subject must have responsibilities (civil liability, administrative responsibility, and possibly even criminal liability) before State agencies and right holders, and must have an obligation to coordinate in the handling requests of the right holders to prevent the storage and transmission of copyrighted objects in the digital environment without their permission.

Joint Circular No. 07/2012/TTLT-BTTTT-BVHTTD stipulates the responsibilities of enterprises providing intermediary services on the Internet. For instance, the right holder must indirectly go through another agency (the Inspector of the Ministry of Information and Communications or the Inspector of the Ministry of Culture, Sports and Tourism or other competent state agencies). Therefore, up to now, copyright holders have not been able to directly contact Internet service providers to request the removal of works that infringe copyright on images on the Internet. This is a huge limitation that makes detecting and handling copyright infringements in the digital environment less effective. Additionally, the regulations on removing copies of infringing works in electronic forms in the Internet environment need to be detailed on the technique of the performance, the authority of the performer, and the responsibilities of individuals and organizations involved in removing infringing works from the Internet.

Furthermore, the law needs to clearly specify the joint responsibility for individuals and organizations that facilitate acts of copyright infringement, such as providing broadcasting equipment or encouraging users to record television programs or cinematographic works broadcast on television for later viewing (yet no liability will be imposed if the provider can prove that he did not abet the infringement, or that such violation has no commercial significance).  

5. CONCLUSIONS

Although there is no separate legal document on copyright protection in the digital environment,

27 US law provides for very high penalties for illegal copying. Specifically, first-time copyright infringement through the Internet can result in fines of up to USD 500,000 or up to five years in prison. For repeated violations, there may be a fine of USD one million or 10 years in prison. (Mike Masnick (2013), How unlocking your phone may now be a crime: $500,000 fines and 5 years in prison for first offense <https://www.techdirt.com/blog/wireless/articles/20130128/02192521803/how-unlocking-your-phone-may-now-be-crime-500000-fines-5-years-prison-first-offense.shtml>).


29 Joint Circular No. 07/2012/TTLT-BTTTT-BVHTTD, Article 5(4).

30 Do Khac Chien (n 27).
Vietnamese law has a legal framework for copyright protection in the digital environment. These regulations are the legal basis for right holders and authorities to enforce copyright and protect the rights and legitimate interests of right holders in the digital environment. However, copyright protection in the digital environment is a very new legal area for Viet Nam, so it is inevitable for certain inadequacies to be present in the legal provisions (most obvious is the lack of specific regulations on handling copyright infringements in the digital environment) as well as limitations from protection really need to be further researched and perfected.

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15. THE ISSUES OF INTERNATIONAL LAW ABOUT PUBLIC HEALTH RELATING TO IP RIGHTS

Zhang Naigen*

ABSTRACT

Public health is highly significant for the common interest of mankind. The rule of international law about public health relating to intellectual property (IP) rights was initially provided by Article 8.1 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) as a general principle which expressly provides the necessary protection of public health in addition to other provisions implied by this issue. This principle was addressed directly or indirectly with limited scope by the dispute settlement body (DSB) during the dispute settlement process of the World Trade Organization (WTO) in respect of public health and IP. The principle was further promoted by the Doha Declaration on the public health and the amendment of the TRIPS Agreement upon considering the needs of developing and least-developed countries (LDCs) regarding accessibility and affordability of medicines. However, the problems arising from the application of this principle in practice reveal the limits of international law such as exceptions to protect IP rights for public health. Facing the unprecedented challenge to combat COVID-19, China proposed to build a global community of health for all by strengthening the rules of international law. By reviewing the origin and evolution of the issues of international law about public health relating to IP rights, it might be better to understand the limits of the existing international laws. Accordingly, the research on the issues of IP rights in international cooperation to fight the COVID-19 pandemic would be helpful to improve the relevant rules of international law.

Keywords: international law, public health, intellectual property rights, COVID-19, medical patent, test data, waiver.

1. INTRODUCTION

The COVID-19 pandemic brought unprecedented challenges for global public health. It may need application of the existing international intellectual property (IP) laws relating to public health such as the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), for effective legal solutions against COVID-19. For instance, Article 8.1 of the TRIPS Agreement provides a general principle for Members of the World Trade Organization (WTO) to adopt measures necessary to protect public health if such measures are consistent with the provisions of this Agreement. This principle was affirmed in the Doha Declaration on the TRIPS Agreement and Public Health (Doha Declaration) with some flexibilities for Members to enforce their rights in this regard. However, it appears to be difficult to apply either this principle or its flexibilities for combating COVID-19. For example, the WTO Members could not reach a consensus on the proposal for a temporary waiver of the TRIPS obligations in response to COVID-19 until the WTO Ministerial Conference adopted a Decision on the TRIPS Agreement recently. The proposal does not mention Article 8.1 and simply requires waiving off the TRIPS obligations of the Members. The adopted Decision provides any eligible developing country with a temporary waiver of obligations under Articles 28.1 and 31(b), (f) and (h), but the adequate remuneration of compulsory licensing will not be waived. It shows the problems of limitation or lack of applicable international laws about public health relating to IP. However, it might be immature to consider and elaborate the Decision in

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1. Legal text of the TRIPS Agreement, see the WTO Agreements, updated edition of the legal texts (Cambridge University Press 2017) 396.
2. The Doha Declaration on the TRIPS Agreement and Public Health, WT/MIN (01)/DEC/2 (20 November 2001).

Draft Ministerial Decision on the TRIPS Agreement, Revision, WT/MIN (21)/W/15/Res.2 (17 June 2022).
detail at the moment and would be updated by another paper in the future.

