Article 39.3 of the TRIPS Agreement: Its Genesis and the Present Context

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1. The Problem

In the long series of disputes that the implementation of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) in developing countries has seen, the controversy around protecting test data as provided for under Article 39.3 has few parallels in terms of enduring impact that it could have. This Article provides that "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."

While Article 39.3 is clearly intended to ensure that "undisclosed test data" was not misappropriated, the pharmaceutical industry associations in the United States and the European Union, representing the larger companies, have argued that Article 39.3 should be interpreted in a manner that provides statutory protection spanning a period of time to data submitted for obtaining marketing approval, among others.

In a submission made in 1999, the Pharmaceutical Research and Manufacturers of America (PhRMA) had argued for the implementation of effective data protection standards that provide the intended level and form of protection as provided for in Article 39.3. An effective implementation of data protection standards in view of PhRMA would require that the following steps should be taken: (i) ensure at least ten years of exclusive marketing rights for the pioneer applicant measured from the date of approval of the pharmaceutical in the WTO member; (ii) not make data protection contingent upon concurrent patent rights covering the pharmaceutical product; and (iii) preclude reliance by third parties on marketing approvals granted to the pioneer applicant by a health regulatory agency in another WTO member. These steps suggested by PhRMA are clearly intended to extend the period of protection that a product would enjoy under the patent laws, thus rendering ineffective the process of dissemination of technology, which is one of the intended objectives of the patent system. In fact, the period of data exclusivity demanded by PhRMA is twice that is currently available in the United States.

The European Federation of Pharmaceutical Industries and Associations (EFPIA) in their position have stated that it is protection against "unfair commercial use" of data relating to pharmaceutical and agricultural chemical products that is the primary objective of

Article 39.3[1]. While arguing their stated position the EFPIA have pointed to an interpretation of "unfair commercial use" as has been suggested by the Office of the United States Trade Representative (USTR). According to the USTR, "TRIPS Agreement understood it [unfair commercial use] to mean that the data will not be used to support, clear or otherwise review other applications for marketing approval for a set amount of time unless authorized by the original submitter of the data. Any other definition of this term would be inconsistent with logic and the negotiating history of the provision".

It is the rationale for the use of Article 39.3 as indicted by EFPIA that is more significant in the present context. The EFPIA have held the view that the relevance of the Article arises primarily because "more and more compounds are being developed which are not patent protected". The development of these compounds, according to EFPIA, "does not require less extensive or complex tests and clinical trial data" and hence the need to introduce data protection.

These views held by the pharmaceutical associations were also articulated in unambiguous terms by the officialdom. The USTR General Counsel stated in 1995 that "negotiators understood it [the term "unfair commercial use"] to mean that data will not be used to support, clear or otherwise review other applications for marketing approval for a set amount of time unless authorized by the original submitter of the data. Any other definition of this term would be inconsistent with logic and the negotiating history of the provision"[2]. More recently, the European Commission submitted thus: "Both the logic and the negotiating history of Article 39.3 of TRIPS leave no doubt that providing data exclusivity for a certain period of time was the envisaged way to protect data against unfair use as prescribed by Article 39.3… Whether any system other than data exclusivity over a reasonable period of time would meet the requirements of Article 39.3 of the TRIPS Agreement is to be assessed on a case-by-case basis, but examples of actual application by WTO Members of alternative – and TRIPS compliant – system to non-reliance over a reasonable period do not appear to exist."[3]

With the associations of the global pharmaceutical majors and their home governments taking strident positions regarding data exclusivity, it is important to consider the major developments that have taken place since the issue was introduced as a part of the negotiations leading up to the adoption of the TRIPS Agreement. This would help not only in putting the debate on data exclusivity in perspective, but would also provide some indications of the possible directions that this issue could take in the future. The present study has been organised with these objectives in view.

At the outset, a brief enumeration of the genesis of the debate for the inclusion of data exclusivity in the TRIPS framework would be provided. The next section reviews the mechanism for protecting test data related to pharmaceuticals in a number of countries. Section 3 would discuss the disputes over protection of test data that have come to the fore in recent years. The more prominent among these involves Argentina and the United

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[1] EFPIA, Position Paper: TRIPS Article 39.3 (Protection of undisclosed data), November 2000.

[2] Quoted by PhRMA, "Special 301" Submission, March 2003.

[3] Quoted by PhRMA, "Special 301" Submission, March 2003.

States, one in which the WTO Dispute Settlement Mechanism was invoked by the latter. This section would also provide the result of the investigations that the USTR has conducted by using the provisions of Special 301 of the Omnibus Trade and Competitiveness Act of 1988 to identify countries that have not been giving adequate protection to intellectual property rights. Section 4 would provide some of the recent developments that have taken place on this issue.

2. Genesis of the Inclusion of Data Exclusivity in the TRIPS Regime

The United States was among the first movers for the inclusion of protection of undisclosed information as a part of the Agreement on TRIPS. In one of its early submissions to the Negotiating Group made in 1987, the United States introduced the concept of trade secrets, which was defined to include undisclosed valuable business, commercial, technical or other proprietary data as well as technical information. According to the United States, misappropriation, including unauthorised use or disclosure of a trade secret had to be prevented. Furthermore, it was argued that trade secrets submitted to governments as a requirement to do business should not be disclosed except in extreme circumstances involving national emergencies, or in case of public health and safety, provided that such disclosure did not impair actual or potential markets of the submitter or the value of the submitted trade secrets.

At least three features of the United States' submission to the TRIPS Negotiating Group are immediately evident. The first is that it introduced some of the key elements of Article 39.3, which included the concept of trade secrets or undisclosed information. Secondly, the submission went quite beyond the applicability of Article 10^{bis} of the Paris Convention, which was intended to check unfair competition as a result of the implementation of the regimes of intellectual property rights that were covered under this Convention. It may be argued that Article 10^{bis} was intended to prevent misuse of any information consequent upon the right holders disclosing their inventions, which may be to the detriment of the commercial interests of the rights holders, and this was indeed the basis of its inclusion in the TRIPS Agreement. And, last but not the least important, particularly in the context of the present debate, the United States proposed a misappropriation regime as opposed to one that conferred rights, for protecting information. This initial position was later to change as has been indicated below.

