

## 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.<sup>1</sup> 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

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<sup>1</sup> In contrast to monist system, in dualist systems passing additional legislation is required for an international legal obligation to become part of national law.

Protocol) to the Convention on Biological Diversity (CBD).<sup>2</sup>

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.<sup>3</sup> 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.<sup>4</sup> 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.<sup>5</sup> 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.<sup>6</sup> 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.<sup>7</sup> 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.<sup>8</sup>

<sup>2</sup> Parvin MR, 'Environmental ethics in Iran' in Alireza Bagheri (1), *Biomedical ethics in Iran* (Eubios Ethics Institute 2014) 39-48.

<sup>3</sup> Kagedan BL, 'The Biodiversity Convention, Intellectual Property Rights and Ownership of Genetic Resources: International Development' (1996) prepared for the IP Policy Directorate Industry Canada <[http://www.iatp.org/files/Biodiversity/Convention/Intellectual\\_Property.pdf](http://www.iatp.org/files/Biodiversity/Convention/Intellectual_Property.pdf)> accessed 3 October 2020.

<sup>4</sup> Morgera E, 'Conceptualizing Benefit-Sharing as the Pursuit of Equity in Addressing Global Environmental Challenges' (2014) BENELEX Working Paper 2014, 43 <<https://ssrn.com/abstract=2524003>> accessed 22 December 2020.

<sup>5</sup> Padmashree GS, Tarasofsky RG, 'Study on the Inter- Relations between Intellectual property law Regimes and the Conservation of Genetic Resources' (2002) prepared for the European Commission Directorate

General <<https://www.cbd.int/doc/meetings/abs/abswg-02/information/abswg-02-inf-ext-en.doc>> accessed 3 October 2020.

<sup>6</sup> Derclaye E, 'Patent law's role in the protection of the environment: re-assessing patent law and its justifications in the 21st century' (2009) 40(3) *International Review of IP and Competition Law*, 249-273 <<http://eprints.nottingham.ac.uk/27696/1/derclaye%20ic%202009.pdf>> accessed 5 October 2020.

<sup>7</sup> Wang F, *et al.*, 'Study on the Ownership of Plant Genetic Resources on Farmers Land' (2013) 5(2) *Asian Agricultural Research*, 75-78 <<http://ageconsearch.umn.edu/record/146096/files/20.PDF>> accessed 17 September 2020.

<sup>8</sup> Malik SS, Singh SP, 'Role of Plant Genetic Resources in Sustainable Agriculture' (2006) 1(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.<sup>9</sup> 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'.<sup>10</sup> 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'.<sup>11</sup> 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.<sup>12</sup>

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.<sup>13</sup> For instance, Principle 21 of the 1972 Stockholm Declaration<sup>14</sup> 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.<sup>15</sup> 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.<sup>16</sup> 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.<sup>17</sup>

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.<sup>18</sup> The

<<https://www.indianjournals.com/ijor.aspx?target=ijor:ijocs&volume=1&issue=1and2&article=004>> accessed 30 June 2012.

<sup>9</sup> Poorhashemi A, 'Emergence of 'International Environmental Law': as a new branch of International Public Law' (2020) 1(2) CIFILE Journal of International Law, 33-39 <[http://www.cifilejournal.com/article\\_106534.html](http://www.cifilejournal.com/article_106534.html)> accessed 3 June 2021.

<sup>10</sup> Charter of Economic Rights and Duties of States, UNGA, Resolution 3281(xxix), 12 December 1974 <[www.un-documents.net/a29r3281.htm](http://www.un-documents.net/a29r3281.htm)> accessed 17 September 2019.

<sup>11</sup> Jaeckel A, *et al.*, 'Conserving the Common Heritage of Humankind – Options for the Deep Seabed Mining Regime' (2017) 78 Marine Policy, 150-157 <<https://www.savethehighseas.org/wp-content/uploads/2012/01/Conserving-the-common-heritage-of-humankind.pdf>> accessed 28 June 2021.

<sup>12</sup> Maftei J, 'Sovereignty in International Law' (2015) 11(1) Acta Universitatis Danub Jus Juridica, 54-65 <[http://journals.univ-](http://journals.univ-danubius.ro/index.php/juridica/article/view/2798/2377)

[danubius.ro/index.php/juridica/article/view/2798/2377](http://journals.univ-danubius.ro/index.php/juridica/article/view/2798/2377)> accessed 22 September 2020.

<sup>13</sup> Poorhashemi A, Arghand B, 'International Environmental law' (1<sup>st</sup> edn, Nashre Dadgostar 2013) 287- 280.