These problems have already been implied by the disputes settlement body (DSB) panels as well as appellate body (AB) in the cases of India-Patents\(^5\) and Australia-Tobacco Plain Packaging\(^6\). The AB ruled that the panel in the India-Patents case misunderstood the concept of legitimate expectation to protect IP rights provided for in the TRIPS Agreement. However, it noted that the panel correctly reached the conclusion that India had not complied with its obligations under the TRIPS Agreement to make a unique way (so-called mailbox) available for other WTO Members’ nationals to apply for medical patents during the transitional period.\(^7\) Article 8.1 was not referred to at all in the India-Patents case because any measure necessary to protect public health was to be adopted only if the measure was consistent with the provisions of the TRIPS Agreement, such as the requirement of a mailbox for application of medical patents. It might be the reason why India and South Africa proposed to waive the TRIPS obligations instead of resorting to the general principle under Article 8.1. The waiver proposal does not mention Article 8.1 at all, because it is not enough to adopt the domestic measures necessary to combat COVID-19 from the Indian and South African perspectives. They proposed to suspend IP rights for fighting against COVID-19.

The panel in the Australia-Tobacco Plain Packaging case believed that the Doha Declaration may be considered as a ‘subsequent agreement’ between the WTO Members for the purpose of treaty interpretation.\(^8\) But the AB does not clarify the legal status of the Doha Declaration in terms of whether it should be regarded as a ‘subsequent agreement’.\(^9\) Therefore, even now, the legal status of the Doha Declaration remains uncertain while the international community battles the COVID-19 pandemic. In case of uncertain legal status of the Doha Declaration, it seems no binding rules relating to domestic measures under Article 8.1. The issues arising from such uncertainty would include the accessibility and affordability of COVID-19 vaccines and protection of medical patents or undisclosed clinical trial data, the special measures of protection for traditional knowledge to treat patients affected by COVID-19. The key issue is how to control the COVID-19 pandemic on account of IP rights resulting from medical research and production.

Additionally, while focusing on exceptions to patent rights under Article 30 of TRIPS Agreement, the panel in the Canada-Pharmaceutical Patents case does mention Article 8.1 saying that ‘the exact scope of Article 30’s authority will be examined with particular care on this point. Both the goals and limitations stated in Articles 7 and 8.1 must obviously be borne in mind when doing so as well as those in other provisions of the TRIPS Agreement which indicate its object and purposes.’\(^10\)

However, the panel did not interpret Article 8.1 through its discussion on exception to patent rights. It ruled that the regulatory review exception (Bolar exception) could be justified for the reasons of no prejudice to the ‘legitimate interests’ of affected patent owners within the meaning of Article 30 because of limited test production for only regulatory review and no conflicts with a normal exploitation of patents. The legal issue of this case is actually related to the conflict of commercial interest between medical patent holders and generic producers. For this reason, it may not be necessarily included in the analysis of public health.

To analyse the issues of international IP law regarding public health from the academic perspective, firstly, the paper traces the origin of Article 8.1 of the TRIPS

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\(^7\) Ibid 5, WT/DS50/AB/R, para. 97.

\(^8\) Ibid 6, WT/DS435.441,458,467/R, para. 7.2409.


Agreement to understand the intentions of the drafter and the legal status of the Doha Declaration. Secondly, it reviews the jurisprudence in the India-Patents and Australia-Tobacco Plain Packaging cases to understand the limits of the TRIPS Agreement with respect to public health. Thirdly, it focuses on the regulatory issues regarding accessibility and affordability of the COVID-19 vaccines and other aspects relating to IP rights. Lastly, the paper presents its conclusions.

2. THE ORIGINAL RULE OF INTERNATIONAL LAW ABOUT PUBLIC HEALTH RELATING TO IP RIGHTS AND EVOLUTIONARY CHANGES

There were no rules about public health in international IP laws until Article 8.1 of the TRIPS Agreement was introduced which requires that WTO Members ‘may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health’, ‘provided that such measures are consistent with the provisions of this Agreement.’ What was the intention to make this rule? The following analysis is based on the official documents of the TRIPS negotiation. There might be different ideas in regarding the TRIPS balance for further tracing of more sources of the negotiation. However, these documents did disclose the original draft of Article 8.1 and its evolutionary changes.

Article 8.1 was drafted originally as an exception to the availability of medical patents. The United States (US) was the initiator to include the TRIPS as the new subject of the multilateral trade negotiation that begun in the later 1980s.11 One of the purposes underlying this initiation was to extend patent protection to all fields of technology, in particular, the pharmaceutical industry, which was reflected in Article 27.1. This Article first appeared in the early draft of the TRIPS Agreement, i.e., the Chairman’s draft of 23 July 1990.12 This draft had the original article on patentable subject matter with several exceptions of patentability including public health, which provides as follows:

‘1.1 Patents shall be [available] [granted] for [any inventions, whether products or processes, in all fields of technologies,] [all products and processes] which are new, which are unobvious or involve an inventive step and which are useful or industrially applicable.

1.4.1 Invention [the publication or use of which would be], contrary to public order, [law,] [generally accepted standards of] morality, [public health,] [or the basic principle of human dignity] [or human values].

1.5B PARTIES may exclude from patentability certain kinds of products, or processes for manufacture of those products on ground of public interest, national security, public health or nutrition.’ (underline added).

The Chairman’s draft also had the original Article 8.1 including the protection for public health:

‘8B.2 In formulating or amending their national laws and regulations on IP rights, PARTIES have the rights to adopt appropriate measures to protect public morality, national security, public health and nutrition, …’ (underline added).

Article 27.1 of TRIPS Agreement finally provides as follows:

‘Subject to the provision of paragraphs 2 and 3, patents shall be available for any inventions, whether products or process, in all fields of technology, provided that they are new, involve


an inventive step and are capable of industrial application [...]'.

