

MODULE VII

UNDISCLOSED INFORMATION, UNFAIR COMPETITION AND ANTI-COMPETITIVE PRACTICES

A Introduction

This module deals with the provisions of TRIPS Agreement that set out standards for protection of undisclosed information, including test data (Article 39 of Section 7 in Part II of the Agreement) and measures for the control of anticompetitive practices in licences (Article 40 of Part II of the TRIPS Agreement). It also deals with the suppression of unfair competition, a matter which is specifically referred to in Articles 22 (relating to protection of geographical indications) and 39 (relating to protection of undisclosed information), and also arises through the reference in Article 2 of the TRIPS Agreement to the Paris Convention: Article 10*bis* of that convention sets out general standards for the suppression of unfair competition. As for all sections of Part II, these sections have to be read together with the relevant provisions of pre-existing treaties in the area of international IP law, which are incorporated by reference into the TRIPS Agreement. Reference will be made to these treaties in the sections below. This module will also have to be read in conjunction with other relevant provisions of the TRIPS Agreement explained in other modules (such as concerning non-discrimination, enforcement of IP rights, and the administration of IP). Wherever appropriate, cross-references are made to other modules.

B Undisclosed information

The protection of undisclosed information, which covers both trade secrets and test data submitted to government agencies, is not explicitly covered by pre-existing international IP law, such as the Paris Convention. However, the protection for this subject matter under Article 39 of the TRIPS Agreement is framed in terms of the more general concept of ensuring effective protection against unfair competition pursuant to Article 10*bis* of the Paris Convention.

Article 10*bis* of the Paris Convention, as incorporated into the TRIPS Agreement, obliges members to ensure effective protection against acts of competition that are contrary to honest practices in industrial or commercial matters. It contains a non-exhaustive list of some acts of unfair competition which must be prohibited by members, including all acts of such a nature as to create confusion by any means whatever with the establishment, the goods, or the industrial or commercial activities, of a competitor; false allegations in the course of trade of such a nature as to discredit the establishment, the goods, or the industrial or commercial activities, of a competitor; and indications or allegations the use of which in the course of trade is liable to mislead the public as to the nature, the manufacturing process, the

characteristics, the suitability for their purpose, or the quantity, of the goods. Section C below discusses unfair competition and Article 10*bis* of the Paris Convention in greater detail.

1 *Undisclosed information (trade secrets)*

The TRIPS Agreement builds on the Paris Convention to introduce specific obligations to protect undisclosed information. Accordingly, its Article 39.2 obliges members to protect information that:

- is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question;

It is not necessarily the case that trade secrets should be only known to one or two persons to be entitled to protection, but they should not be generally known to the public or other persons in the same trade or business. The information as a whole can be secret, such as the formula for 'Coca-Cola', or the information may be composed of individual pieces of information that may be in the public domain, but the compilation of which is not, such as a law firm's client list.

- has commercial value because it is secret;

The information should be of commercial value to its holder or the holder's competitors and this value would be lost or impaired if the information ceased to be secret. For example, the formula for 'Coca-Cola' would be of less value to that company if all competitors also had access to it.

- has been subject to reasonable steps under the circumstances by the person lawfully in control of the information, to keep it secret.

What constitutes 'reasonable steps' to keep information secret may vary from case to case, mostly depending on the nature and value of the information to be protected. For example, in one case, an issue before a court was whether a chemical company should be required, as a reasonable step, to put a roof over the machinery in its plant in order to protect its secret process of making methanol from aerial photography. The court held that, as such a requirement would be too costly to the company, it was not reasonable.

Article 39.2 requires that a natural or legal person lawfully in control of such undisclosed information must have the possibility of preventing it from being disclosed to, acquired by, or used by others without his or her consent in a 'manner contrary to honest commercial practices'. According to a footnote to the provision, a manner contrary to honest commercial practices means at least the following practices:

- breach of contract,

- breach of confidence,
- inducement to breach of contract or confidence,
- acquisition of undisclosed information by third parties who knew, or were grossly negligent in failing to know, that the above-mentioned practices were involved in the acquisition.

Unlike other IPRs, such as patents and copyright, for which the term of protection is finite, the protection of undisclosed information continues unlimited in time as long as the conditions for its protection continue to be met, i.e. it meets those conditions mentioned above. However, unlike patent protection, there is no protection against a competitor that develops the information independently.

