28: Undisclosed Information

Article 39

1. In the course of ensuring effective protection against unfair competition as provided in Article 10bis of the Paris Convention (1967), Members shall protect undisclosed information in accordance with paragraph 2 and data submitted to governments or governmental agencies in accordance with paragraph 3.

2. Natural and legal persons shall have the possibility of preventing information lawfully within their control from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices* so long as such information:

(a) 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;

(b) has commercial value because it is secret; and

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

3. Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.

[Footnote*]: For the purpose of this provision, "a manner contrary to honest commercial practices" shall mean at least practices such as breach of contract, breach of confidence and inducement to breach, and includes the acquisition of undisclosed information by third parties who knew, or were grossly negligent in failing to know, that such practices were involved in the acquisition.

1. Introduction: terminology, definition and scope

"Undisclosed information" is one of the categories of "intellectual property" as defined in Article 1.2 of TRIPS (see Chapter 3). Though such information has often

been referred to as "trade secrets" or "know-how", Article 39 does not use these terms nor does it provide a definition of "undisclosed information". The difficulty of finding a common and acceptable understanding of what those notions mean favoured the adoption of more neutral terminology that does not characterize the contents of the information, but only its "undisclosed" nature.

"Undisclosed information" covers any secret information of commercial value, including

- technical know-how, such as design, process, formula and other technological knowledge often resulting from experience and intellectual ability;
- data of commercial value, such as marketing plans, customers lists and other business-related information that provides an advantage over competitors;
- test and other data submitted for the approval of pharmaceutical and chemical products for agriculture.

The obligation established under Article 39.1 is limited to the protection of undisclosed information "against unfair competition as provided in Article 10*bis* of the Paris Convention".

The discipline of unfair competition provides a remedy against acts of competition contrary to honest business practices, such as confusing or misleading the customer and discrediting the competitor. An act of unfair competition may be defined as

> "any act that a competitor or another market participant undertakes with the intention of directly exploiting another person's industrial or commercial achievement for his own business purposes without substantially departing from the original achievement."[1013]

Unfair competition rules supplements in some cases the protection of industrial property rights, such as patents and trademarks. Unlike the latter, however, the protection against unfair competition does not entail the granting of exclusive rights. National laws must only provide for remedies to be applied in cases where dishonest practices have occurred.

Article 39.2 does not define what "undisclosed information" consists of. It only specifies the conditions that the information needs to meet in order to be deemed "undisclosed" and protectable: it should be secret, possess a commercial value and be subject to reasonable steps, under the circumstances, to be kept secret. The conditions set forth are substantially based on the U.S. Uniform Trade Secrets Act, as adopted by many states in the USA.[1014]

The scope of Article 39.3 is limited to undisclosed data which are required by a national authority as a condition for obtaining approval for the marketing of pharmaceutical or of agricultural chemical products "which utilize new chemical entities", provided that the origination of the data involved a "considerable effort".

[1013] WIPO, Protection against Unfair Competition, Geneva 1994, p. 55.

[1014] See, e.g., J. H. Reichman, *Universal minimum standards of intellectual property protection under the TRIPS component of the WTO Agreement*, The International Lawyer 1995, vol. 29, No. 2, p. 378 [hereinafter Reichman 1995].

This provision is, therefore, applicable, when:

a) There is an obligation to submit test data for obtaining marketing authorization for pharmaceuticals and agrochemicals;

b) The pertinent information is not publicly available;

c) The submission should refer to a "new chemical entity". Hence, there is no obligation with regard to new dosage forms, new uses or combinations of known products; and

d) In order to qualify as protectable the origination of the data should have involved a "considerable effort".

2. History of the provision

2.1 Situation pre-TRIPS

Trade secrets were protected under common law rules laid down by courts or under unfair competition statutes in many countries before the adoption of TRIPS. In some countries (e.g., the USA) specific statutes had been adopted.[1015] However, at the time of TRIPS negotiations there were significant differences in comparative law with regard to the scope and modalities of protection of undisclosed information of commercial value. Doubts about the availability of an effective protection for trade secrets in developing countries had also been raised.[1016]

Differences in pre-existing comparative law were even greater with regard to test data relating to pharmaceuticals and agrochemicals. Only a few countries had developed rules on the matter before the negotiation of TRIPS. Thus, the USA introduced a regulatory data protection regime for pesticides in 1972, and in 1984 adopted regulatory exclusivity provisions for medicines. The latter provided for five years of exclusivity for new chemical entities, and three years for data filed in support of authorizations based on new clinical research relating to chemical entities which have already been approved for therapeutic use. The EU member states provided exclusivity protection for the data filed in support of marketing authorization for pharmaceuticals since 1987.

TRIPS is the first international convention specifically imposing obligations on undisclosed information, including test data.

2.2 Negotiating history

2.2.1 Early national proposals

Trade secrets were initially included as part of a future agreement on IPRs in the U.S. proposal of 28 October 1987, as well as in the European and Swiss proposals.[1017] In their earlier positions in the negotiations, developing countries rejected any form of protection for know-how under a future agreement. In 1989,

[1015] See the Uniform Trade Secrets Act (1, 14 ULA 438 (1985), which has been widely adopted in the USA.

[1016] See R. Gadbaw and T. Richards, *Intellectual Property Rights – Global Consensus, Global conflict*?, Boulder 1988, p. 60.