<sup>14</sup> Stockholm Declaration, Declaration of the United Nations Conference on the Human Environment (1972), <<http://www.unep.org/documents.multilingual/default.asp?documentid=97&articleid=1503>> accessed on 17 September 2020.

<sup>15</sup> Habibi MH, 'Environmental law' (2<sup>nd</sup> edn, Nashre Mizan 2011) 342-352.

<sup>16</sup> Virginie B, 'Sovereignty Over Natural Resources; Environmental Challenges and Sustainable Development' in Morgera E, Kulovesi K (eds), *Research Handbook on International Law and Natural Resources* (Edward Elgar Publishing 2016) 15-25.

<sup>17</sup> 'The 2030 Agenda for Sustainable Development, Resolution adopted by The General Assembly', 25 September 2015, A/RES/70/1. <<https://sdgs.un.org/2030agenda>> accessed 3 October 2020.

<sup>18</sup> Davalos LM, 'Regulating Access to Genetic Resources under the Convention on Biological Diversity: An Analysis of Selected Case Studies'

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.<sup>19</sup> 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.<sup>20</sup> 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.<sup>21</sup> 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.<sup>22</sup>

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.<sup>23</sup> 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.<sup>24</sup> 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<sup>25</sup> 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.<sup>26</sup> 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.<sup>27</sup>

(2003) 12(7) Biodiversity & Conservation Journal, 1511-1524 <<https://link.springer.com/article/10.1023/A:1023615303748>> accessed 12 September 2020.

<sup>19</sup> Parks L, Morgera E, 'An Interdisciplinary Model for Mapping the Normative Diffusion of Fair and Equitable Benefit-Sharing' (2015) BENELEX Working Paper 2015, 3 <<http://ssrn.com/abstract=2637302>> accessed 30 June 2021.

<sup>20</sup> Article 1(1) of the International Treaty on Plant Genetic Resources for Food and Agriculture <[www.fao.org/3/a-i0510e.pdf](http://www.fao.org/3/a-i0510e.pdf)> accessed on 30 June 2021.

<sup>21</sup> Tsioumani E, 'Exploring Benefit-Sharing from the Lab to the Land (Part1): Agricultural Research and Development in the Context of Conservation and Sustainable' (2014) BENELEX Working Paper 2014, 4 <<https://zenodo.org/record/1921457>> accessed 2 November 2019.

<sup>22</sup> Brahmi P, Vandana, Tyagi, 'Access and Benefit Sharing Mechanism under the Multilateral System of the International Treaty on Plant Genetic Resources for Food & Agriculture' in Laladhas KP, et al. (eds), 'Biodiversity for Sustainable development Environmental Challenges and Solutions' (Springer 2017) 17-30.

<sup>23</sup> Morgera E, 'Justice, Equity and Benefit-Sharing under the Nagoya Protocol to the Convention on Biological Diversity' (2015) BENELEX

Working Paper 2015, 5 <<https://ssrn.com/abstract=2610528>> accessed 2 November 2019.

<sup>24</sup> Correa CM, 'Sovereign and Property Rights over Plant Genetic Resources' (1994), Study Paper of the FAO Commission on Plant Genetic Resources <<http://www.fao.org/tempref/docrep/fao/meeting/015/aj596e.pdf>> accessed 11 August 2020.

<sup>25</sup> Mandel GN, 'Promoting Environmental Innovation with Intellectual Property Innovation: A New Basis for Patent Rewards' (2005) 24(1) Temple Journal of Science, Technology & Environmental Law <<https://ssrn.com/abstract=756844>> accessed 18 September 2020.

<sup>26</sup> 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/ir00000\\_.html](http://www.servat.unibe.ch/icl/ir00000_.html)> accessed 2 November 2020.

<sup>27</sup> Mashhadi A, Mohtashami M, 'Reflection on Relationship between intellectual property law and environmental law' (2015) 45(3) Journal of Private Law Studies, 485-504

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.<sup>28</sup> 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://jfq.ut.ac.ir/article\\_55031\\_92e3f272e7f0f4ebe75d54f75a34c72a.pdf](https://jfq.ut.ac.ir/article_55031_92e3f272e7f0f4ebe75d54f75a34c72a.pdf)> accessed 27 January 2021.

<sup>28</sup> 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.<sup>29</sup> 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.<sup>30</sup>

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.<sup>31</sup> 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.<sup>32</sup> 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.<sup>33</sup> 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

<sup>29</sup> Biermann F, 'Common Concern of Humankind: The Emergence of a New Concept of International Environmental Law' (1996) 34(4) *Archive des Völkerrechts* <<https://www.jstor.org/stable/40798942>> accessed 11 August 2019.