A similar approach was also adopted by the business communities of Europe, United States and Japan, who made a joint statement proposing a framework for the regime of intellectual property protection that, in their view, should be adopted at the end of the TRIPS negotiations. In their submission the business communities proposed the following in respect of protection of test data:

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.

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 the government approval based on the information was given. The reasonable period shall be adequate to protect the commercial interests of the registrant.

The business communities were thus clearly aiming for the realisation of a regime, which provided exclusive rights over the data that was submitted to the government for the registration of the product.

In a later submission before the TRIPS Negotiating Group the United States put forth the view that issue underlying the protection of trade secrets was the same as that underlying the protection of intellectual property rights generally, namely that of not benefiting from

the fruits and labours of others improperly. It was suggested that a two-pronged approach should be taken to the protection of trade secrets. First, in regard to the transfer of know-how between private parties, the confidentiality of information given to employees and restrictions on its divulgation should be protectable through the courts; protection against use in a competing enterprise should also be available when such information had been improperly obtained by a third party. Secondly, there should be restrictions on the use and disclosure of information made available to governments. The need for exceptions in this respect was acknowledged in the United States' proposal, for example in the case of a national emergency or for environmental reasons, but in no event should the recipient of the information be allowed to use such information to compete with the person who had generated it. In regard to the question of the definition of trade secrets, he referred to the definition contained in the relevant United States law. The definition contained in the Uniform Trade Secrets Act of the United States was that a trade secret is any information, including a formula, pattern, compilation, program, device, method, technique or process that (i) derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use, and (ii) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy. In essence, a trade secret was considered identifiable information, which (i) was protected from disclosure by reasonable efforts by its owner and (ii) had value because it was not known and could not be ascertained easily by others.

The rulings by the courts in the United States were also quoted in this context. In a prominent decision of the courts it had been stated that, if a company had invested time, effort and money in developing a trade secret which gave it an advantage over its competitors, those competitors should no more be permitted to take and use that trade secret without the owner's consent than they would be permitted to take and use or give away machinery in the trade secret owner's plant or office without permission of that owner. In another case it was stated that a person may use his competitor's secret process if he had discovered the process by reverse engineering applied to the finished product or by his own independent research; but he could not avoid these labours by taking the process from the discoverer without his permission at a time when he was taking reasonable precautions, to maintain its secrecy. As to what constituted reasonable precautions the courts had stated that the tolerance of espionage must cease when the protection required to prevent another's spying cost so much that the spirit of inventiveness was dampened. A person or corporation should not be required to take unreasonable precautions to prevent another from doing that which he ought not to do in the first place.

Some delegations reiterated their view that trade secrets did not constitute a form of intellectual property and therefore fell outside the scope of the work of the Negotiating Group. It was argued that trade secret could not be regarded as a form of intellectual property since the requirement of disclosure, which was an essential part of all forms of intellectual property rights, could not be enforced in this case. Some of these participants said that this did not mean that they did not recognise the need for know-how to be protected and also its importance for the transfer of technology. However, such protection should be accorded under other civil and criminal law, including contract law,

not by IPR law. One participant believed that the appropriate form of legislation to deal with this matter was that concerning the abuse of economic power. He argued that protection of trade secrets could not help developing countries have access to technology if the know-how was not disclosed.

The Chairman of the TRIPS Negotiating Group provided the initial formulation for including undisclosed information in the proposed Agreement, which read thus:

"Parties which require that trade secrets be submitted to carry out governmental functions, shall not use the trade secrets for the commercialisation or competitive benefit of the government or of any person other than the right holder except with the right holder's consent. Proprietary information submitted to a government agency for the purposes of regulatory approval procedures such as clinical or safety tests, shall not be disclosed …".

The draft submitted in 1990 to the Brussels Ministerial Conference, which was supposed to conclude the Uruguay Round negotiations according to the time-table agreed to in Punta del Este where the eighth round of GATT negotiations was launched, presented the following text to the Contracting Parties in respect of undisclosed information:

"Parties, when requiring as a condition of approving the marketing of pharmaceutical products or of a new agricultural chemical product, the submission of undisclosed tests or other data, the origination of which involves a considerable effort shall [protect such data against unfair commercial use. Unless the person submitting this 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" (emphasis added).

The final text of the Agreement on TRIPS adopted in 1994 made no mention about the period for which undisclosed information was to be granted protection. According to the European Union, "the US negotiators had decided to drop the more explicit language of the earlier drafts since they did not view such wording as essential" because the common understanding of protection against unfair commercial use included granting of protection for a fixed period of time.

It may however be mentioned in this context that WIPO had developed the "Model Provisions on Protection Against Unfair Competition" in 1996, essentially to give effect to Article 10^{bis} of the Paris Convention and which forms the basis of Article 39 of the TRIPS Agreement. This Model Law spells out the requisites, which in view of the WIPO would be essential for implementing Article 10^{bis}. The Model Law does not indicate that a fixed term of protection of undisclosed information is what is necessary for effectively implementing the above-mentioned Article of the Paris Convention. More importantly, under the discipline of unfair competition, protection is not based on the existence of "property" rights[4].

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[4] Carlos Maria Correa, Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the standards of the TRIPS Agreement, South Centre, 2002.

The foregoing shows that at the time of its formalisation, it was not envisaged that the implementation of Article 39.3 of the TRIPS Agreement would require the kind of solutions that the European Union and the United States are suggesting at the present juncture under the influence of the associations of pharmaceutical majors. Moreover, these solutions are not part of the current administrative/legal framework in most countries, a fact that has prompted the United States Trade Representative to threaten action against a number of countries. A later discussion will provide the details.

3. Legislations for the Protection of Undisclosed Information in Select Countries

This section provides information on the legislative cover that is provided by several countries for the protection of undisclosed information. A majority of these are either developed countries or economies in transition.

3.1 Developing countries

The status of protection of undisclosed information is provided in respect of seven countries. All these countries provide legal means for protection of undisclosed information. None of these countries, however, provide for exclusive rights to the owners of the data/information.