[1017] EC Draft Text, Article 28; Switzerland Draft Text, Article 241(1), U.S. Draft Text, Article 31(1).

the Indian Government exposed, for example, that trade secrets were not a form of intellectual property right. It further held that the protection against unfair competition under Article 10*bis* of the Paris Convention would suffice, and that protection by contract and under civil law was to be preferred to intellectual property rules.[1018]

The EC insisted that the protection of trade secrets be subject to unfair competition rules as provided for under the Paris Convention.[1019] This conception finally prevailed over the consideration of undisclosed information as a form of "property", as suggested in informal submissions by the USA.[1020]

Developed countries were also the proponents of a specific provision for the protection of test data relating to pharmaceuticals and agrochemicals, which included the establishment of a minimum period of protection (five years). A precedent of such proposals may be found in the "Statement of Views of the European, Japanese and United States Business Communities", which influenced the drafting of several articles of TRIPS. This proposal clearly specified the obligation to establish a data exclusivity period:

> "1. Information required by a government to be disclosed by any party shall not be used commercially or further disclosed without the consent of the owner.
>
> 2. Information disclosed to a government as a condition for registration of a product shall be reserved for the exclusive use of the registrant for a reasonable period from the day when government approval based on the information was given. The reasonable period shall be adequate to protect the commercial interests of the registrant".

The same approach was adopted in the U.S. proposal:

> "Contracting parties which require that trade secrets be submitted to carry out governmental functions, shall not use the trade secrets for the commercial or competitive benefit of the government or of any person other than the right-holder except with the right holder's consent, on payment of the reasonable value of the use, or if a reasonable period of exclusive use is given to the right-holder".

2.2.2 The Anell Draft

"SECTION 7: ACTS CONTRARY TO HONEST COMMERCIAL PRACTICES INCLUDING PROTECTION OF UNDISCLOSED INFORMATION

1. Protection of Undisclosed Information

1A.1 In the course of ensuring effective protection against unfair competition as provided for in Article 10bis of the Paris Convention (1967), PARTIES shall provide in

[1018] Communication from India, MTN.GNG/NG11/W/37, 10 July 1989, p. 18, quoted in F. Dessemontet, *Protection of trade secrets and confidential information*, in C. Correa and A. Yusuf, Intellectual Property and International Trade, Kluwer Law International, London, 1998, p. 238 [hereinafter Dessemontet].

[1019] See, e.g., J. Reinbothe and A. Howard, *The state of play in the negotiations on TRIPS (GATT/Uruguay Round)*, European Intellectual Property Review 1991, vol. 13, No.5, p. 163; T. Cottier, *The prospects for intellectual property in GATT*, Common Market Law Review 1991, No.2, p. 396; A. Font Segura, *La protección internacional del secreto empresarial*, MONOGRAFIAS, Eurolex, Madrid 1999, p. 106.

[1020] These different approaches are mirrored in the Anell and Brussels Drafts, see below.

their domestic law the legal means for natural and legal persons to prevent information within their control from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices insofar as such information:

1A.1.1 is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known or readily accessible; and

1A.1.2 has actual [or potential] commercial value because it is secret; and

1A.1.3 has been subject to reasonable steps, under the circumstances, by the person in possession of the information, to keep it secret.

1A.2 "A manner contrary to honest commercial practice" is understood to encompass, practices such as theft, bribery, breach of contract, breach of confidence, inducement to breach, electronic and other forms of commercial espionage, and includes the acquisition of trade secrets by third parties who knew [or had reasonable grounds to know] that such practices were involved in the acquisition.

1A.3 PARTIES shall not limit the duration of protection under this section so long as the conditions stipulated at point 1A.1 exist.

2. Licensing

2Aa PARTIES shall not discourage or impede voluntary licensing of undisclosed information by imposing excessive or discriminatory conditions on such licences or conditions which dilute the value of such information.

2Ab There shall be no compulsory licensing of proprietary information.

3. Government Use

3Aa PARTIES, when requiring the publication or submission of undisclosed information consisting of test [or other] data, the origination of which involves a considerable effort, shall protect such data against unfair exploitation by competitors. The protection shall last for a reasonable time commensurate with the efforts involved in the origination of the data, the nature of the data, and the expenditure involved in their preparation, and shall take account of the availability of other forms of protection.

3Ab.1 PARTIES which require that trade secrets be submitted to carry out governmental functions, shall not use the trade secrets for the commercial or competitive benefit of the government or of any person other than the right holder except with the right holder's consent, on payment of the reasonable value of the use, or if a reasonable period of exclusive use is given to the right holder.

3Ab.2 PARTIES may disclose trade secrets to third parties, only with the right holder's consent or to the degree required to carry out necessary government functions. Wherever practicable, right holders shall be given an opportunity to enter into confidentiality agreements with any non-government entity to which the PARTY is disclosing trade secrets to carry out necessary government functions.

3Ab.3 PARTIES may require right holders to disclose their trade secrets to third parties to protect human health or safety or to protect the environment only when the right holder is given an opportunity to enter into confidentiality agreements with any non-government entity receiving the trade secrets to prevent further disclosure or use of the trade secret.

3Ac.1 Proprietary information submitted to a government agency for purposes of regulatory approval procedures such as clinical or safety tests, shall not be disclosed without the consent of the proprietor, except to other governmental agencies if necessary to

protect human, plant or animal life, health or the environment. Governmental agencies may disclose it only with the consent of the proprietor or to the extent indispensable to inform the general public about the actual or potential danger of a product. They shall not be entitled to use the information for commercial purposes.