2 Undisclosed test and other data

Most countries require pharmaceutical or agricultural chemical producers to submit test and other data as a condition of approving the marketing of their products, especially when they utilize new chemical entities. Pharmaceutical test data are generated through extensive pre-clinical trials on animals and clinical trials on humans and submitted to governmental agencies in order to provide evidence with respect to the safety, quality and efficacy of these products. Data on the efficacy and environmental effect of agricultural chemicals, such as pesticides or herbicides, are collected through field trials and similar tests. Considerable efforts by the originator company may be required to obtain such test data, both in terms of time and costs. The TRIPS Agreement is the first international instrument in the field of IP that contains obligations specifically with respect to the protection of undisclosed test and other data required to be submitted in order to get marketing approval for pharmaceutical or for agricultural chemical products. This issue is dealt with in Article 39.3, which tries to achieve a balance between competing interests. Protection under Article 39.3 is available independently of other IPRs, including patents. Members have to provide for test data protection irrespective of whether or not the products are covered by patents. The test data may have been generated by a firm or entity that is entirely different from the holder or holders of one or more patents that cover the use of the product in question, and if a patent has been filed on the product, this usually takes place years before the bulk of the trials or tests that produce data on safety, efficacy and environmental effect.

Article 39.3 requires members to protect such test or other data when:

- the data have not been disclosed;
- their submission is required as a condition of approving the marketing of pharmaceutical or agricultural chemical products;
- the products utilize new chemical entities; and

- the origination of the test or other data has required a considerable effort.

There are two forms of protection to be accorded to such test and other data. First, the TRIPS Agreement requires members to protect them against unfair commercial use. In addition, members are required to protect such data against disclosure. An exception to this obligation is available where disclosure is necessary to protect the public or where steps are taken to ensure that the data are protected against unfair commercial use.

An issue that has been much debated is whether a pharmaceutical regulatory authority can rely on test data supplied by the originator of a drug in its application for marketing approval to show its safety and efficacy when granting marketing approval for generic versions; in other words, whether it can limit itself to requiring only data necessary to demonstrate the bio-equivalency, or the same uptake in the body, of the generic version.

Members have differing perspectives on the obligation to protect test data against unfair commercial use under Article 39.3 of the TRIPS Agreement. Some are of the view that the most effective method of implementing Article 39.3 is to give the originator of the data a reasonable period of exclusivity during which the regulatory authorities must not rely on the data when approving other versions. Others believe that there are other ways in which such data can be protected against 'unfair commercial use' other than through periods of data exclusivity.

There is no WTO jurisprudence on the question. The matter was at issue in *Argentina – Certain Measures on the Protection of Patents and Test Data* (DS196). While on other issues the parties reached a mutually satisfactory solution, they only agreed on this issue that differences should be resolved under the rules of the WTO dispute settlement system.

C Unfair competition

As noted above, TRIPS Agreement provisions on GIs and undisclosed information refer to the repression of unfair competition, and the incorporated provisions of the IPIC Treaty provide for unfair competition as one means of protecting integrated circuit layout-designs. In addition, the provisions of Article 10*bis* of the Paris Convention relating to unfair competition are incorporated into the TRIPS Agreement by means of a reference in its Article 2.1.⁷² Article 10*bis*(2) of the Paris Convention specifies that '[a]ny act of competition contrary to honest practices in industrial or commercial matters constitutes an act of unfair competition'.⁷³ Article 10*bis*(1) requires members to assure to nationals of other members effective protection against unfair

⁷² This was clarified by the Panels in *Australia – Tobacco Plain Packaging* (DS435, 441, 458, 467). This finding is consistent with an earlier finding by the Appellate Body clarifying that 'trade names' fall within the scope of protection required under the TRIPS Agreement, despite lacking a specific reference in Part II (see Module III, section B1(a) above).

⁷³ See the discussion in G.H.C. Bodenhausen, *Guide to the Application of the Paris Convention for the Protection of Industrial Property, as Revised at Stockholm in 1967* (BIRPI, 1969), pp. 143-144.

competition. Article 10bis(3) further provides for specific acts that must be prohibited, namely:

(i) all acts of such a nature as to create confusion by any means whatever with the establishment, the goods, or the industrial or commercial activities, of a competitor;

(ii) false allegations in the course of trade of such a nature as to discredit the establishment, the goods, or the industrial or commercial activities, of a competitor;

(iii) indications or allegations the use of which in the course of trade is liable to mislead the public as to the nature, the manufacturing process, the characteristics, the suitability for their purpose, or the quantity, of the goods.