3.1.1 Argentina

In the case of Argentina the protection of undisclosed information is carried out as per the Law No. 24.766, passed on 18 December 1998 and published in the Boletín Oficial of 20 December 1996, enacts the Law on Confidential Information.

Provision is also made for protection against dishonest commercial use of information submitted to the local health authority for approval of new chemical entities, provided that the information meets the requirements of Article 1 and is the outcome of significant technical and economic effort, meaning that it may not be disclosed. The procedure for registration of pharmaceutical products is regulated by Decree No. 150/92 (harmonized text, Decree No. 177/93).

As regards the registration, manufacture, prescription, dispensing, marketing, import and export of drugs, and in order to safeguard public health, Decree No. 150/92 (partly amended by Decree No. 177/93) lays down the requirements for obtaining registration. It thus establishes:

The procedures for registration of drugs by the Ministry of Health and Social Welfare in order to secure sanitary approval and marketing authorization;

The operating conditions for companies involved in drug production and packing for retail sale;

The responsibilities of importers of drugs.

The implementing authority is the National Drug, Food and Medical Technology Administration (ANMAT).

3.1.2 China

Article 35 of the Implementation Provisions of the Drug Administration Law of the People's Republic of China provides protection to undisclosed test and other data, which is gathered and submitted by the manufacturer or distributor as required in support of applications for marketing approval of pharmaceutical products which utilised new chemical entities, against unfair commercial use. Within six years from the date on which a manufacturer or distributor is granted marketing approval of a pharmaceutical product utilised new chemical entities, if any second applicant applies for market authorization

using the undisclosed data that is under protection, without the permission of the prior applicant, the competent authority for drug administration does not grant the market authorization, unless the second applicant submits his own data. The competent authority for drug administration does not disclose the protected data, except in cases where (a) the disclosure of such data was necessary to protect the public, or (b) steps were taken to ensure that the data are protected against unfair commercial use.

3.1.3 Israel

All undisclosed test and other data submitted to a government agency for the purpose of obtaining marketing approval for new or existing chemical entities contained in a pharmaceutical and agricultural chemical product are held in confidence and are not open to public inspection (section 23B of the Law for the Protection of Privacy 5731-1981; Rule 42.5 *et seq.* of the Civil Service Bylaws). The transgression of such bylaws constitute both disciplinary violations and criminal violations.

3.1.4 Mexico

The Mexican legislation for the protection of undisclosed information is taken up under Article 86*bis* of the Law on Industrial Property. It states that information required by special laws to determine the safety and efficacy of pharmaceutical and agricultural chemicals are to be protected in accordance with international treaties to which Mexico is a party.

The records of government proceedings are confidential and only the interested parties may have access to them in accordance with the provisions of the Federal Law on Administrative Procedure, Article 33 of which provides that the parties to administrative proceedings shall be entitled at any time to ascertain the status of their files, by seeking the pertinent information in the offices concerned, except where they contain information on defence and **national security**, have a bearing on matters protected by trade or industrial secrets, where the interested party is neither the owner nor an assignee, or deal with matters concerning which prohibitory legislation exists.

Moreover, Article 47 of the Federal Law on Public Servants' Responsibilities provides that all public servants shall be required to uphold the standards of legality, honour, loyalty, impartiality and efficiency incumbent on them in the exercise of their employment, responsibilities or mission, subject to the appropriate procedures and sanctions; this requirement includes the obligation under subparagraph IV of the above-mentioned Article to protect and preserve documentation and information which, by reason of their employment, responsibilities or mission, are kept under their care or to which they have access by preventing or averting the improper use, removal, destruction, concealment or non-utilization of such documentation and information.

However on the issue related to the registration of drugs, the Ministry of Health has been taking account of two factors: first, an effort is made to ensure that the list of active substances that can be incorporated in the Catalogue of Interchangeable Generic Drugs does not include products which are still patent-protected, for cases have arisen where products that were already included in the lists and did not fulfil those requirements were

withdrawn and no registration was granted for products submitted by a manufacturer other than the original one. As for other products not regarded as interchangeable generic drugs, the Ministry of Health has refused registration when such products are registered in Mexico by the innovator and the latter has reported the situation to the authorities.

3.1.5 South Africa

In terms of the common law of South Africa, confidential information or trade secrets are given protection against unauthorised disclosure or use by others.

South Africa protects test data submitted with applications for marketing approval of pharmaceutical products against (a) disclosure and (b) unfair commercial use under the following specific provisions.

The section 34 of the Medicines and Related Substance Control Act No. 101 of 1965 provides for the preservation of secrecy and no person shall, except for the purpose of the exercise of his powers or the performance of his functions under this Act, or for the purpose of legal proceedings under this Act, or when required to do so by any competent court or under any law, or with the written authority of the Director-General, disclose to any other person any information acquired by him in the exercise of his powers or the performance of his functions under this Act and relating to the business or affairs of any person, or use such information for self-gain or for the benefit of his employer."

Under the both these general secrecy protection specific provisions the issue of unfair commercial use is not addressed expressly, except for the prohibition on self-gain or any benefit to the employer in the Medicines Act. The circumstances under which such information could be disclosed are set out in the two sections quoted above. Hence as also seen in the other developing countries no clear exclusivity for the registered companies is provided in South Africa.

3.1.6 South Korea

In South Korea, the "independent economic value" of information as provided in the definition of "trade secrets" in Article 2 of the Unfair Competition Prevention and Trade Secret Protection Act. In determining "trade secrets", it is not sufficient that the holder of information deems such information to be "trade secrets", but rather, such information should hold a certain "independent economic value." The "independent economic value" of the information should be derived from the confidential nature of the information. Furthermore, since such information is not generally known among or readily accessible to persons within the circles that normally deal with that kind of information, it holds an actual or potential economic value. However, it should be noted, that this does not in anyway mean that such information needs to be the subject of an economic transaction.