3Ac.2 Disclosure of any proprietary information to a third party, or other governmental agencies, in the context of an application for obtaining intellectual property protection, shall be subject to an obligation to hear the applicant and to judicial review. Third parties and governmental agencies having obtained such information shall be prevented from further disclosure and commercial use of it without the consent of the proprietor."[1021]

2.2.3 The Brussels Draft

"1A In the course of ensuring effective protection against unfair competition as provided in Article 10bis of the Paris Convention (1967), PARTIES shall protect undisclosed information in accordance with paragraphs 2 and 3 below and data submitted to governments or governmental agencies in accordance with paragraph 4 below.

2A PARTIES shall provide in their domestic law the legal means for natural and legal persons to prevent information lawfully within their control from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices [footnote] so long as such information:

• 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;

• has commercial value because it is secret; and

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

3A PARTIES shall not discourage or impede voluntary licensing of undisclosed information by imposing excessive or discriminatory conditions on such licenses or conditions which dilute the value of such information.

4A PARTIES, when requiring, as a condition of approving the marketing of new pharmaceutical products or of a new agricultural chemical product, the submission of undisclosed test or other data, the originator of which involves a considerable effort, shall [protect such data against unfair commercial use. Unless the person submitting the information agrees, the data may not be relied upon for the approval of competing products for a reasonable time, generally no less than five years, commensurate with the efforts involved in the origination of the data, their nature, and the expenditure involved in their preparation. In addition, PARTIES shall] protect such data against disclosure, except where necessary to protect the public.]

[Footnote]: For the purpose of this provision, "a manner contrary to honest commercial practices" shall [include] [mean] practices such as breach of contract,

[1021] Chairman's report to the Group of Negotiation on Goods, document MTN.GNG/NG11/W/76, of 23 July 1990.

breach of confidence and inducement to breach, and includes the acquisition of undisclosed information by third parties who knew, or were grossly negligent in failing to know, that such practices were involved in the acquisition."[1022]

As opposed to the final text of Article 39, the Brussels Draft proposed the establishment of a defined period (not less than five years) of data exclusivity, as illustrated by the bracketed text under paragraph 4A, above. According to this approach, data submitted for marketing approval for new pharmaceutical products or new agricultural chemical products could not be relied upon for the approval of competing products for a reasonable time, generally no less than five years, commensurate with the efforts involved in the origination of the data, their nature, and the expenditure involved in their preparation. This meant, in other words, that WTO Members would have been obligated to grant the originator of the data an exclusive right in his data. Such right would have entitled the right holder to prevent third parties from relying on the protected data in the context of obtaining marketing approval for competing products, or to subject use of such data to claims of compensation.

This approach differs considerably from the final version under Article 39, according to which Members arguably are not obligated to provide the originator of the data with exclusive property rights. Article 39 is based on the concept of unfair competition rules. According to this approach, data originators may prevent third parties from using their data only in the event that the third party has acquired the data through dishonest commercial practices. This enhances the possibilities of using existing data for the market entry of competing pharmaceutical products (see further discussion of this controversial issue under Section 3 of this chapter). In this context, it is important to note that the TRIPS flexibilities accorded to Members under the unfair competition approach are being rapidly narrowed down through bilateral and regional trade agreements (see below, Section 6 of this chapter).

3. Possible interpretations

3.1 Article 39.1

> In the course of ensuring effective protection against unfair competition as provided in Article 10bis of the Paris Convention (1967), Members shall protect undisclosed information in accordance with paragraph 2 and data submitted to governments or governmental agencies in accordance with paragraph 3.

Article 39.1 establishes the main rule applicable in the field of undisclosed information. It also provides the context for the correct interpretation of paragraphs 2 and 3 of the same provision.

[1022] Draft Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, Revision, Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods, MTN.TNC/W/35/Rev. 1, 3 Dec. 1990.

The initial wording of Article 39.1 ("In the course of ensuring effective protection against unfair competition . . . ") makes it clear that the protection to be conferred under paragraphs 2 and 3 is to be based on the discipline of unfair competition, as provided for in Article 10*bis* of the Paris Convention, which reads as follows:

> "(1) The countries of the Union are bound to assure to nationals of such countries effective protection against unfair competition.
>
> (2) Any act of competition contrary to honest practices in industrial or commercial matters constitutes an act of unfair competition.
>
> (3) The following in particular shall be prohibited:
>
> 1. 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;
>
> 2. 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;
>
> 3. 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".

It is generally accepted that unfair competition is one of the disciplines of industrial property.[1023] Such protection requires, as mentioned, remedial action against "dishonest" commercial practices, but does not give rise to exclusive rights. The fact that the undisclosed information is deemed to be a "category" of intellectual property (Article 1.2 of the Agreement) does not imply the existence of "property" rights in undisclosed information. There is only "possession" or *de facto* "control" of that information. Thus, Articles 39.2 and 39.3 of the Agreement refer to a person who is "in control" of undisclosed information, in clear contrast to the ownership concept used in the sections relating to other categories of IPRs.[1024]

The ordinary meaning of "unfair" is "not equitable or honest or impartial or according to rules".[1025] The protection against unfair competition does not exclude the legitimate exploitation of externalities emerging from competition in the market, it does not deal with the protection of market interests, but rather of market behaviour. As noted by Kamperman Sanders:[1026]

> "Where exploitation of another's achievements becomes inequitable, unfair competition law acts provide a remedy. This means that the mere fact that another's achievement is being exploited does not call for any impediment on the basis of unfair competition provisions. On the contrary, appropriating and building on others' achievements is the cornerstone of cultural and economic development. The axiom of freedom to copy epitomizes the principles of the free market system."