The Panels in *Australia – Tobacco Plain Packaging* (DS435, 441, 458, 467) clarified that the definition of ‘an act of unfair competition’ in paragraph 2 refers to something that is done by a *market actor* to compete against other actors in the market in a manner that is contrary to what would usually or customarily be regarded as truthful, fair and free from deceit *within a certain market*. How industrial and commercial matters are usually or customarily carried out differs from market to market, as do the perceptions of and the standards for determining what constitutes ‘honest’ commercial practices.⁷⁴

The Panels added that the term ‘act of competition’ refers to something that is done by a market actor to compete against other actors in the market. Laws and other instruments that a member adopts to regulate the market, or the overall regulatory environment within which the market operates, do not *per se* amount to ‘acts of unfair competition’.

The Panels further elaborated that protection against unfair competition serves to protect competitors as well as consumers, together with the public interest. When determining ‘honesty’ in business dealings, all of these factors have to be taken into account. This approach is consistent with TRIPS Article 7 on ‘Objectives’, which reflects the intention of establishing and maintaining a balance between the societal objectives mentioned therein. Consequently, a determination of what amounts to an act that is contrary to honest practices in commercial matters may, depending on the circumstances, reflect a balancing of these interests.

Paragraph 3 of Article 10bis requires members to *prohibit* the types of dishonest commercial practices mentioned in its subparagraphs. The Panels clarified that the scope of other practices in industrial and commercial matters against which a member is bound to assure effective protection pursuant to paragraph 1 needs to be

⁷⁴ The Panels also observed that ‘in the circumstances of a particular case, honest practices established in international trade, if discernible, should [...] also inform the meaning of “[a]ny act of competition contrary to honest practices in industrial or commercial matters” under paragraph 2 of Article 10bis’. *Australia – Tobacco Plain Packaging*, fn 5359.

considered in the context of the legal systems and conceptions of what constitutes an act contrary to what would usually or customarily be regarded as truthful, fair and free from deceit within the domestic market at issue.

D Control of anti-competitive practices

1 Introduction

An important element of the overall balance embodied in the TRIPS Agreement is a recognition of the legitimate role of competition law and policy *vis-à-vis* IPRs. The term ‘competition law and policy’ refers to laws and related policies that address anticompetitive practices of enterprises (in some contexts, they are termed ‘antitrust’ or ‘anti-monopoly’ laws and policies). These laws typically address anticompetitive and collusive agreements (cartels), mergers that lessen competition, and abuses of a dominant position or ‘monopolization’.⁷⁵ Some countries’ competition laws incorporate specific provisions relating to the abuse of IPRs, and a number have established competition policy guidelines specifically dealing with IP.

National IP systems, and the TRIPS Agreement, are generally understood not to be intrinsically in conflict with competition law and policy: to the contrary, both systems of regulation serve the same overall objectives – generally, promoting a dynamic and innovative economy, while also facilitating appropriate diffusion of new technologies, and thereby promoting the welfare of citizens. For example, competition law and policy can serve to prevent or deter practices such as collusive pricing or the use of abusive clauses in licensing agreements that unreasonably restrict access to new technologies or the uses to which such technologies can be put.

IPRs normally do not confer ‘monopolies’ in the sense understood in competition policy. In almost all cases, substitutes are available for products and technologies that are protected by IPRs. Hence, while there is no harmonised international standard, it is widespread practice in national competition laws that the mere existence or exercise of IPRs is not, by itself, treated as being in violation of competition law. In practice, competition law has come into play only in the exceptional cases when there are no, or very limited, close substitutes for IP-protected technology or products, or when rights are deliberately employed in an abusive manner.

2 Overview of relevant TRIPS provisions

The main provisions of the TRIPS Agreement that relate to the application of competition policy are Article 8.2 (dealing with the abuse of IPRs generally, without referring specifically to competition policy as such), Article 40 (dealing expressly with anti-competitive licensing practices), and elements of Article 31, particularly Article 31(k) (relating to the use of a patent without the authorization of the right

⁷⁵ See, for general background, ‘Special study on trade and competition policy’, in *Annual Report of the World Trade Organization for 1997* (Geneva, 1997), Chapter IV.

holder, or compulsory licensing, as a remedy for anti-competitive practices). These provisions give scope to governments to implement appropriate remedies in response to harmful anti-competitive practices, so long as the remedies remain consistent with the relevant provisions of the Agreement.⁷⁶ And Article 67 foresees that technical assistance provided under the Agreement would address the abuse of IPRs.

Hence, Article 8.2 of the Agreement stipulates that:

Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

This Article does not expressly mention violations of competition law but mentions the general concept of ‘abuse’ of IPRs.