<sup>30</sup> MacManis CR, 'The Interface Between International Intellectual Property and Environmental Protection: Biodiversity and Biotechnology' (1998) 76(1) *WASH. U. L. R.A.*, 255-280 <[https://openscholarship.wustl.edu/cgi/viewcontent.cgi?article=1516&context=law\\_lawreview](https://openscholarship.wustl.edu/cgi/viewcontent.cgi?article=1516&context=law_lawreview)> accessed 30 June 2021.

<sup>31</sup> Rodriguez CR, Dooren TV, 'Shifting Common Spaces of Plant Genetic Resources: An International Regulatory Appraisal' (2008) 11(3) *The Journal of World Intellectual Property*, 176-202

<<https://doi.org/10.1111/j.1747-1796.2008.00342.x>> accessed on 12 September 2019. See also Rabitz F, 'Managing Genetic Resources: International Regimes, Problem Structures, National Implementation' (2017) *Earth System Governance Working Paper 2017*, 37 <<https://www.researchgate.net/publication/322118076>> accessed 12 September 2019.

<sup>32</sup> 'Understanding Industrial Property', (WIPO publication, Geneva, 2016) <[http://www.wipo.int/edocs/pubdocs/en/wipo\\_pub\\_895\\_2016.pdf](http://www.wipo.int/edocs/pubdocs/en/wipo_pub_895_2016.pdf)> accessed 2 November 2020.

<sup>33</sup> Parvin MR, 'Les Aspects Juridiques de la Brevetabilité des Inventions Biotechnologiques : Comparaison Internationale' (PhD thesis, Université de Paris 2007) 47.

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.<sup>34</sup> 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).<sup>35</sup> 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.<sup>36</sup>

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.<sup>37</sup> 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.<sup>38</sup> 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

<sup>34</sup> MacManis CR (n 30) 260-279.

<sup>35</sup> Habibi MH, 'Environmental law' (1<sup>st</sup> edn, Tehran University Publication 2017) 218.

<sup>36</sup> Lightbourne M, 'Plant and Intellectual Property Rights in the US, Japan and Europe' (Institute of Intellectual Property, Tokyo, 2005) 78-84.

<sup>37</sup> Henning Grosse Ruse – Khan, 'Sustainable Development in international Intellectual Property Law- New Approaches from EU Economic Partnership Agreements?' (2010) International Center for Trade and

Sustainable Development Geneva  
<<https://www.ictsd.org/sites/default/files/research/2011/12/sustainable-development-e28093-new-approaches-from-eu-economic-partnership-agreements.pdf>> accessed 18 September 2020.

<sup>38</sup> Morgera E, 'Conceptualizing Benefit-Sharing as the Pursuit of Equity in Addressing Global Environmental Challenges' (2014) BENELEX Working Paper 2014, 41 <<https://ssrn.com/abstract=2524003>> accessed 11 August 2020.

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.<sup>39</sup>

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.<sup>40</sup> 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).<sup>41</sup> 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.<sup>42</sup> 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

<sup>39</sup> Dutfield G, 'The Role of the International Union for the Protection of New Varieties of Plants (UPOV)' (2011) 12 Quaker United Nation Office, Geneva <[http://agrobiodiversityplatform.org/files/2011/04/UPOV-study-by-QUNO\\_English1.pdf](http://agrobiodiversityplatform.org/files/2011/04/UPOV-study-by-QUNO_English1.pdf)> accessed on 2 November 2019.

<sup>40</sup> Dutfield G, 'Intellectual Property, Biogenetic Resources and Traditional Knowledge' (1<sup>st</sup> edn, Earthscan 2004) 67.

<sup>41</sup> Momenirad A, *et al.*, 'Protection of biodiversity & Traditional Knowledge in World IP System' (2013) 1(49) International Legal Journal, 233-262

<[http://www.cilamag.ir/article\\_16005\\_65c98b0eba70292b43f30b2aaff0d4e8.pdf](http://www.cilamag.ir/article_16005_65c98b0eba70292b43f30b2aaff0d4e8.pdf)> accessed 18 September 2020.

<sup>42</sup> Bala Ravi S, 'Effectiveness of Indian *sui generis* Law on Plant Variety Protection and Its Potential to Attract Private Investment in Crop Improvement' (2004) 9 Journal of Intellectual Property Rights, 533-548 <<http://nopr.niscair.res.in/bitstream/123456789/4887/1/JIPR%209%286%29%20533-548.pdf>> accessed 12 September 2019.