[1023] "Protection against unfair competition has been recognized as forming part of industrial property protection for almost a century", WIPO, *Intellectual property reading material*, Geneva 1998, p. 124.

[1024] See, e.g., Articles 16.1 and 28.1 which refer to the "owner" of a trademark and of a patent, respectively.

[1025] *The Concise Oxford Dictionary*, Seventh Edition, Oxford University Press, Oxford, 1989.

[1026] See, A. Kamperman Sanders, *Unfair Competition Law*, Clarendon Press, Oxford 1997, p. 7.

3.2 Article 39.2

> Natural and legal persons shall have the possibility of preventing information lawfully within their control from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices so long as such information: . . .

The carefully drafted chapeau of this provision confirms the main elements of the framework of protection for undisclosed information as described above. The persons in control of undisclosed information "shall have the possibility of preventing" certain acts of disclosure, acquisition and use of information, but only when such acts have been made without their consent and "in a manner contrary to honest commercial practices". This clearly indicates that the right to prevent such acts only arises when the means used are condemnable. That is, there is not an absolute protection against non-authorized disclosure, acquisition and use of information, but only against acts made in a condemnable manner.

The concept of "honest" is relative to the values of a particular society at a given point in time. It varies among countries. As noted by one of the main commentators of the Paris Convention,

> "Morality, which is the source of the law of unfair competition, is a simple notion in theory only. In fact it reflects customs and habits anchored in the spirit of a particular community. There is no clear objective standard of feeling, instincts, or attitudes toward a certain conduct. Therefore, specific prescriptions involving uniform evaluation of certain acts are extremely difficult.
>
> The pressures existing in the various countries for the suppression of acts of unfair competition differ greatly. Generally, the development of law of unfair competition depends on active and intense competition in the marketplace by competing enterprises. It is the pressure of conflicting interests which leads to the establishment of clear rules of law. This pressure is not uniform in all countries and indeed it is evolving continuously . . . We look for a standard by which we may judge the act complained of. This is an objective standard: the honest practices in the course of trade in the particular community and at the particular time."[1027]

Given this diversity, different countries may judge certain situations differently. "Honest" is an inherently flexible notion, and this flexibility has been the cornerstone of unfair competition law in civil law systems.[1028]

The footnote to Article 39.2 indicates the practices that "at least" are to be considered as "contrary to honest practices", thus reducing the possible divergences in interpretation. The referred practices include those that may take place in the framework of or in relation to a contractual relationship (breach of a contract, breach of confidence and inducement to breach), as well as the acquisition by third parties of undisclosed information knowing – or being grossly negligent in failing to know – that such unfair practices are involved in the acquisition.

[1027] S. Ladas, *Patents, Trademarks, and Related Rights. National and International Protection*, vol. III, Cambridge 1975, pp. 1685–1686, 1689 [hereinafter Ladas].

[1028] See, e.g., A. Kamperman Sanders.

> . . . as long as such information:
>
> (a) 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;

This provision incorporates an objective standard of secrecy. In order to establish whether protection is to be conferred, it should be proven that the relevant information is "not generally known" or "readily accessible".

The established secrecy standard is relative[1029] in the sense that it does not require that the person seeking protection be the single one in control of the information. This may be available to other competitors (who also keep it as confidential) but should not be known to or readily accessible to most or every competitor in the circles that normally deal with that kind of information.

An important interpretive issue is whether this provision allows for reverse engineering[1030] as a means to obtain information embedded in products put in commerce by the person who is in control of the information. Article 39.2 (a) does not disallow the use of such method;[1031] to the extent that the secret information is "readily accessible", it would not be considered secret under such provision.

> (b) has commercial value because it is secret;

This requirement is an essential element for the protection of confidential information which, in order to be protectable, must have *actual* commercial value.[1032] The generality of this provision indicates that any business-related information is covered. National laws and courts should determine when a given information is deemed to possess "commercial value". In some countries,[1033] the basic test is the extent to which the information provides an opportunity to obtain an advantage over competitors who do not know or use it.

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

[1029] See Dessemontet, p. 251.

[1030] "Reverse engineering" is the study of a product to understand its functional aspects and underlying ideas. It starts with the known product and works backwards to analyze how the product operates or was made.

[1031] See, e.g., Reichman 1995, p. 378. Reverse engineering is accepted in many jurisdictions (e.g., in the USA) as a legitimate means to obtain access to information embodied in the goods. See, e.g., R. Neff and F. Smallson, *NAFTA. Protecting and Enforcing Intellectual Property Rights in North America*, SHEPARD'S, Colorado 1994, p. 102.

[1032] Members may extend protection to information of *potential* commercial value, but this is not required by the Agreement.

[1033] See, e.g., the Mexican Industrial Property Law (1991) (R. Pérez Miranda *Propiedad Industrial y Competencia en México*, Editorial Porrúa, México 1999, p. 162).

The adoption of reasonable steps to preserve secrecy is one of the conditions of protection, inspired, like the other two conditions, by U.S. law. The provision does not identify the type of steps that could be taken, such as encryption, safes, division of work, contractual restrictions.

3.3 Article 39.3

> Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.