However the data submitted to the government authorities for the marketing approval of pharmaceutical products are prohibited from being disclosed to the public when the person who submitted such data requests the protection of the data. However, when authorities see the need to disclose the data to the public, the data may be disclosed under Article 72-9 of the Pharmaceutical Affairs Act. When there is a violation of these

provisions, a penalty of imprisonment for up to three years or a fine not exceeding ten million won is imposed under Article 75 of the Pharmaceutical Affairs Act.

3.1.7 Venezuela

Protection of undisclosed information in Venezuela is provide for in Articles 260 and 262 of Decision 486 – Common Industrial Property Regime – define what should be considered a business secret, who may use this information, and the criteria for protecting undisclosed information, and set out a list of acts performed in relation to a business secret which constitute unfair competition.

Undisclosed test or other data the production of which entailed a considerable effort, which is submitted for obtaining marketing approval for pharmaceutical products that utilize new chemical entities, are protected against unfair commercial use. Furthermore, such data are protected against any disclosure, except where necessary to protect the public or unless steps are taken to ensure that the data are protected against unfair commercial use.

Any person has the right to request and obtain from the competent authorities authorization to market their own version of a previously approved pharmaceutical product provided that it complies with the relevant regulations. The authority which approves marketing may not discriminate between previous or subsequent applicants and treats them all equally in accordance with the law. Pursuant to Article 266 of Decision 486, the marketing approval authority does not grant third parties access to undisclosed test or other data the production of which entailed a considerable effort, and which have been provided by another person (subject to the exceptions specified in Article 266. This protection is for an indefinite term and is maintained as long as the requisite conditions persist.

3.2 Developed Countries

Most of the developed countries provide exclusive rights to the owners of data/information. Countries belonging to the European Union have the flexibility to decide whether they would provide a 5-year or a 10-year period of data exclusivity.

3.2.1 The United States

The protection of undisclosed information are a matter of concern of the individual States, given that trade secrets are a unique state law domain and that each US state is free to develop - and many indeed have developed - a range of different rules in this area. In the United States, the Federal Government has not sought to divest the States of the authority to provide protection for undisclosed information through State rather than Federal law. The laws of the various states of the United States of America protecting trade secrets provide the protection required by the TRIPS Agreement for the protection of undisclosed information. Forty states now have adopted the Uniform Trade Secret Act with only minor variations. The remaining states base the protection of undisclosed information on the Restatement of Torts, which also forms the basis the Uniform Trade Secret Act. In addition to protection under states trade secret laws, protection is provided

for undisclosed information in many cases through contract law, which is uniform throughout the United States, and under recently enacted Federal criminal legislation.

The standard used by United States courts in determining what is or is not a "trade secret" is whether the information is generally known to, or readily ascertainable by proper means by, those who can obtain economic value from its disclosure or use.

The standard used to determine culpability for misappropriation of undisclosed information in the United States is whether the information has been appropriated through "improper means." "Improper means" includes, *inter alia*, theft, bribery, misrepresentation, breach or inducement of a breach of a duty to maintain secrecy, or espionage through electronic or other means. As such, the United States standard is broader than that referred to in the TRIPS Agreement.

Given that materials provided to US authorities as a condition of approving the marketing of pharmaceutical or agricultural chemical products which utilize new chemical entities are subject to release under the US Freedom of Information Act. Trade secrets and commercial or financial information that is privileged or confidential, is explicitly excepted from the requirements of disclosure under Section 552(b)(4) of title 5, United States Code (the US Freedom of Information Act).

3.2.2 Canada

Test or other data which are submitted to the Government of Canada, as a condition of approving the marketing of pharmaceutical or agricultural chemical products which utilize new chemical entities, are not disclosed to third parties by administrative practice reflecting common law principles and consistent with Section 20 of the Access to Information

Confidential test data are not disclosed to third parties. At no time can a third party obtain access to the data. A relevant legislative provision, which protects information from disclosure, is section 20 of the Access to Information Act, which provides as follows:

"(1) [...] the head of a government institution shall refuse to disclose any record requested under this Act that contains:

Trade secrets of a third party;

Financial, commercial, scientific or technical information that is confidential information supplied to a government institution by a third party and is treated consistently in a confidential manner by the third party;

Information the disclosure of which could reasonably be expected to result in material financial loss or gain to, or could reasonably be expected to prejudice the competitive position of, a third party; or

Information the disclosure of which could reasonably be expected to interfere with contractual or other negotiations of a third party."

By administrative practice reflecting common law principles and consistent with Section 20 of the Access to Information Act, third parties are not given access to confidential information provided in another manufacturer's new drug submission

3.2.3 Japan

With respect to the approval of manufacturing pharmaceuticals or veterinary medical products, the Pharmaceutical Affairs Law requires submission of data at the time of application for the approval or registration, respectively (paragraph 3 of Article 14 of the Pharmaceutical Affairs Law), and this Law has no provisions which allow these submitted data to the government to be disclosed to the public.

In addition, under the National Public Service Law, an employee who deals with such data shall be under obligation not to divulge any confidential information which may have come to his/her knowledge in the performance of his/her duties (paragraph 1 of Article 100), and such data are kept undisclosed to the public.

Regulations in Japan do not require that all data which are required to be attached to an application for the marketing approval be published. Data that are difficult to publish for some reasons may be accepted after consultation. Such data are kept undisclosed to the public.

What is required to be disclosed under the said notification by the Director-General of Pharmaceutical Affairs Bureau, is only a summary of the test data which have already been made public through presentation in academic meetings or through contribution to journals. The notification does not require the applicant to disclose raw data which it does not wish to be disclosed.

More concretely, what is to be disclosed under the said notification, is only a brief summary of the data of the tests on efficacy and safety, including those of a toxicology test, a pharmacology test, a test on absorption, distribution, metabolism and an excretion (ADME) and a clinical test, which are compiled by the applicant at his/her own discretion. Usually, the length of the summary is from a few dozen pages.

The purpose of establishing the requirements of disclosing materials in the said notification is to enable medical professionals and patients to know scientific grounds of efficacy and safety of a drug, and to facilitate promotion of proper use thereof, early detection of adverse drug reaction and their prevention. Moreover, as long as contents and extent of the disclosure are not specified in the notification, it cannot be said that the applying pharmaceutical manufacturers are compelled to disclose the data which they do not wish to disclose.