By contrast, Article 40 expressly refers to anti-competitive licensing practices, reflecting concerns about potential anticompetitive effects of IPRs that arose in the TRIPS negotiations. Thus this Article notes WTO members’ agreement that ‘some licensing practices or conditions pertaining to intellectual property rights which restrain competition may have adverse effects on trade and may impede the transfer and dissemination of new technology’. To address this concern, the Article recognizes that members are entitled to take measures to prevent licensing practices or conditions that may, in particular cases, constitute an abuse of IP rights having an adverse effect on competition in the relevant market. It also gives a short illustrative list of practices that may be treated as abuses, namely grantback conditions, conditions preventing challenges to validity and coercive package licensing.

This Article also entitles WTO members to ask for consultations with other members in cases of possible anticompetitive practices, and to obtain their cooperation by supplying relevant publicly available non-confidential information, and other information available to that member, subject to domestic law and to arrangements to safeguard confidential information. It also provides that a member whose nationals are subject to proceedings in another member concerning alleged violation of that other member’s laws shall, upon request, be granted an opportunity for consultation by the other member.

TRIPS provisions on patents recognize the interplay between competition safeguards and the exercise of patent rights. Article 31 sets out detailed conditions for granting compulsory licences, and the Doha Declaration on the TRIPS Agreement and Public Health confirmed that members have ‘the freedom to determine the grounds’ for compulsory licensing (see Module X, below). Article 31(k) confirms that, when a compulsory licence is granted ‘to remedy a practice determined after judicial or

⁷⁶ See Robert D. Anderson, Anna Caroline Müller and Antony Taubman, ‘The WTO TRIPS Agreement as a Platform for the Application of Competition Policy in the Contemporary Knowledge-Based Economy: Origins and Prospects’, WTO Staff Working Paper (forthcoming), to be available at: www.wto.org/workingpapers.

administrative process to be anticompetitive’, members are not obliged to meet two specific conditions, firstly the Article 31(b) requirement to show that a proposed user had made efforts to obtain voluntary authorization from the right holder on reasonable terms and conditions within a reasonable period of time, and secondly the Article 31(f) requirement that authorization under a compulsory licence be predominantly for the supply of the domestic market. And TRIPS permits taking into account the need to correct anticompetitive practices when determining the amount of remuneration due to the patent holder in the event of a compulsory licence.

These provisions leave significant questions to be resolved at the domestic level. For example, neither Article 8.2 nor Article 40.2 indicates that specific practices *must* be treated as abuses or specifies remedial measures that must be taken. Thus the provisions of the Agreement relating to competition policy are permissive rather than mandatory. The Agreement does not define the full set of IP licensing practices that may be deemed anti-competitive, and Article 40 simply lists three examples of possible practices. Concerning the compulsory licensing of patents, this provision does not define the standards according to which practices may be evaluated to be anti-competitive. The Agreement also provides relatively little in the way of guidance regarding the remedies that may be adopted in particular cases, beyond making clear that any measures adopted must be consistent with other provisions of the Agreement.⁷⁷ In this context, a number of developed and developing members have put in place guidelines and advocacy initiatives that address some or all of these matters.⁷⁸

⁷⁷ See Anderson, Müller and Taubman, fn 76 above.

⁷⁸ See, e.g. US Department of Justice and Federal Trade Commission, *Antitrust Guidelines for the Licensing of Intellectual Property* (US Government Printing Office, 2017), available at: www.justice.gov/atr/IPguidelines/download; European Commission, *Guidelines on the Application of Article 101 of the Treaty on the Functioning of the European Union to Technology Transfer Agreements* (2014), available at: [eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52014XC0328\(01\)&from=EN](http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52014XC0328(01)&from=EN); Competition Bureau Canada, *Intellectual Property Enforcement Guidelines* (Ottawa, 2019), available at: www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/O4421.html; and Japan Fair Trade Commission, *Guidelines for the Use of Intellectual Property under the Antimonopoly Act* (2007, as revised 2016), available at: www.jftc.go.jp/en/legislation_gls/imonopoly_guidelines_files/IPGL_Frand.pdf. For additional commentary, see Robert D. Anderson, Jianning Chen, Anna Caroline Müller, Daria Novozhilkina, Philippe Pelletier, Nivedita Sen and Nadezhda Sporysheva, ‘Competition Agency Guidelines and Policy Initiatives Regarding the Application of Competition Law vis-à-vis Intellectual Property: An Analysis of Jurisdictional Approaches and Emerging Directions’, WTO Staff Working Paper ERSD-2018-02 of 6 March 2018, available at: www.wto.org/english/res_e/reser_e/ersd201802_e.pdf.