3.3.1 Conditions for protection of data submitted for marketing approval

A basic premise for the application of Article 39.3 is that a Member imposes an obligation to submit data as a condition to obtain the marketing approval of pharmaceutical or agrochemical products. This provision does not apply when it is not necessary to submit such data, for instance, when marketing approval is granted by the national authority relying on the existence of a prior registration elsewhere.[1034]

The subject matter of the protection under this Article is *undisclosed* information contained in written material which details the results of scientific health and safety testing of drugs and agrochemicals, in relation to human, animal and plant health, impact on the environment and efficacy of use. This information is not "invented" or "created" but developed according to standard protocols. The protected data may also include manufacturing, conservation and packaging methods and conditions, to the extent that their submission is needed to obtain marketing approval.

The data to be protected must relate to a "new chemical entity". The Agreement does not define what should be meant by "new". Members may apply a concept similar to the one applied under patent law, or consider that a chemical entity is "new" if there were no prior application for approval of the same drug. Article 39.3 does not clarify either whether newness should be absolute (universal) or relative (local).[1035]

Based on the ordinary meaning of the terms used, Article 39.3 would not apply to new uses of known products, nor to dosage forms, combinations, new forms of administration, crystalline forms, isomers, etc., of existing drugs, since there would be no novel chemical entity involved.

[1034] In this case the authority does not require test data, but takes its decision on the basis of the registration granted in a foreign country.

[1035] See T. Cook, *Special Report: The protection of regulatory data in the pharmaceutical and other sectors*, Sweet & Maxwell, London 2000, p. 6.

Article 39.3 does not define any substantive standard for granting protection (like inventive step or novelty), but simply mandates protection when obtaining the data involved "a considerable effort". The text is vague about the type of effort involved (technical, economic?) and also with respect to its magnitude. (When would it be deemed considerable?) The wording used here is broader than that employed in Article 70.4 – where reference to "significant investment" is made. A reasonable understanding would be that the "effort" involved should not only be significant in economic terms but also from a technical and scientific point of view, including experimental activities.

3.3.2 Forms of protection of data submitted for marketing approval

The protection to be granted under Article 39.3 is twofold: against "unfair commercial use" and against disclosure of the relevant protected information.

Considerable controversy exists about the interpretation of the extent of the obligation to protect against "unfair commercial use". According to one view, the sole or most effective method[1036] for complying with this obligation is by granting the originator of data a period of *exclusive* use thereof, as currently mandated in some developed countries. Under this interpretation, national authorities would not be permitted, during the exclusivity period, to rely on data they have received in order to assess subsequent applications for the registration of similar products.[1037]

According to another view, Article 39.3 does not require the recognition of exclusive rights, but protection in the framework of unfair competition rules. Thus, a third party should be prevented from using the results of the test undertaken by another company as background for an independent submission for marketing approval, if the respective data had been acquired through dishonest commercial practices. However, under that provision a governmental authority would not be prevented from relying on the data presented by one company to assess submissions by other companies relating to similar products. If the regulatory body were not free, when assessing a file, to use all the knowledge available to it, including data from other files, a great deal of repetitive toxicological and clinical investigation will be required, which will be wasteful and ethically questionable. This position is also grounded on the pro-competitive effects of low entry barriers

[1036] See, e.g., the Communication from the EU and its Member States on *The relationship between the provisions of the TRIPS Agreement and access to medicines*, IP/C/W/280, 12 June 2001. A similar view is expressed by R. Kampf, *Patents versus Patients?* Archiv des Völkerrechts, vol. 40 (2002), pp. 90–234, on p. 120, 121.

[1037] The rationale behind this position is that "equity demands that protection be provided for data, which can cost the original submitter several million dollars to produce. Disclosing this data to the public or allowing its use by another applicant unfairly denies the compiler of the data the value of its efforts and grants an economic advantage to later applicants for marketing approval, enabling them to avoid the cost of developing test data for their own products. Countries that allow such unfair advantages to later applicants discourage developers of new pharmaceuticals and agricultural chemicals from seeking to introduce their state-of-the-art products in the country's market. So, not only is such protection required by the TRIPS Agreement, it is both equitable and wise from a public and health policy standpoint." See C. Priapantja, *Trade Secret: How does this apply to drug registration data?* Paper presented at "ASEAN Workshop on the TRIPS Agreement and its Impact on Pharmaceuticals", Department of Health and World Health Organization, May 2–4 2000, p. 4 [hereinafter Priapantja].

for pharmaceutical product. The early entry of generic competition is likely to increase the affordability of medicines at the lowest possible price.[1038]

On the other hand, protection is to be ensured against disclosure of the confidential data by governmental authorities, subject to the two exceptions mentioned in Article 39.3: a) when disclosure is necessary to protect the public; and b) when steps are taken to ensure that the data will not be used in a commercially unfair manner. Under these exceptions, disclosure may be permissible, for example, to allow a compulsory licensee to obtain a marketing approval, particularly when the license is aimed at remedying anti-competitive practices or at satisfying public health needs.

4. WTO jurisprudence

There is no WTO jurisprudence so far on this subject. However, the USA requested consultations under the DSU against Argentina in relation to, *inter alia*, Article 39.3 as applied to pharmaceuticals and agrochemicals.[1039] On 20 June 2002, the USA and Argentina notified the DSB of a mutually agreed solution.[1040] In their DSU notification, they stated that:

> "The Governments of the United States and Argentina have expressed their respective points of view on the provisions of Article 39.3 of the TRIPS Agreement, and have agreed that differences in interpretations shall be solved under the DSU rules. The Parties will continue consultations to assess the progress of the legislative process . . . and in the light of this assessment, the United States may decide to continue consultations or request the establishment of a panel related to Article 39.3 of the TRIPS Agreement."
>
> "In addition, the Parties agree that should the Dispute Settlement Body adopt recommendations and rulings clarifying the content of the rights related to undisclosed test data submitted for marketing approval according to Article 39.3 of the TRIPS Agreement, and should Argentinean law be inconsistent with Article 39.3 as clarified by the above-mentioned recommendations and rulings, Argentina agrees to submit to the National Congress within one year an amendment to Argentinean law, as necessary, to put its legislation in conformity with its obligations under Article 39.3 as clarified in such recommendations and rulings."[1041]