3.2.4 Switzerland

Switzerland provides a 10-year period of data exclusivity. The main laws and regulations containing provisions, which are of for the purposes of protecting undisclosed information, are the following (this list - with titles in French only - is indicative):

Loi fédérale du 21 mars 1969 sur le commerce des toxiques (RS 814.80)

Ordonnance du 19 septembre 1983 sur les toxiques (RS 814.801)

Loi fédérale du 9 octobre 1992 sur les denrées alimentaires et les objets usuels (RS 871.0)

Ordonnance du 1er mars 1995 sur les denrées alimentaires (RS 817.02)

Ordonnance du 26 juin 1995 sur les substances étrangères et le composants dans les denrées alimentaires (RS 817.021.23)

Loi fédérale du 3 octobre 1951 sur l'amélioration de l'agriculture et le maintien de la population paysanne (RS 910.1)

Ordonnance du 26 janvier 1994 sur la mise dans le commerce des produits de traitement des plantes et de protection des récoltes (RS 916.161)

Ordonnance du 26 janvier 1994 sur la mise dans le commerce des engrais et des produits assimilés aux engrais (RS 916.171)

Ordonnance du 26 janvier 1994 sur la mise dans le commerce des aliments pour animaux (RS 916.307)

Directives pour le dépôt des demandes d'examen et d'authorisation pour les produits pour le traitement des plantes en Suisse (Station de recherches de Wädenswil, 1994)

Loi fédérale du 7 octobre 1983 sur la protection de l'environnement (RS 814.01)

Ordonnance du 9 juin 1986 sur les substances dangereuses pour l'environnement (RS 814.013)

Loi fédérale du 24 janvier 1991 sur la protection des eaux (RS 814.20)

Loi fédérale du 16 janvier 1991 sur la protection de la nature et du paysage (RS 451.1)

Loi fédérale du 18 décembre 1970 sur la lutte contre les maladies transmissibles de l'homme (Loi sur les épidémies) (RS 818.101)

Ordonnance concernant les produits immunobiologiques du 23 août 1989 (RS 812.111)

Arrêté fédéral du 22 mars 1996 sur le contrôle du sang, des produits sanguins et des transplants (RS 818.111)

Convention intercantonale du 3 juin 1971 sur le contrôle des médicaments (RS 812.101)

Règlement d'exécution du 25 juin 1972 de la Convention intercantonale sur le contrôle des médicaments (état au 23 novembre 1995) (RS 110.1)

Directives de l'OICM du 16 décembre 1977 concernant la documentation requise pour l'enregistrement de médicaments destinés à l'usage humain (RS 221.11)

Instructions de l'OICM du 14 février 1989 pour la présentation des demandes d'enregistrement de spécialités pharmaceutiques contenant de nouveaux principes actifs (''New Chcmical Entities = NCE) et destinées à l'usage humain (RS 221.11.3)

Instructions de l'OICM du 23 mai 1991 pour la préparation des demandes d'enregistrement de préparations génériques à un seul principe actif destinées à l'usage humain (RS 221.11.4)

A federal law on the *control of medicinal products* covers all the products which are currently dealt with by three different authorities, FOPH, OICM and the Federal Veterinary Office, that is to say human and veterinary medicinal products, including

immunobiological products, as well as medical devices. This law, contains a provision regarding the protection of test data against unfair commercial use. According to this provision, test data submitted in a previous registration procedure can be used in a subsequent registration procedure if the first registration enterprise agrees or if its product has been sold on the Swiss market for at least ten years.

Other measures have been taken to ensure the protection of confidential test data. Concerning *pharmaceutical products*, an amendment to the present "intercantonal" registration regulations was prepared with a view to protection of test data submitted to support the application for marketing approval of a product against unfair commercial use. This amendment envisages the introduction of a time period during which the non-use of test data submitted for the registration of a product would be guaranteed. The length of this time period would correspond to those contained in the EC's legislation, i.e. six years or ten years, depending on the level of technology of the product.

Federal laws or regulations contain strict provisions of "official secrecy", or obligation for staff members to observe full confidentiality with regard to the information or documentation, which is in their possession). This duty of "official secrecy" is to be found in Article 320 of the Swiss Criminal Code (RS 311.0). This obligation of official secrecy is also reflected in specific laws and regulations dealing with the approval and registration procedures.

3.2.5 Members of the European Union

The fifteen Members of the European Union provide for data exclusivity using Directive 65/65 as amended by Directive 21/87, which allows the Member States to provide for data exclusivity periods from 6 to 10 years from the first marketing of the product, or of 6 years maximum dependent on the term of patent protection of the relevant product. 6-year periods of exclusivity are in operation in a majority of EU Member States, which include, Austria, Denmark, Finland, Ireland, Luxembourg, Spain, Greece and Portugal. Ten-year periods of exclusivity are in operation in Belgium, France, Italy, Germany, the Netherlands and the UK. The country specific regulations are indicated below.

3.2.5.1 Austria

In regard to the protection of confidential information provided to Austrian regulatory authorities pursuant to a request for marketing approval, e.g. concerning pharmaceuticals, Article 20, subsection 3 of the Federal Constitution Law states the basic principle that all authorities dealing with federal administration are sworn to secrecy in regard to all facts they get to know exclusively through their acting as an official authority and where there is - *inter alia* - an overwhelming interest of the involved parties to keep these facts secret.

Exceptions to this principle have to be made by law. According to Section 17 of the General Law on Administrative Procedure - unless there are no contrary regulations in the specific administrative laws - only the involved parties have a subjective right to request inspection of records. Therefore, files concerning the marketing approval of pharmaceuticals may only be inspected by the involved party.

According to Section 15a of the Pharmaceutical Law, which had been introduced to implement a provision of EU-Directive 65/65, a new applicant may claim reference to parts of files concerning already approved pharmaceuticals if the first applicant agrees or the first approval has taken place 6 years (respectively 10 years in regard to special products) ago in a member state of the EEA-Agreement.