But, the final text of Articles 27.2 and 27.3 provides exceptions of patentability without referring to ‘public health’. This means that public health should not be regarded as the legitimate exception of patentability. In comparison with the early draft of TRIPS Agreement on the exception of patentability including public health, the final text of this matter indicates the particular favour for the pharmaceutical industry because of no exception of medical patentability for public health. However, the final text of Article 8.1 preserves the public health as a general principle to adopt necessary regulatory measures in formulating or amending the Members’ IP laws and regulations. It must be noted that this preservation of public health and other reasons for such measures includes a substantial condition: ‘provided that such measures are consistent with the provisions of this Agreement’. It was added in the last stage to finalize Article 8.1.13 In contrast with eliminating the public health as an exception of patentability in Article 27, the added restriction would be mandatory for any such measure possibly taken. It is interesting that the Brussels Draft of December 199044 had no such restriction as the previous Chairman’s draft, but the Dunkel Draft of December 199115 added it as the final legal text of the TRIPS Agreement. It was disclosed that, during the last phase of negotiation, delegations from developing and least-developed countries (LDCs) strongly called for a balance between the interests of IP holders and public policies in the TRIPS Agreement;16 but the final results did not favour them because the final text of Articles 27.2 and 27.3 provide the exceptions of patentability excluding public health while allowing Members to adopt necessary measures to protect public health under the restrictive condition in Article 8.1. No further official information was disclosed in respect of such evolutionary changes. It might be the reason that Article 8.1 as a principle for protection of public health to favour developing countries and LDCs. However, the wordings of restriction in fact are not favoured. It is unknown why and how such restriction was proposed and finally added.

The intention to finalize Article 8.1 would be understood by the above examination of its origin and evolution. It seems that the drafters did not want to make Article 8.1 a mandatory rule to protect public health relating to IP rights, because the text uses the word ‘may’, thereby providing an option to Members to adopt necessary measure to protect public health while imposing a mandatory obligation, i.e., such measure to be consistent with provisions of the TRIPS Agreement, especially those relating to patent protection. Professor Daniel Gervais, a member of the drafting team of TRIPS, believes that ‘Article 8 is thus essentially a policy statement that explains the rationale for measures taken under Articles 30, 31 and 40.’17 The principle under Article 8.1 as ‘a policy statement’ is definitely different from the exceptional provision as a substantial right. The draft of the Article about public health relating to IP rights was originally an exception to the availability of medical patents, which would provide the WTO Members with substantial rights to adopt necessary measures to protect public health without restricted conditions. However, the final text of the TRIPS Agreement has no such substantial right and instead places a restricted option to protect public health as a principle. It is obviously not balanced because the principle to protect public health as ‘a policy statement’ and the substantive exception of patentability for public health are not equivalent. The Doha

13 Gervais D, The TRIPS Agreement: Drafting History and Analysis (Sweet & Maxwell 1998) 68.
44 Draft Final Act Embodying the Results of the Uruguay Round of Multilateral Negotiations, MTN.TNC/W/35/Rev.1 (3 December 1990). This draft was submitted to Ministers meeting in Brussels including the draft on TRIPS, therefore it is entitled as “Brussels Draft”.
17 Ibid 13. Articles 30, 31 and 40 provide respectively the exception to patent rights conferred, other use without authorization of patent right holder and control of anti-competitive practice in contractual licenses.
Declaration intended to balance public health and IP rights as follows:

We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all.

In this connection, we reaffirm the right of WTO Members to use to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.’

The problem is the uncertainty of its legal status. Shortly after adopting it, some comments were made, such as ‘[T]he legal status of the Doha Declaration is ambiguous. One possibility is that they are merely political statements or moral commitments of trade ministers.’

It was also asserted that ‘...except for that application deadline for LDCs on patents and trade secrets regarding pharmaceuticals, the Ministerial Declaration does not provide anything new nor offer further clarity than already existed.’ These negative comments further indicated the intention to finalize Article 8.1 with the principle on public health that would be difficult to apply in practice because Article 8.1 remains unchanged as ‘a policy statement’ after the Doha Declaration in the view of these comments. Of course, Article 31 has been amended in accordance with the Doha Declaration for developing countries and LDCs to obtain affordable medicine, which demonstrates the mandatory restriction on any measures of public health. Article 31 had to be amended, otherwise, such measures would be inconsistent with the provisions of the TRIPS Agreement.

In addition to Article 8.1 as a general principle expressly providing the necessary protection of public health, other provisions may imply public health. For example, Article 27.3(a) provides an optional exception of patentability for “diagnostic, therapeutic and surgical methods for the treatment of humans”. It might be relevant to public health. However, the drafting history as discussed above has indicated that it would not be regarded exclusively for public health. “It also remains uncertain whether the exclusion also applied to invention that is only partly, or even just potentially, used to treat human”. It is uncertain whether other implied provisions are in fact relevant to public health, which depends on a case-by-case analysis such as with the India-Patents and Australia-Tobacco Plain Packaging cases.

3. JURISPRUDENCE OF CASES ABOUT PUBLIC HEALTH RELATING TO IP RIGHTS

The jurisprudence of the India-Patents and Australia-Tobacco Plain Packaging cases tells us more about the limits of the TRIPS Agreement with respect to public health. The India-Patents case was the first TRIPS case with rulings passed by a WTO panel and the AB in 1997. The US and European Union (EU) accused India of violating the TRIPS Agreement because of its failure to provide medical patent holders with the required way to apply for a patent while granting them exclusive marketing rights during the transitional period. Traditionally, India produced generic drugs to meet the needs of public health without patent protection. Articles 65.2 and 65.4 of the TRIPS Agreement offer developing countries a maximum transitional period of

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20 The TRIPS Agreement was amended to have Article 31bis on special arrangement of compulsory license for medical patent through the Protocol Amending the TRIPS Agreement, done at Geneva on 6 December 2005, which entered into force on 23 January 2017.
22 See Chaudhuri S, the WTO and India’s Pharmaceuticals Industry: Patent Protection, TRIPS, and Developing Countries (Oxford University 2005).
10 years to establish their patent regime. However, Articles 70.8(a) and 70.9 respectively provide as follows:

8. Where a Member does not make available as of the date of entry into force of the WTO Agreement patent protection for pharmaceutical and agricultural products commensurate with its obligations under Article 27, the Member shall:
   (a) Notwithstanding the provisions of Part VI, provide as from the date of entry into force of the WTO Agreement a means by which applications for patents for such inventions can be filed;

9. Where a product is the subject of a patent application in a Member in accordance with paragraph 8(a), exclusive marketing rights shall be granted, notwithstanding the provisions of Part VI, for a period of five years after obtaining marketing approval in that Member or until a product patent is granted or rejected in that Member, whichever period is shorter, provided that, subsequent to the entry into force of the WTO Agreement, a patent application has been filed and a patent granted for that product in another Member and marketing approval in such other Member.

These provisions were drafted carefully to protect essentially the interests of medical patent holders in developing countries during the transitional period. Although within that period of time there would be no obligations for developing countries to protect patent, they had to provide, upon the entry into force of the WTO Agreement, the medical patent holders with the exclusive marketing rights. It requires that patentees have already obtained the patents and marketing approvals in their home countries before applying for the medical patents for future examination through the 'mailbox' in developing countries. In comparison with the normal application of the TRIPS Agreement even for developed countries from 1 January 1996 under Article 65.1, it shall be begun on 1 January 1995 under Article 70.8(a) to protect the exclusive marketing rights for medical patents. One year earlier even in the transitional period for developing countries under Article 65.2. The India-Patents case clarified the meaning of the term 'a means' as 'mailbox' under Article 70.8(a) and the date begun on 1 January 1995 to grant the exclusive marketing rights under Article 70.9.

India-Patents is a case relating to medical patents. However, India did not claim the necessary protection of public health for its domestic measures because of possible inconsistency with Articles 70.8(a) and 79.9. India argued that 'a means' as the transitional way had existed for a patent application, but the exclusive marketing rights could not be granted upon entry into force of the WTO Agreement. The panel rejected India's arguments by interpreting the relevant Articles based on the principle of legitimate expectations derived from the jurisprudence of pre-WTO dispute settlement. 'In conclusion, we find that, when interpreting the text of the TRIPS Agreement, the legitimate expectations of WTO Members concerning the TRIPS Agreement must be taken into account.' In applying this principle, the panel interpreted the words 'a means' as 'mailbox' to receive applications of medical patents to 'sufficiently protect the legitimate expectations of other WTO Members as to the competitive relationship between their nationals and those of other Members, by ensuring the preservation of novelty and priority in respect of products which were the subject of mailbox applications.' The panel also traced the same approach to find that 'India failed to implement its obligation under Article 70.9 and honour the legitimate expectations of its trading partners to that effect.'

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23 ibid 5, WT/DS50/R, para. 7.22. The panel refers the pre-WTO case 'United States – Taxes on Petroleum and Certain Imported Substances' (adopted on 17 June 1987, BISD345/136, para. 5.2.2).

24 ibid 5, WT/DS50/R, para. 7.31.

25 ibid 5, WT/DS50/R, para. 7.63.
The AB, on the other hand, stated that:

‘we do not agree with the Panel that the legitimate expectations of Members and private rights holders concerning conditions of competition must always be taken into account in interpreting the TRIPS Agreement.’

However, it upheld the panel’s final rulings. It found that India had failed to fulfil its burden of proof by not providing sufficient evidence of the existing ‘means’ in the form of ‘mailbox’ and consequently violated its obligation to grant exclusive marketing rights for the medical patent holders of other Members upon entry into force of the Agreement.

The AB’s ruling in the *India-Patents* case is quite interesting, especially its interpretation of the Agreement provisions. The panel misunderstood the principle of interpretation, but its conclusion could be correct based on India’s failure of its burden of proof in accordance with the AB’s rulings. In fact, this conclusion mainly came from the panel’s misinterpretation of the Agreement to find India’s failure to sufficiently protect the legitimate expectations of other WTO Members. It is very unusual in WTO dispute settlements to misinterpret the Agreement while getting a correct conclusion. In other words, it is an unique case with the AB’s affirmation of the panel’s decision and partial rejection of its legal reasoning on the legitimate expectations. Of course, there are a number of cases where the AB reversed the panels’ interpretations of the covered agreements while upholding their decisions. However, in some cases, the panel actually correctively made its interpretation. It might be a different understanding of the AB’s interpretation on case-by-case basis. For example, the AB reversed the panel’s interpretation of the word ‘seek’ under Article 13 of Understanding on Rules and Procedures Governing the Settlement of Disputes broadly without properly considering its text (‘to seek’) and context (‘Each panel shall have right to seek information...’ underline added) in compliance with Article 31 of Vienna Convention on the Law of Treaty. In essence, the AB grants the rights of submission to the non-requested information provider.

Returning to the *India-Patents* case, the underlying idea of the jurisprudence might be described by a commentator’s words: ‘securing compliance with the TRIPS Agreement’. That’s all. It does not matter whether the domestic measures have been taken to protect public health or not, the priority is compliance with the mandatory provisions of the TRIPS Agreement. The unbalanced rules inevitably restrict the application of the principle to protect public health. As described above, the final text of TRIPS Agreement does not have the original proposed exception of patentability for public health instead of a principle to protect public health with mandatory restriction. Meanwhile, Articles 70.8(a) and 70.9 provide the medical patentees with exclusive marketing rights in developing countries upon entry into force of the Agreement in the case to meet ‘mailbox’ requirements. It is unblanced overall. India could not resort to the principle of Article 8.1 as the exception of applications of these articles regarding ‘mailbox’ because of compliance requirements with the mandatory restriction which prevail over the principle as such. It must be noted that the *India-Patent* case did not address the principle of Article 8.1 to interpret the words ‘necessary’ and ‘consistent’. The above comment on the rulings of the panel and AB of this case aims to reveal the limits of Article 8.1 in regard of public health relating to IP rights. Therefore, it is not necessary to discuss further on the test of necessity and consistency of this Article as some commentators made.