5. Relationship with other international instruments

As mentioned, Article 39 is based on and develops the disciplines on unfair competition contained in Article 10*bis* of the Paris Convention, for the particular case of

[1038] See Carlos Correa, *Protection of Data Submitted for the Registration of Pharmaceuticals. Implementing the Standards of the TRIPS Agreement*, South Centre, Geneva 2002 (available at <http://www.southcentre.org/publications/protection/toc.htm>).

[1039] See WT/DS 171/1; WT/DS 196/1. (Other controversial issues were the Argentinean provisions on compulsory licences; exclusive marketing rights; import restrictions; process patents, including the question of burden of proof; preliminary injunctions; patentability of micro-organisms and transitional patents.)

[1040] See WT/DS171/3.

[1041] Ibid., para. 9 ("Protection of Test Data Against Unfair Commercial Use").

undisclosed information. Hence, the interpretation of the Convention, including its negotiating history, is of relevance to the implementation of Article 39.[1042]

6. New developments

6.1 National laws

After the adoption of TRIPS, some countries have reportedly changed their legislation in order to implement Article 39.3. In some cases, the exclusivity approach, as applied in United States and Europe, has been followed. Thus, the U.S. government initiated in April 1996 an investigation under Special Section 301 of the U.S. Trade Act against Australia, where no exclusivity was granted and generic companies only had to demonstrate bio-equivalence[1043] in order to obtain marketing approval of a similar product. In addition, Australian authorities granted certificates of free sale that permitted generic companies to export to other countries where marketing approval was automatically granted on the basis of the Australian certificates. The USA argued that Australia was in contradiction with Article 39.3. This action led to an amendment to the Australian law. Under the Therapeutic Goods Legislation Amendment Act 1998 (No.34, 1998) test data have five (5) years of exclusivity. During this time, another company wishing to register a generic copy of the product will be required to seek the agreement of the originator company to use its data, or to develop its own data package.[1044]

Other countries have followed a non-exclusivity model. Thus, Argentina passed a law (No. 24.766) on the matter in 1996,[1045] according to which test data should only be submitted for the registration of *new* chemical entities. However, when a pharmaceutical product is already marketed in Argentina or in other countries that comply with certain standards defined by the law, the national health authority may rely on the prior registration. There is no need in these cases for the applicant to submit test data.

In Thailand, the Food and Drug Administration (FDA) established in 1989 a Safety Monitoring Program (SMP), according to which new drugs were approved conditionally and placed under the SMP for at least two years. During this period, those new drugs could only be available in either public or private hospitals/clinics where physicians would closely monitor adverse drug reactions. Producers were required to submit to the FDA substantial credible safety data of the products using proper statistical methodology during the SMP. Once the data satisfactorily supported safety of the products, an unconditional license was issued. Meanwhile, it was required that a bio-equivalence study be conducted for generic drugs to prove their quality and efficacy to be comparable with those of the original ones. No application for generic drugs could be made until the original product was released

[1042] See, in particular, Ladas.

[1043] Two pharmaceutical products are bioequivalent if they are pharmaceutically equivalent and their bioavailabilities (rate and extent of availability), after administration in the same molar dose, are similar to such a degree that their effects can be expected to be essentially the same.

[1044] Priapantja, p. 6.

[1045] The USA applied economic sanctions to Argentina in 1997, arguing insufficient protection of confidential information. As mentioned, the USA later on requested consultations under the DSU on, *inter alia*, Argentina's compliance with Article 39.3.

from the SMP and received unconditional licenses. Since the SMP delayed the entry of generic drugs into the market, the scheme led in some cases to high drug prices and limited drug accessibility to patients, particularly those suffering from such disease as HIV/AIDS. As a result, the Drug Committee decided to allow, as of January 2001, the bio-equivalence study to be done at any time regardless of whether or not the original products are under the SMP. However, if the original products are still under the SMP, those generic products must be under the SMP as well.

6.2 International instruments

Article 10*bis* of the Paris Convention, discussed above, provides the basic framework for the protection of trade secrets against unfair competition. In this context, WIPO has recommended a model provision to address the protection of secret information (see box). There are no other international instruments specifically dealing with the matter.

WIPO MODEL PROVISION ON UNFAIR COMPETITION IN RESPECT OF SECRET INFORMATION

Article 6

(1) [General Principle] Any act or practice, in the course of industrial or commercial activities, that results in the disclosure, acquisition or use by others of secret information without the consent of the person lawfully in control of that information (hereinafter referred to as "the rightful holder") and in a manner contrary to honest commercial practices shall constitute an act of unfair competition.

(2) [Examples of Unfair Competition in Respect of Secret Information] Disclosure, acquisition or use of secret information by others without the consent of the rightful holder may, in particular, result from

(i) industrial or commercial espionage;

(ii) breach of contract;

(iii) breach of confidence;

(iv) inducement to commit any of the acts referred to in items (i) to (iii);

(v) acquisition of secret information by a third party who knew, or was grossly negligent in failing to know, that an act referred to in items (i) to (iv) was involved in the acquisition.