3.2.5.2 Belgium

There is no specific provision imposing upon the regulatory authority responsible for dealing with a marketing approval request an obligation of confidentiality with respect to confidential tests or other data concerning a pharmaceutical or agricultural chemical product. This administrative authority follows an administrative practice that respects the confidentiality required in connection with such a procedure; this administrative practice has been strengthened by the Law of 11 April 1994 on administrative transparency (Moniteur belge of 30 June 1994).

3.2.5.3 Denmark

The Danish Ministry of Health issued a regulation, which will exempt documents in cases concerning applications for marketing approvals for pharmaceutical products from public access. The legal authority for this regulation is the generally applicable law regulating public access to file, i.e. the Danish Access to Public Administration Files Act.

The new regulation provides companies with even greater certainty that documentation submitted by them for purposes of their applications will not be accessible for competing companies. However, the exemption does not cover the approval as such, or the accompanying resume of the product indicating the composition and characteristics of the product. The time period during which the documents are exempted from public access under the regulation is unlimited.

3.2.5.4 Finland

In the pharmaceutical sector, under the EU Directive 21/87 the Member State of the EU may condition the enjoyment of protection in test data on the coexistence of patent rights. Finland has not taken advantage of this possibility. The Article 4.2 of the National Agency for Medicines Regulation No. 1/1995 is intentionally silent about this possibility. Therefore, the enjoyment of protection of information provided to a Finnish regulatory authority is not dependent on the coexistence of patent rights in the regulated product.

3.2.5.5 France

Confidential, commercial or personal data in pharmaceutical product marketing approval files (hereafter "MA") filed pursuant to the French procedure cannot be disclosed to the public in accordance with paragraph 5 of Article 1 of the Order of 13 March 1986 published in the Official Journal of 19 March 1986.

The same rules govern data contained in MA applications filed pursuant to Community Directive 65/65. Article 12 of Regulation 2309/93 establishing the European Agency for the Evaluation of Medicinal Products provides that third parties may have access to a part of the file after all confidential business information has been removed.

3.2.5.6 Germany

The Drug Law of the Federal Republic of Germany (GDL Arzneimittelgesetz) protects parties in Germany that have provided confidential test or other data concerning a finished medical product in order to obtain a marketing authorization from the national competent authority. In Section 24a of the GDL, documentation - required for a marketing authorization - from a previous applicant is regulated. This documentation might include relevant and undisclosed information. This Section refers to new pharmaceutical substances as well as to their correspondent preparations (Section 49 subsection 1 GDL).

The analytical expert opinion (Section 24 subsection 1 GDL) as well as the data of the analytical testing (Section 22 subsection 2 No. 1 GDL) are kept strictly confidential and well protected.

The general right of exploitation of restricted data by the national competent authority is laid down by law in Section 24c GDL. Therefore, documents concerning the physical quality of drug determining parameters (manufacture, preservation, method of quality control, analytical testing and analytical expert opinion) must be restricted as well.

In addition to the above, the provisions of the German Penal Law are applicable to protect data in the licensing application regarding industrial and intellectual property.

3.2.5.7 Greece

For the protection of studies on compounds containing active substances, known to the European Union, the provisions of the national legislation viz., Law 721/77, Law 1845/89 and the relative Ministerial Decisions are in operation. No specific time interval is foreseen for the protection of the studies.

As regards protection of the test data relating to medicinal products, the National Drug Organization has adopted all the EU directives and regulations for the procedures leading to a marketing authorization of medicinal products. In particular Directive 65/65 as amended in Article 4 paragraph 8 describes some aspects of data protection, which has been implemented.

According to the Greek Law 1316/83 all National Drug Organization personnel (including members of committees) is obliged to keep required confidentiality for all kind of information related with their duties.

3.2.5.8 Ireland

Protection of data, which is the property of an applicant, is covered by EC Directive 65/65/EEC and is never disclosed to a third party. The original data may not be used to support an application by a second applicant except with the formal written agreement of the owner of the data. This is most likely to occur in cases covered by Article 4.8(a)(i) of EC Directive 65/65/EEC.

The compulsory period of exclusivity covering medicinal products protect a product for six years from date of first authorization in the European Union. Public health is an overriding consideration, which would require disclosure any matter of public health importance to an appropriate agency.

3.2.5.9 Italy

The protection of confidential information is guaranteed in Italy by Article 6*bis* of Decree No. 1127 of 29 June 1939, as amended by Article 14 of Decree No. 198 of 19 March 1996. Paragraph 2 of that Article prohibits the disclosure of confidential data submitted to the competent authorities to obtain approval for marketing pharmaceutical products.

3.2.5.10 Netherlands

Dutch regulatory authorities dealing with the marketing approval of pharmaceutical products have the obligation by Article 2.5 of the General Administrative Act (AWB) to maintain secret the information they obtain in fulfilling their duties. For civil servants there is a special provision with the same contents (Article 125a of the Civil Servant Act). The obligation to maintain secrecy lasts in principle as long as the information has not been made public by the owner of the information.

Date and other information submitted by an applicant to the competent authorities have to be maintained secret by these authorities, unless the applicant decides otherwise. When other persons want to have access to this information, they have to ask the owner to provide this information.

3.2.5.11 Portugal

The protection of undisclosed information is not a question that is dealt with explicitly by the current Industrial Property Code (IPC). However, such protection will be provided explicitly in the IPC as part of the improvements being made.

Meanwhile, it is considered that the main aspects of the protection of undisclosed information are covered by the provisions against unfair competition, Article 260 of the IPC.

3.2.5.12 Spain

Spain has been complying with the confidentiality of undisclosed information since 1993. Article 15 of Royal Decree 767/1993 of 21 May on the evaluation, approval, registration and conditions for dispensing proprietary medicines for human use, entitled "Guarantee of Confidentiality", contains the obligation to keep the application for approval and the accompanying documentation secret.

Article 32 ("confidentiality"), of Law 25/1990 on Medicaments (BOE 22.12.1990) contains an obligation of confidentiality: it stipulates that "the content of the applications for approval in respect of proprietary medicines shall be confidential, without prejudice to the information required for inspection purposes".