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Could the Doha Declaration be applied in practice to have a balanced effect? We may get either a ‘yes’ or ‘no’ from the jurisprudence in the *Australia-Tobacco Plain Packaging* case. No doubt, this case touches upon the issue of public health. Australia promulgated the Tobacco Plain Packaging Act (TPP measures) in 2011 to regulate retail packaging and appearance of tobacco products in order to improve public health and give effect to certain obligations in the Convention on Tobacco Control which Australia joined in 2004. The TPP measures would be considered as legitimate measures for public health purposes under Article 8.1 if they are consistent with its provisions. Article 20, in particular, is relevant, and it reads as follows:

‘The use of a trademark in the course of trade shall not be unjustifiably encumbered by special requirements, such as use with another trademark, use in a special form or use in a manner detrimental to its capability to distinguish the goods or services of undertaking from those of other undertakings.’

The critical issue is the interpretation of the terms “special requirements” and “unjustifiably encumbered”. Do the TPP measures constitute such “special requirements”? If the answer is in the affirmative, then do they “unjustifiably encumber” the use of a trademark in the course of trade? The complaints’ claim in the case stood affirmed. The panel, firstly, interpreted the elements and clarified that the term ‘special requirements’ referring to a condition that must be complied with, has a close connection with or specifically addresses the ‘use of trademark in the course of trade’, and is limited in application. This may include a requirement not to do something, in particular a prohibition on using a trademark. The TPP measures are ‘special requirements’ because of its prohibition on using any trademark or other mark appearing anywhere on tobacco products, therefore, ‘encumbrances arising from special requirements’ may include a prohibition on the use of a trademark in certain situation.

Secondly, the panel interpreted ‘unjustifiably encumber’ stating that ‘Article 20 does not expressly identify the types of reasons that may form the basis for the ‘justifiability’ of an encumbrance.’ Then, the panel opined that ‘Article 8 offers, in our view, useful context guidance for the interpretation of the term ‘unjustifiably’ in Article 20.’ Additionally, the Doha Declaration could be considered as a ‘subsequent agreement’ of WTO Members. The panel’s conclusion is that ‘Article 20 reflects the balance intended by the drafters of the TRIPS Agreement between the existence of legitimate interests of trademark owners in using their trademarks in the marketplace, and the right of WTO Members to adopt measures for the protection of certain social interests that may adversely affect such use.’ Overall, the AB agreed with the panel’s interpretation stating that ‘encumbrance on the use of trademarks by special requirements under Article 20 may also be imposed in pursuit of public health objectives.’ The AB did not clarify whether the Doha Declaration constitutes a ‘subsequent agreement’ or not. It is vague that the AB confirmed the panel’s decision based on interpretation of Article 20 in the context of Article 8.1 and kept silence on the legal status of the Doha Declaration. It might be understood that the AB used to be cautious to confirm a subsequent agreement. It was only once in the case of US-Clove Cigarettes the AB interpreted that “in our view, paragraph 5.2 of the Doha Ministerial Decision can be characterized as a ‘subsequent agreement’ with the meaning of Article 31(3)(a) of the Vienna Convention [on the Law of Treaties] provided that it clearly expresses a

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30 *Australia-Tobacco Plain Packaging* is the biggest case ever in the history of dispute settlement under the TRIPS Agreement. It was initiated by five WTO Members, Honduras, Dominican Republic, Cuba, Indonesia and Ukraine in 2012. The Reports of the Panel and the AB issued respectively in 2018 and 2020 have more than 1000 pages. Ukraine withdrew from the panel proceeding, then Honduras and Dominican Republic continued the appeal.


32 Ibid 6, WT/DS435.441,458,467/R, para. 7.2231.

33 Ibid 6, WT/DS435.441,458,467/R, para. 7.2397.

34 Ibid 6, WT/DS435.441,458,467/R, para. 7.2404.


common understanding, and an acceptance of that understanding among Members with regard to the meaning of the term ‘reasonable interval’ in Article 2.12 of the TBT Agreement.\textsuperscript{37} The AB may believe that Doha Declaration should not be regarded as a subsequent agreement as US-Clove Cigarettes case because of no decision to express ‘common understanding’ and ‘an acceptance of that understanding among Members’ regarding the public health under Article 8.1. The Declaration may not be equivalent to the decision as the legislative interpretation under Article 9.2 of Marrakesh Agreement Establishing the World Trade Organization.

The Australia-Tobacco Plain Packaging case favours public health as the Doha Declaration requires having the balanced effects over the trademark owners’ rights. That is the answer of ‘yes’ referred above. It refers to Article 8.1 expressly and the Doha Declaration for the purpose of interpretation of Article 20. It appears to have clarified the term ‘unjustifiability’ to mean that the necessary measures may be justifiable to pursue the public health objectives. However, it should be noted that the text of Article 20 itself already provides the types of reasons that may form the basis to find the unjustifiability of an encumbrance, i.e., ‘such as use with another trademark, use in a special form or use in a manner detrimental to its capability to distinguish the goods or services of undertaking from those of other undertaking’. Those listed types of special requirements should be interpreted as acts with potential effects to unjustifiably encumber the use of a trademark in the course of trade. Professor Daniel Gervais explained that the use of the term ‘such as’ shows that the Article lists \textit{prima facie} forms of unjustifiable special requirements.\textsuperscript{38} Article 20 is not silent on the types of reasons that may form the basis for the justifiability of an encumbrance. Therefore, it seems unreasonable for both the panel and the AB in Australia-Tobacco Plain Packaging to disregard the ‘\textit{prima facie} forms’ listed in Article 20 as the primary contextual guidance to interpret the relevant terms.