(3) [Definition of Secret Information] For the purposes of this Article, information shall be considered "secret information" if

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

(ii) it has commercial value because it is secret; and

(iii) it has been subject to reasonable steps under the circumstances by the rightful holder to keep it secret.

(4) [Use or Disclosure of Secret Information Submitted for Procedure of Approval of Marketing] Any act or practice, in the course of industrial or commercial

activities, shall be considered an act of unfair competition if it consists or results in (i) an unfair commercial use of secret test or other data, the origination of which have been submitted to a competent authority for the purposes of obtaining approval of the marketing of pharmaceutical or agricultural chemical products which utilize new chemical entities; or (ii) the disclosure of such data, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use."[1046]

6.3 Regional and bilateral contexts

6.3.1 Regional

6.3.1.1 The EU. The issue of data protection has been dealt with within the Union under the exclusivity approach, on the basis of Directive 65/65, as amended by Directive 87/21/EEC. Similar provisions for veterinary products are contained in Directive 81/851/EEC, as amended by Directive 90/676/EC. According to recently proposed legislation, new pharmaceutical products would be entitled to 8 years of data exclusively, 2 years of marketing exclusively (during which generic companies would be allowed to engage in "Bolar" – type activities) and an additional year of protection for new indications of existing products.[1047]

6.3.1.2 NAFTA. The NAFTA Agreement contains a specific provision on the matter (Section 1711). Though it is based on the concept of "trade secret" rather than "undisclosed information", it closely follows Article 39.3 with regard to the definition of protected subject matter.[1048] There are, nevertheless, two important differences with respect to TRIPS. First, the NAFTA provision does not include a text similar to paragraph 1 of Article 39, which clearly sets out the framework for the regulation of undisclosed information. Second, while para. 5 of section 1711 of NAFTA resembles paragraph 3 of Article 39 of the Agreement, paragraphs 6 and 7 add a "TRIPS-plus" obligation in terms of a minimum five-year period, as follows:

"6. Each Party shall provide that for data subject to paragraph 5 that are submitted to the Party after the date of entry into force of this Agreement, no person other than the person that submitted them may, without the latter's permission, rely on such data in support of an application for the product approval during a reasonable period of time after their submission. For this purpose, a reasonable period shall normally mean not less than five years from the date on which the Party granted

[1046] WIPO, (1996), Model Provisions on Protection Against Unfair Competition, Geneva.

[1047] See Resolution of the European Parliament, Amendment 14, Article 1, Point 8 (17 December 2003). This Resolution is based on the recommendations of the European Parliament Committee on the Environment, Public Health and Consumer Policy. *Draft Recommendation for Second Reading on the Council Amending Directive 2001/83/EC on the Community Code Relating to Medicinal Products for Human Use* (28 November 2003), A5-0425/2003. See also Meir Perez Puzatch, *Intellectual Property and Pharmaceutical Data Exclusively in the Context of Innovation and Market Access* [hereinafter Puzatch], Third UNCTAD-ICTSD Dialogue on Development and Intellectual Property, 12–16 October 2004, Bellagio, Italy (paper available at <http://www.iprsonline.org/unctadictsd/bellagio/dialogue 2004/bell3_documents.htm>).

[1048] The NAFTA definition, however, covers information that "has or may have" commercial value.

approval to the person that produced the data for approval to market its product, taking account of the nature of the data and the person's efforts and expenditures in producing them. Subject to this provision, there shall be no limitation on any Party to implement abbreviated approval procedures for such products on the basis of bioequivalence and bioavailability studies.

7. Where a Party relies on a marketing approval granted by another Party, the reasonable period of exclusive use of the data submitted in connection with obtaining the approval relied on shall begin with the date of the first marketing approval relied on".

6.3.1.3 The Andean Community. Provisions on the protection of business secrets are also established in the Common Regime on Industrial Property of the Andean Community. The definition of such secrets (Article 260) is based on Article 39.2. Though the regulation of business secrets is made separately from unfair competition, the prohibited acts are those contrary to proper commercial practices, including breach of contract. Decision 486 introduced an important amendment to the pre-existing regulation (Decision 344) in relation to the protection of data (Article 266): it eliminated an exclusivity period for the use of such data that Decision 344 had established.

6.3.1.4 CAFTA. On 28 May 2004, the USA, Costa Rica, El Salvador, Guatemala, Honduras and Nicaragua signed the Central American Free Trade Agreement (CAFTA).[1049] This agreement considerably modifies the TRIPS approach toward protecting undisclosed information. In essence, it obligates Parties to introduce in their domestic laws exclusive rights to data submitted for marketing approval purposes.[1050] As opposed to the TRIPS approach of unfair competition law, the originator of the data in order to prevent third parties from relying on his data, does not have to prove unfair commercial practices on the part of the third party.[1051]

In addition, CAFTA establishes a link between the exclusive patent right and the marketing approval process by subjecting marketing approval for competing generic products to the consent or acquiescence of the patent holder:

"3. Where a Party permits, as a condition of approving the marketing of a pharmaceutical product, persons, other than the person originally submitting safety or efficacy information, to rely on evidence or information concerning the safety and efficacy of a product that was previously approved, such as evidence of prior marketing approval in the Party or in another territory, that Party:

shall implement measures in its marketing approval process to prevent such other persons from marketing a product covered by a patent claiming the product or its

[1049] For the text of the agreement, see <http://www.ustr.gov/new/fta/Cafta/final/index.htm>.