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 Act<sup>43</sup> (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 Seedlings<sup>44</sup> 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 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.<sup>45</sup> Nevertheless, accepting morality as an explicit reason to exclude any inventions contrary to public order and morality from

<sup>43</sup> 2007 Patents, Industrial Designs and Trademarks Registration Act <<https://www.wipo.int/edocs/lexdocs/laws/en/ir/ir003en.pdf>> accessed 17 December 2020.

<sup>44</sup> 2003 Act of Plant Varieties Registration, Control and Certification of Seeds and Seedlings <<http://www.wipo.int/wipolex/en/details.jsp?id=7705>> accessed 17 December 2020.

<sup>45</sup> Khademi H, Abbasi M, 'Protecting Genetic Resources in the Light Article 4(d) of Iran Patent, Industrial Designs and Trademarks Act' (2010) 4(12) Iranian Journal of Medical Law, 105-130 <<http://ijmedicalaw.ir/article-1-463-en.html>> accessed 2 November 2019.

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.<sup>46</sup>

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<sup>47</sup>, 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<sup>48</sup>, but the same genetic resources are excluded from patentability for moral or bio piracy reasons under the Patent Act.

<sup>46</sup> *ibid* 115.

<sup>47</sup> 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.

<sup>48</sup> 2006 Law on Comprehensive System of Animal Husbandry <<http://rc.majlis.ir/fa/law/show/136267>> accessed 18 June 2020.

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.<sup>49</sup> 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.<sup>50</sup>

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

<sup>49</sup> Moodi O, 'Addressing Biopiracy through an Access and Benefit Sharing Regime-Complex: In Search of Effective Protection for Traditional Knowledge Associated with Genetic Resources' (2016) 16(231) *Asper Rev. Int'l Bus. & Trade L* <<https://heinonline.org/HOL/LandingPage?handle=hein.journals/asperv16&div=10&id=&page=>> accessed 12 September 2020.

<sup>50</sup> The Law on Protection and Exploitation of Genetic Resources <[https://rc.majlis.ir/fa/law/print\\_version/1076978](https://rc.majlis.ir/fa/law/print_version/1076978)> accessed 3 January 2022.

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.<sup>51</sup>

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

<sup>51</sup> See also WIPO Report, *Study on Patents and the Public Domain, Committee on Development and Intellectual Property*, CDIP/8 (2012) <[https://www.wipo.int/meetings/en/doc\\_details.jsp?doc\\_id=203799](https://www.wipo.int/meetings/en/doc_details.jsp?doc_id=203799)> accessed June 2021.

<sup>52</sup> ILA Resolution No. 5 of 2010, *The International Law on Biotechnology* at preamble <<https://ila.vettoreweb.com/Storage/Download.aspx?DbStorageId=1171&StorageFileGuid=41ebb8ce-87d1-4fc5-b6cc-9d5e488a3df7>> accessed on 28 June 2021.

#### 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.<sup>52</sup> 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'.<sup>53</sup> 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.<sup>54</sup>

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

<sup>53</sup> Declaration on the Right to Development, Adopted by General Assembly resolution 41/128 of 4 December 1986 <<https://www.ohchr.org/en/professionalinterest/pages/righttodevelopment.aspx>> accessed 30 June 2021.

<sup>54</sup> Rio Declaration, Declaration on Environment and Development, UNESCO, Rio de Janeiro, 1992, A/CONF.151/26 <[https://www.un.org/en/development/desa/population/migration/generalassembly/docs/globalcompact/A\\_CONF.151\\_26\\_Vol.I\\_Declaration.pdf](https://www.un.org/en/development/desa/population/migration/generalassembly/docs/globalcompact/A_CONF.151_26_Vol.I_Declaration.pdf)> accessed 17 June 2021.

environmental protection on the government and its legislative and economic instruments.<sup>55</sup> 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.<sup>56</sup> 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.<sup>57</sup>

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.<sup>58</sup>

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.

<sup>55</sup> Abdol Majid M, *et al.*, 'The Principle of Integration in International Sustainable Development Law with Reference to the biological Weapons Convention' (2018) 8(2) Sustainability, 166-167 <https://www.mdpi.com/2071-1050/8/2/166> accessed 18 June 2021.

<sup>56</sup> 1995 Copenhagen Declaration on Social Development – A/CONF.166/9 Chapter I, Annex I – UN Documents: Gathering a body of global agreements

<https://www.un.org/en/development/desa/population/migration/gene>

[ralassembly/docs/globalcompact/A\\_CONF.166\\_9\\_Declaration.pdf](ralassembly/docs/globalcompact/A_CONF.166_9_Declaration.pdf) accessed 20 June 2021.