Protection of documentation submitted by an applicant for marketing approval is not conditioned on the holding of patent rights, as is clear from Article 11 (accelerated applications) of the above-cited Royal Decree 767/1993. Specifically, this Article contains two precautions with respect to the indicated procedure:

First precaution: "Without prejudice to the right to the protection of industrial and commercial property". In other words, the procedure with respect to the second sanitary approval is regulated independently of whether or not there exists a patent right.

Second precaution: "A second applicant for approval of a medicament essentially similar to another already approved medicament (...) may, with the express consent of the holder of the approval, refer certain parts of his application to the original file". In other words, the secrets of the file cannot be revealed without the express consent of the first applicant for sanitary approval.

3.2.5.13 Sweden

Protection against unfair competition for those parties that have provided confidential information or other data concerning a pharmaceutical product to Swedish regulatory authorities follows from the provisions of Chapter 8 of the Secrecy Act (Act 1980:100) and from the corresponding, more detailed provisions in the Secrecy Regulation (Regulation 1980:657). Thus, Chapter 8, Article 6, of the Secrecy Act provides: "Secrecy applies, to the extent prescribed by the Government, in such activities of public authorities which consist of study, planning, price regulation, grant of authorizations, supervision or assistance, relating to production, commerce, transportation or otherwise in industrial or commercial activities, as regards information on:

Private persons' commercial or industrial activities, inventions or scientific research results, where it may be assumed that a private person will suffer injury if the information is revealed.

Other economic or personal circumstances relating to a person who has entered into a business relation or other similar relation with the person who is the subject of the activity of the public authority."

The "Government provisions" referred to in the Secrecy Act are contained in the above-mentioned Secrecy Regulation. Section 2 and some provisions in the Annex to the Regulation address the matters mentioned in Chapter 8 of the Secrecy Act. Thus, the Annex refers, *inter alia*, to information submitted in the context of requests for marketing approval of pharmaceutical products (item 39 of the Annex).

The protection is further strengthened through the provisions in the Act on the Protection of Trade Secrets (Act 1990:409). That Act protects, through various types of penalties, any "trade secret" by which is meant such information concerning the business or industrial relations of a person conducting business or industrial activities which that person wants to keep secret and the divulgation of which would be likely to cause a damage to him from the point of view of competition.

3.2.5.14 United Kingdom

The United Kingdom protects test data submitted to an UK regulatory agency to support a request for marketing approval of a pharmaceutical product against disclosure, and also protects such data against unfair commercial use, including by preventing later applicants from relying directly or indirectly on the data provided by the first applicant to support their application for marketing approval.

All data submitted in support of applications for marketing authorizations for medicinal products for human use in the United Kingdom is protected from disclosure by Section 118 of the Medicines Act 1968 which makes it a criminal offence for any person to

disclose such information unless the disclosure is made in "performance of his duty". Additionally, we apply the "Code of Practice on Access to Government Information" which exempts commercially confidential material from the presumption in favour of disclosure and such material will only be disclosed where there is a clear public interest favouring disclosure against confidentiality.

Data submitted in support of applications for marketing authorizations for medicinal products utilising new chemical entities (NCEs) is protected (including against later applicants relying directly or indirectly on the data originally supplied) by Article 4.8(a)(iii) of European Directive 65/65/EEC (which applies in the United Kingdom by virtue of the Medicines for Human Use (Marketing Authorizations etc.) Regulations 1994) which specifies that later applicants cannot rely on the data supplied unless they can show that there is an essentially similar product which has been authorized in the European Community for 10 years and is marketed in the Member State concerned

In the case of veterinary medicinal products, authorisation to place such products on the market is issued under the Marketing Authorizations for Veterinary Medicinal Products Regulations 1994. Regulation 14 provides that, except in the performance of his duty, no person shall disclose:

Any information in respect of any manufacturing process or trade secret obtained by him in premises which he has entered by virtue of these Regulations, or

Any information obtained by him or furnished to him in pursuance of the Regulations.

Furthermore, Regulations 4(8) and 4(9) of the 1994 Regulations provide, in accordance with European Directive 81/851/EEC, that an applicant for a new marketing authorization for a veterinary medicinal product may only rely on data submitted in support of another (essentially similar) product authorized in the United Kingdom, either with the agreement of the holder of the marketing authorization for the reference product or, where the reference product has been authorized within the European Community for 10 years.

3.2.6 Norway

Undisclosed information of commercial value are in general protected form disclosure and unfair commercial use by the provisions on business secrets in the marketing Act 16 June 1972 No. 47, which, in addition to marketing in a narrow sense, deals with unfair commercial practices in general. Undisclosed test and other data are protected from unfair commercial use by an administrative practice that prevents an applicant from relying on data provided by another applicant without the latter's consent. For medicinal products this protection expires when the other applicant has himself had a marketing approval for six years. Such data are protected from disclosure by the administrative agency's statutory duty to prevent third parties from gaining access to such data.

3.2.7 Turkey

There are five pieces of legislations are significant from the point of view of protection of confidential test data in Turkey. These are as follows:

Contract Law, No. 818 brings obligation on the workers not to divulge business secrets of the employee. They may also be prohibited from dealing with competing works. The remedy for the infringement is compensation of the damages.

The second piece of legislation is the Commercial Code. The Code provides that:

(a) Seducing the employees, agents etc. into divulging trading secrets of their employer;

Taking an illicit advantage from trade secrets obtained incompatible with good faith, or divulging them to others constitute unfair competition. The Code provides civil (compensation for damages), and criminal sanctions (Imprisonment and/or fine).

3. Within this framework the Patent Decree 551 obliges public authorities (who take application for marketing permission for pharmaceutical or veterinary products) not to disclose information and test results, and keep them secret; and

4. The Regulation for Pharmaceutical Products, which is in force since 1996, brings the same responsibility on Ministry of Health to protect secrecy of information and test results disclosed by the applicant during marketing approval for pharmaceutical.

5. Lastly, the Civil Servants Act No 657 supports the implementation of last two pieces of legislation by bringing responsibility on civil servants employed in the Ministries and public institutions not to divulge secret business information related to their services. Infringing the act of those two pieces of legislation brings responsibility of the public administration in accordance with Administrative Law Principles and legislation prepared within the framework of Article 125 of the Turkish Constitution. (Article allows action to be taken against all acts and transactions of the public administrations). In such cases the remedy is compensation apart from the disciplinary and criminal responsibility of the civil servant.