Article 8.1 and the Doha Declaration are simply purported to be taken as the ‘context’ or ‘supplementary means’ of interpretation (not applicable laws) for supporting the public health objectives. It might have good intentions; however, it is not appropriate for treaty interpretation. That is the answer ‘no’ in the terms of proper interpretation. The embarrassing situation as such in practice reflects again the limits of applicable law under the TRIPS Agreement regarding public health. The cases discussed above show that India could not resort to the principle of Article 8.1 to protect public health by non-application of ‘mailbox’ obligation, and Australia argued its TTP measures for public health under Article 20 by the WTO adjudicator’s unsound interpretation. The limits of TRIPS Agreement on public health are inherited in the unbalanced regime of public health and medical patent protection.

More discussions might be needed on the Australia-Tobacco Plain Packaging case regarding Article 8.1. However, the critical review above seems enough to explain the uncertain legal status of the Doha Declaration and limits of existing international law about public health related to IP rights.

4. **THE REGULATORY ISSUES UNDER THE TRIPS AGREEMENT TO COMBAT COVID-19**

We know from the drafting history of Article 8.1 and its applications as well as the uncertain legal status of the Doha Declaration that there are limited rules of international law relating to IP rights in practice. The India-Patents case does not resort to Article 8.1 because of Indian domestic measures being inconsistent with its provisions, even though they may concern public health. The ruling in the Australia-Tobacco Plain Packaging case refers to Article 8.1 as the interpretive context to clarify Article 20, however, Article 20 itself already has the ‘\textit{prima facie} forms’ of unjustifiable special requirements, which may not be interpreted to support the domestic


\textsuperscript{38} Ibid 13, 117.
measures for public health. These are the limits of applicable law regarding public health related to IP rights under the TRIPS Agreement when the international community is cooperating to combat COVID-19. The COVID-19 pandemic is a public health emergency of international concern with huge impacts on world trade. However, it may not constitute ‘other emergency in international relations’ under Article 73(b)(iii) of TRIPS Agreement in the panel’s view of the Russia-Traffic in Transit case.\(^{39}\) The fight against COVID-19 had to be primarily relied on medical control instead of resorting to anything of security exception, and meanwhile the great efforts must be made to improve the existing international laws about public health relating to IP rights. It appears obvious by learning from the jurisprudence in WTO cases in distinguishing the security exception from public health emergency of international concern.

China proposed to build a global community of health for all by international cooperation under the rules of international law. From these viewpoints, several regulatory issues should be analyzed. The ‘regulatory issues’ refer to the issues regarding the measures necessary to control the COVID-19 pandemic at the national and international levels, in compliance with both the provisions of the TRIPS Agreement and the flexibilities under the Doha Declaration.

A. THE ACCESSIBILITY AND AFFORDABILITY OF THE COVID-19 VACCINES

The first issue is the accessibility and affordability of the COVID-19 vaccines as public goods. Some pharmaceutical companies have made the COVID-19 vaccines available for emergency use. In addition to a few vaccines listed by the World Health Organization (WHO) for international use,\(^{40}\) several other vaccines have been approved by the national authorities for domestic use.\(^{41}\) The COVID-19 vaccines are mostly purchased by national governments and international organizations at reasonable prices to cover the costs of researchers, developers, and manufacturers so as to be accessible and affordable for anyone, anywhere. It might be free for citizens seeking to vaccinated, but it is not free to purchase the vaccines from producers. Otherwise, it would be impossible for pharmaceutical companies to continue their innovative research and production of the COVID-19 vaccines.

The utilization of the patent or its know-how may be a regulatory issue of the COVID-19 vaccines relating to IP rights. For example, Ms. Chen Wei, the Chinese vaccine scientist, invented the COVID-19 vaccine Adenovirus Type 5 Vector that was firstly put into domestic phase I clinical trial in March 2020 and then had successful phase II and III trails overseas.\(^{42}\) This vaccine was developed through cooperation between the Chinese pharmaceutical company CanSino Biological Inc. and the Beijing Institute of Biotechnology. They are the co-owners of the granted patent of this invented vaccine.\(^{43}\) It has been approved by the Chinese medical regulator for domestic emergency use. Under Chinese patent law in compliance with the TRIPS Agreement, it is prohibited to make, use, sell, offer for sale, and import the patented products, or to use the patented process for production without the patent owner’s consent.\(^{44}\) It would be an appropriate approach to first invent the COVID-19 vaccine through an individual or institutional scientist’s research or clinic trail supported by the developer, and then allow the developers to use the invented or

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\(^{39}\) The panel interpreted the terms of ‘other emergency in international relations’ as ‘a situation of armed conflict, or of latent armed conflict, or of heightened tension or crisis, or of general instability engulfing or surrounding a state’. Russia-Measures Concerning Traffic in Transit, WT/DS512/R (5 April 2019), para. 7.76. It was confirmed by the case Saudi Arabia-Measures Concerning the Protection of Intellectual Property Rights, WT/DS567/R (16 June 2020), para.7.256.\(^{40}\) The WHO listed COVID-19 vaccines are Pfizer, Astraneca, Janssen, Moderna, Sinopharm/BIBP, Sinavac, Bharat Biotech, Novavax and CanSinoBIO. See Status of COVID-19 vaccines within WHO EUL/PQ evaluation process, 26 May 2022.

\(^{41}\) For an example, the Chinese company produced the vaccine (CanSinoBIO) which has been approval for domestic emergent use while waiting approval of WHO until 26 May 2022. Ibid 40.

\(^{42}\) See Phase I Registration No. ChiCTR2000030906 (2020-03-17), Phase III ChiCTR2000034780 (2020-07-19) and NCT04540419 (2020-09-07).