[1050] See Chapter 15, Article 15.10(1)(a). For a detailed legal analysis of CAFTA and the implications in the area of undisclosed information, see Frederick Abbott, *The Doha Declaration on the TRIPS Agreement and Public Health and the Contradictory Trend in Bilateral and Regional Free Trade Agreements*, Quaker United Nations Office, Geneva 2004 [hereinafter Abbott, *Contradictory Trend*]. Available at <http://www.geneva.quno.info/main/publication.php?pid=113>.

[1051] Considering that during the Uruguay Round negotiations, inclusion of a provision on data exclusivity was not feasible (see above, Section 2.2 of this chapter), CAFTA provides an opportunity to introduce such exclusivity "through the back door".

approved use during the term of that patent, unless by consent or acquiescence of the patent owner [. . .]."[1052]

In other words, the term of data protection is effectively extended to the full term of a patent, which is not required under TRIPS.[1053]

Next to the difficulties created for regulatory authorities to determine the validity of patents, this provision has been interpreted as possibly precluding governments' possibilities to use compulsory licensing as a means of making available low-priced pharmaceutical products.[1054] Since marketing approval is independent of patent law, the third party authorized to produce a patented product under compulsory license would arguably depend on the patentee's consent or acquiescence for the actual marketing of the product.

6.3.2 Bilateral

On the bilateral level, there have been similar trends as observed in the context of CAFTA, above. For instance, the FTA between the USA and Morocco provides for data exclusivity and, as under CAFTA, for the right of a patent holder to preclude marketing approval of medicines during the patent term.[1055] The Chile – USA FTA also includes a provision on data exclusivity.[1056]

6.4 Proposals for review

There are so far no proposals for review of Article 39. However, several countries, including the EU and its member states,[1057] developing countries[1058] and the USA have referred to the interpretation of Article 39.3 in written or oral submissions made on occasion of the Special Session on Intellectual Property and Access to Medicines held by the Council for TRIPS on 18–20 June, 2001.[1059] A number of developing countries have advocated that the establishment of exclusive rights – as is the case, e.g., in the USA and Europe – would delay the market entry of generic versions of products for which patents have expired, thereby unjustifiably limiting access to medicines.

7. Comments, including economic and social implications

Trade secrets protection covers business information of various natures, including mere commercial data as well as technical know-how. Such information may

[1052] See Chapter 15, Article 15.10(3)(a).

[1053] Abbott, *Contradictory Trend*, p. 8.

[1054] Ibid.

[1055] See Abbott, *Contradictory Trend*, p. 11.

[1056] For a detailed analysis of the USA – Chile FTA, see Roffe, 2004. This paper also provides an overview of other bilateral free trade agreements and their rules on undisclosed information.

[1057] See IP/C/W/288, 12 June 2001.

[1058] See IP/C/W/296, 19 June 2001.

[1059] See IP/C/M/31, 10 July 2001.

be of considerable economic value, particularly, but not exclusively, in process industries, such as chemicals production.[1060]

The protection of know-how and other business information may be of importance for large as well as small and medium enterprises, both in developed and developing countries. A distinct advantage of trade secrets protection is that no registration is necessary to acquire the relevant rights, and that protection lasts as long as the information is kept secret. These features make this form of protection particularly suitable to small/medium companies in developing countries. However, enforcement costs may be high.

Trade secrets protection may also be applied in relation to traditional knowledge. It has been noted that

> "The provisions against unfair competition may also be used to protect undisclosed traditional knowledge, for instance, traditional secrets kept by native and indigenous communities that may be of technological and economic value. Acknowledgement of the fact that secret traditional knowledge may be protected by means of unfair competition law will make it possible for access to that knowledge, its exploitation and its communication to third parties to be monitored. Control over the knowledge, and regulation of the manner in which it maybe acquired, used and passed on, will in turn make it possible to arrange contracts for the licensing of secret traditional knowledge and derive profits from its commercial exploitation. It is necessary to publicize more, within the sectors and communities concerned, the opportunities that the secrecy regime offers for controlling the dissemination and exploitation of traditional knowledge."[1061]

The protection of data submitted for the registration of pharmaceuticals and agrochemicals has been deemed of considerable economic importance by the so-called "research-based industry." The basic reasoning is that the manufacturer has invested, often heavily, in the research necessary to develop the relevant data, and where patent law fails to provide protection[1062] (for example, because the active component was shortly to be out of patent, or because the drug was based on a combination of known substances used in a novel manner) the secrecy of the testing work would provide the only barrier to a competitor rapidly producing and registering an exact copy of the drug. From a public health perspective, however, the early entry of generics competition is also seen as an important policy objective, whose realization is facilitated by regulations that allow health authorities to rely on existing test data to approve subsequent applications for generic products. Thus, developing country Members should be aware of recent developments on the regional and bilateral levels that limit existing TRIPS flexibilities in this respect.

[1060] According to a study by the USITC, for instance, trade secrets had gained growing importance in the 1980's. They were deemed of "great importance" by 43% of the surveyed U.S. industry (USITC, 1988, pp. 2–4).

[1061] GRULAC, *Traditional knowledge and the need to give it adequate intellectual property protection*, WO/GA/26/9, September 2000, 14. See also Graham Dutfield, *Protecting Traditional Knowledge and Folklore. A review of progress in diplomacy and policy formulation*, Issue Paper No. 1, UNCTAD-ICTSD, Geneva 2003.

[1062] The protection of test data is, in effect, particularly relevant when there is *no* patent protection. If the latter exists, the title-holder may exclude competitors on the basis of their exclusionary rights. See Puzatch.