<sup>57</sup> Johannesburg Declaration on Sustainable Development – A/CONF.199/20, UN Documents: Gathering a body of global agreements 2002 <<https://digitallibrary.un.org/record/478154?ln=en>> accessed 20 June 2021.

<sup>58</sup> Agreement on Trade-Related Aspects of Intellectual Property Rights (*TRIPS Agreement*), WIPO Lex No: TRT/WTO01/001 (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.<sup>59</sup>

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.<sup>60</sup> 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.<sup>61</sup>

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

<sup>59</sup> *Plant Genetic Systems N.V., et al. v. Greenpeace Ltd.* (1995) EPO, ECLI: EP: BA: 1995.

<sup>60</sup> Poorhashemi A, Arghand B (n 12) 282.

<sup>61</sup> Taghizadeh Ansari M, '*International Environmental law*' (1<sup>st</sup> edn, Khorsandi 2014) 218- 221.

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.<sup>62</sup>

As clarified in the Biosafety Protocol, the subject of the precautionary principle seems to be different from the subject of the prevention principle.<sup>63</sup> 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.<sup>64</sup> 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<sup>65</sup>). 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'.<sup>66</sup> Hence, the application of the precautionary principle in the IP context could be also different based on the two mentioned approaches.<sup>67</sup> However, any extreme

<sup>62</sup> Habibi MH (n 15) 344-350.

<sup>63</sup> Pereira Di Salvo CJ, Raymond L, 'Defining the precautionary principle: an empirical analysis of elite discourse' (2010) 19(1) Environmental Politics, 86-106 <<https://doi.org/10.1080/09644010903396119>> accessed 2 November 2020.

<sup>64</sup> Annual report of EEA 2013, 681 <<http://erda-rte.eu/projects/precautionary>> accessed 10 June 2021.

<sup>65</sup> 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.

<sup>66</sup> Ansari AH, Wartini S, 'Precautionary Principle under the SPS Agreement: A Critical Exposition' (2013) 7(4) Advances in environmental Biology, 653–

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<[https://www.researchgate.net/publication/282720825\\_Precautionary\\_principle\\_under\\_the\\_SPS\\_Agreement\\_A\\_critical\\_exposition](https://www.researchgate.net/publication/282720825_Precautionary_principle_under_the_SPS_Agreement_A_critical_exposition)> accessed 18 September 2019.

<sup>67</sup> Reynolds G, 'The Precautionary Principle and its Application in the Intellectual Property Context: Towards a Public Domain Impact Assessment' in Scassa T, Goudreau M, B Doagoo BX, Saginur M, *Intellectual Property for the 21<sup>st</sup> Century: Interdisciplinary Approaches*, (1<sup>st</sup> edn, Irwin Law 2013) 95-113 <<https://ssrn.com/abstract=2347922>> accessed 2 November 2018.

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.<sup>68</sup> 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.<sup>69</sup> 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

<sup>68</sup> Schueler B, 'Methods of Application of Proportionality Principle in Environmental Law' (2008) 35(3) *Legal Issues of Economic Integration*, 231-240  
<<https://heinonline.org/HOL/LandingPage?handle=hein.kluwer/liei0035&div=23&id=&page=>> accessed 8 August 2019.

<sup>69</sup> Boyle A, 'Human Rights or Environmental Rights? A Reassessment' (2006) 18(3) *Fordham Environmental Law Review*, 471-511  
<<https://ir.lawnet.fordham.edu/cgi/viewcontent.cgi?article=1634&context=elr>> accessed 14 October 2018.

embodied in terms of 'necessary to', which refers indeed to a requirement for establishing causal links between actions and objectives.<sup>70</sup> 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)<sup>71</sup> 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<sup>72</sup> 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 agrobiotechnology.

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.

<sup>70</sup> Veinla H, 'Determination of the Level of Environmental Protection and the Proportionality of Environmental Measures in Community Law' (2004) 9(89) *Juridical International Journal*, 91-95 <[http://www.juridicainternational.eu/public/pdf/ji\\_2004\\_1\\_89.pdf](http://www.juridicainternational.eu/public/pdf/ji_2004_1_89.pdf)> accessed 14 October 2018.

<sup>71</sup> [2020] WT/DS 435/28 and WT/DS 441/29 <[https://www.wto.org/english/tratop\\_e/dispu\\_e/435\\_441abr\\_e.pdf](https://www.wto.org/english/tratop_e/dispu_e/435_441abr_e.pdf)> accessed 5 May 2022.

<sup>72</sup> 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<sup>73</sup> 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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<sup>73</sup> The Law on Protection and Exploitation of Genetic Resources (n 50).

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