\(^{43}\) See China Patent No. 20201039587.8 (2020-08-11).

\(^{44}\) Patent Law of People’s Republic of China was promulgated on 12 March 1984 and the new amendment was made on 17 October 2020.
patented technologies for the manufacture and marketing of vaccine. It is the same for other COVID-19 vaccines such as Vero cell developed by Sinopharm, the Chinese pharmaceutical manufacturer, and Wuhan Institute of Biological Products as well as, AZD1222 developed by AstraZeneca, the global leading biopharmaceutical company and the University of Oxford. It has been accounted that ‘the legal status of the 74 patent families involved in the 10 COVID-19 vaccines is highly divergent across different jurisdictions’. The transfer of IP rights has not been disclosed in detail for any licensing of foreign patents or know-how about COVID-19 vaccines at national level. No dispute has arisen from the activities of research, manufacture and marketing of the COVID-19 vaccines in domestic forums. In considering many patents relating to COVID-19 vaccine existed in different countries including developing countries such as India and South Africa, it is understandable for developing countries to propose the waiver of IP rights to control the COVID-19 pandemic. It is necessary to protect the public health by utilizing the patents owned mostly by the leading companies of developed countries for manufacture of COVID-19 vaccines in these developing countries.

It is apparently not enough to develop and manufacture COVID-19 vaccine by a few leading companies themselves. “Safe and effective vaccines have been developed and approved at record speed, giving us a crucial new way, in addition to traditional public health measures, to protect people from the virus. Now we must ensure they are available to everyone, everywhere.” It is a top priority to make the COVID-19 vaccines available globally as public goods. Under the existing regime, there are parallel ways to supply COVID-19 vaccines to countries without sufficient capacity to manufacture. The WHO led program, COVAX, is the primary way as a global pool with financial sources donated or provided by the national governments, international organizations and private companies to purchase the WHO listed vaccines supplied by its allied members and to allocate these countries in a fair and equitable basis. The license shall be given for the multi-national manufacture of the listed vaccines so as to maximize production. For example, the listed vaccine AZD1222 in the first round of allocation by the COVAX facility was manufactured by AstraZeneca and licensed to and manufactured by Serum Institute of India (SII/AZ). The SII/AZ shall obtain the license from AstraZeneca to produce the AZD1222 in India as required under the TRIPS Agreement. The second way is a bilateral agreement between the supplying and receiving countries to provide the COVID-19 vaccines that may not be listed by WHO yet. So far, there are no disputes referred to any adjudicators in these transnational ways to afford the vaccines. In addition, it could be requested for compulsory patent licensing under Article 31bis.

Overall, it is true that the current battle against COVID-19 has not brought out any disputes at national or international forums in terms of violation of any provisions of the TRIPS Agreement. National governments adopted the necessary measures to speed up research on COVID-19 vaccines with clinic trial so as to produce them for emergency use domestically or abroad.

45 COVAX, the vaccines pillar of the Access to COVID-19 Tools (ACT) Accelerator, is co-led by the Coalition for Epidemic Preparedness Innovations (CEPI), Gavi, the Vaccine Alliance (Gavi) and the WHO working in partnership with developed and developing country vaccine manufacturers, UNICEF, the World Bank, and others. It is the only global initiative that is working with governments and manufacturers to ensure the COVID-19 vaccines are available worldwide to both higher-income and lower-income countries.


47 Bolivia formally notified the WTO of the country’s need to import the COVID-19 vaccine, taking another step towards using flexibilities of Article 31bis of TRIPS Agreement as part of its pandemic response. See Notificación en virtud del acuerdo sobre los adpic enmendado, IP/N/9/BOJ/1 (11 May 2021).

while protecting possible patents and other IP rights with flexibilities under the TRIPS Agreement. No compulsory patent licensing has been enforced yet. Therefore, it seems that the limits of existing international law on public health relating to IP rights has not blocked the ways for the international community to combat COVID-19, at least in respect of medical patent protection. However, the exceptional circumstances of the COVID-19 pandemic still necessitate to have a special arrangement to waive eligible developing countries’ obligations under the TRIPS Agreement to utilize patents as effective as possible.

B. PROTECTION OF CLINIC TRIAL DATA OF THE COVID-19 VACCINES

The second issue is that of clinical trial data. It is mandatory to submit sufficient data of clinical trials of safe and effective COVID-19 vaccines for emergency use for national approval or approval through the WHO emergency use listing. There are two kinds of information in the clinical trial data of COVID-19 vaccines. The first is the updated information posted on the WHO website for public awareness or the data with scientific analysis published by the medical journals for professional discussion. Public awareness is very important because vaccination is based on individual voluntary consent. WHO posts updated information twice a week of the global COVID-19 vaccines candidates in clinical development, including the vaccine platform, type of vaccine candidate, number of doses, schedule of vaccination, route of administration, developer, phase and current status of clinical evaluation (trial registries and public reports).\textsuperscript{52} This kind of information is not relevant to IP.

The second should be test data, in particular for regulatory purposes. The Chinese medical regulatory authority issued guidelines for submission of clinical trial data for marketing\textsuperscript{53} in 2020 that improved the previous policies. The guidelines apply to emergency use of the COVID-19 vaccines requiring the applicants to submit the original database, database of analysis, explanatory documents of data, explanation for reading data, report table of cases and codes of procedure. These clinical trial data shall be submitted for regulatory review only. The WHO emergency use listing of the COVID-19 vaccines might need more submission of clinical trial data in comparison with the national requirements. For example, the Chinese vaccine, Vero cell developed by Sinopharm had been approved for emergency use in China and other countries respectively by early 2021, but it was still in the process of the WHO’s assessment for global emergency use and not listed until 26 May 2022. It is obvious that the test data submitted for national and international regulatory review is more than that for public awareness. This kind of information is relevant to IP rights.

Article 39.3 of the TRIPS Agreement provides that WTO Members shall protect the test data as undisclosed information submitted for regulatory review of marketing pharmaceutical chemical products against unfair commercial use. It does not specifically require a term of protection. The national medical regulatory authorities may take further measures to protect such test data for certain period of time. China provides six years of protection.\textsuperscript{54} The COVID-19 vaccines are not pharmaceutical chemical products; however, they should be protected as the biological medicine, along with the clinical trial data. A few regional trade agreements having IP provisions impose obligations on contracting parties to protect undisclosed test data or other data of a new pharmaceutical product that is or contains a biologic for certain period of time from the date of the first marketing approval of that product by that party. However, they

\textsuperscript{52} Ibid 40.
\textsuperscript{53} China National Medical Product Administration: The Principles of Guideline for Submission of the Medical Clinical Trial Data (provisional measure), July 2020.
\textsuperscript{54} China National Medical Product Administration: The Implementation of Protection for Pharmaceutical Clinical Trial Data (provisional measure), April 2018.
were either suspended\textsuperscript{56} or finally taken out.\textsuperscript{56} It is still a public health issue for the necessary sharing of clinical trial data of COVID-19 vaccines globally if such data submitted for regulatory review shall be protected.\textsuperscript{57} Currently, no case has been filed for national or international disclosure of such vaccine data for emergency use.

C. PROTECTION FOR TRADITIONAL KNOWLEDGE TREATING THE COVID-19 PATIENTS

The third issue is the protection of traditional knowledge. The new medicines treating COVID-19 patients have not been available everywhere. It was reported that an American pharmaceutical company used the existing drug “Remdesivir” to treat COVID-19 patients with effective results and had applied for patent of the second-use medicine in China.\textsuperscript{58} It was also disclosed that a new drug LY-CoV016 Etesevimab developed by the Chinese company, Junshi Biosciences, in cooperation with an American company, Eli Lilly, had been approved by European Medical Regulations Authority respectively for emergency use to treat COVID-19 patients together with another drug Bamlanivimab after an effective clinical trial.\textsuperscript{59}

However, Chinese experiences to treat the COVID-19 patients mostly depend on combination of existing chemical and traditional Chinese medicines.\textsuperscript{60} As traditional knowledge, Chinese medicine could not be protected by the existing IP regime because of its unknown individual right holder. Chinese Patent Law requires the patent applicant to disclose the genetic resources of the invention made based on such resources\textsuperscript{61} that might be related to traditional knowledge. Experts have made great efforts to define the traditional knowledge associated with genetic resources as the knowledge ‘which is dynamic and evolving, generated in a traditional context, collectively preserved and transmitted from generation to generation including but is not limited to know-how, skills, innovations, practices and learning genetic resources.’\textsuperscript{62} The TRIPS Agreement does not require disclosure of the possible genetic resources for patent application. Therefore, it lacks applicable laws under the TRIPS Agreement incorporated with other IP conventions, in particular, industrial property for the protection of traditional knowledge associated with genetic resources.

5. CONCLUSIONS

The COVID-19 pandemic is a crisis of global public health that affected over hundreds of millions of people. The proposal of India and South Africa to waive the TRIPS obligations exposed the limits of existing international IP laws with regard to public health. It is reflected in Article 8.1 as the original rule of international law in this regard. The Doha Declaration aims to balance IP protection and the public health interest, but its legal status remains uncertain. These limits were also reflected in the WTO jurisprudence under the TRIPS Agreement. However, no dispute on IP rights has resulted from the battle against COVID-19 in developing vaccines and medicines yet. The barrier of IP rights may not be the

\textsuperscript{55} Article 18.51, Comprehensive and Progressive Agreement for Trans-Pacific Partnership. This Article has been suspended in accordance with Article 2 of Preamble of this Agreement. See Annex 7(f).

\textsuperscript{56} Article 20.49, Agreement between the US, United Mexican States, and Canada. This Article were included by a version of this Agreement in October 2019 but removed by the final version in December 2019.

\textsuperscript{57} It has been proposed by the G7 health ministers to make an agreement entitled as “therapeutics and vaccines clinical trials charter for globally sharing test data of the COVID-19 vaccines”. G7 Health Ministers’ Declaration, 4 June 2021. <https://www.gov.uk/government/publications/g7-health-ministers-meeting-june-2021-communique> accessed 5 June 2021.


\textsuperscript{59} See The scientific opinion under Article 5.3 of regulation 726/2004 provided by European Medicines Agency’s (EMA) Committee for Medical Products for Human Use (CHMP), 5 March 2021. Lilly licensed LY-CoV016 etesevimab from Junshi Biosciences after it was jointly developed by Junshi Biosciences and the Institute of Microbiology, Chinese Academy of Science (IMCAS).


\textsuperscript{61} Ibid 44, Article 26. 5.

\textsuperscript{62} Article 1, ALT 1, Consolidated Document relating to Intellectual Property and Genetic Resources, WIPO/GRTKF/40/6 (9 April 2019).
block to supply COVID-19 vaccines to countries not having the capacity to produce vaccines. The real problem might be the capacity to develop and manufacture more effective and safe vaccines as global public goods. The COVAX facility must be operated in a fair and equitable way to favour developing countries and LDCs. Meanwhile, it should be encouraged to promote more international cooperation in multilateral or bilateral agreements to provide any countries with vaccines or to transfer technology for joint manufacture of vaccines. There are some regulatory issues relating to IP rights in fighting the COVID-19 pandemic such as protection of patent, clinical trial data and traditional knowledge. The recent WTO ministerial decision on the TRIPS Agreement is a remarkable balance of different claims between developing and developed countries. It would be a challenge for international community to make the possible permanent amendment of relevant provisions of the TRIPS Agreement in the future.

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