3.2.8 New Zealand

New Zealand provides data exclusivity for 5 years, besides providing an administrative structure for ensuring that undisclosed information is protected.

The Official Information Act (1982) allows any New Zealander to request of any government department access to any information held by that department. However, the Act also gives the department in possession of the information the right to refuse the request if certain conditions pertain. Two such conditions are that releasing the material would be contrary to the provisions of a specified enactment (Section 18(c)(i)), or that the material is commercially sensitive (Section 9(2)(b)). However, Section 9(2)(b) can be outweighed by public interest considerations, e.g. strong public health and safety reasons.

There is no requirement for the Boards or Departments to disclose confidential information to other government departments or statutory bodies. Furthermore, Section 35C(1)(b) of the Animal Remedies Act, Section 35C(1)(b) of the Pesticides Act, and Section 23C(1)(b) of the Medicines Amendment Act allow the Boards or Departments to disclose the information only if, in the opinion of the Board or Department, the receiving Government Department or statutory body, as the case may be, will take reasonable steps to ensure that information is kept from unfair commercial use.

Therefore, if a request is made, and the relevant Board or Department were to decide to release confidential information, after consultation with the company that submitted the data, then it would formulate appropriate protocols before releasing the confidential information in order to ensure that the confidentiality of the information is respected. There are no limitations as to the content of the conditions that Boards or Departments can impose in such protocols - they can impose whatever conditions are felt to be necessary in order to respect the confidentiality of the information.

3.2.9 Australia

In December 1996 Australia announced its intention to introduce a new regime of data exclusivity. Under this regime confidential data submitted to the Therapeutic Goods Administration (TGA) or the National Registration Authority for Agricultural and Veterinary chemicals (NRA) to register a new pharmaceutical, agricultural and veterinary chemical product containing a new chemical entity will be protected for a period of five years from the date of registration of the originator product. Legislation is currently being prepared to implement the new regime.

3.3 Economies in Transition

3.3.1 Czech Republic

The protection of information of pharmaceutical products in Czech Republic is provided by the Law on medicines No. 79/1997 Coll. of Laws.

This protection is ensured by special regulations within the competence of Ministry of Agriculture and Ministry of Health, on medicines and plant-medical care, which regulate the registration procedure for obtaining an approval for the marketing of products. According to these regulations, data submitted in the framework of the registration procedure of medicament must not be disclosed to other people without the authorization of applicant for registration. In the registration procedure of another medicament these data may be used only if a) the applicant for registration submits a written authorization of the holder of a registration decision with the use of these data, specifying the scope and giving limitations, if any, for their disposal or b) at least six years has expired since the issue of registration decision. Similar provisions concern also other relevant products.

For the protection of data, the general provisions on protection of trade secrets and further special protection according to Article 32 of Law No. 79/1997 Col. on pharmaceuticals are applicable. According to these provisions the data submitted by the applicant for registration cannot be disclosed to other subjects without the consent of the applicant. These data cannot be used also in a procedure on registration of another product without a written agreement of the owner of the registration decision or in case since the issue of the valid registration decision has not expired at least six years in case of pharmaceuticals and 10 years in case of effective substances.

3.3.2 Hungary

According to the practice of the competent authority, the National Institute of Pharmacy, such data and test cannot be disclosed without express consent of the applicant for marketing approval.

The relevant Hungarian authorities are obliged under the general rules of administrative procedure not to reveal any information on the test data submitted to them in any form to any person who is not a party of the procedure of applicants for marketing approval of pharmaceutical products. In compliance with this obligation the Agreement on Intellectual Property between the Government of the Republic of Hungary and the Government of the United Sates of America (signed on 24 September 1993) contains in Article VI relating to Acts Contrary to Honest Commercial Practices and Protection of Trade Secrets the following obligations:

"Government use

Parties, when requiring, as a condition of approving the marketing of pharmaceutical … products which utilize 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, Parties 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."

As to the direct or indirect reliance on such data to support later-filed applications, reference is made to the Protocol of the above Agreement, which reads as under:

"When applying for an application for marketing approval of a generic product, the applicant (the "second" submitter) can prove the equivalence of its own product with the original one, on the basis of a sample of the commercially available original product, while referring to the original documentation if needed. When deciding on the approval of the "second" application, the competent authority bases its decision on the examination of the documentation attached to this application.

During the procedure the authority in question does not reveal any information in any form on the documentation of the original product."

3.3.3 Poland

Any documentation and data submitted to the Office for Registration of Pharmaceutical and Medicinal Products for the purposes of obtaining registration and regulatory approval are kept confidential, they are protected against disclosure and are not made available to third parties.

The Registration Commission verifies whether a given pharmaceutical or medicinal product satisfies the requirements of quality, efficiency and safety.

The following legal acts govern in Poland the procedure for market authorization of pharmaceutical products:

Pharmaceutical Act of 10 October 1991 on pharmaceuticals, medicinal products, pharmacies, wholesalers and pharmaceutical administration (O.J. No 105, item 452 of 19 November 1991); and

The Decree of the Ministry of Health and Social Welfare on the register of pharmaceutical agents and medicinal devices (O.J. No 6, item 24 of 17 January 1994).

3.3.4 Slovak Republic

The protection of undisclosed information against unfair commercial use such as results of tests which are to be submitted as a condition of approving the marketing of pharmaceutical products is provided by the institute of the trade secret which is amended in Sections 17 to 20 of the Commercial Code. The party is entitled to legal protection against the breach of or threat to the trade secret, the same as against unfair competition. Unfair competition is amended by the provisions Sections 44 to 55 of the Commercial Code. The criminal legal protection against unfair competition is specified in Section 149 of the Penal Law (Law No. 140/1961 Coll. in the wording of the subsequent laws).

Available information on the mechanisms prevailing in various countries across the development spectrum shows that except in the developed world, undisclosed data does not enjoy protection for fixed period of time. Various statutes and regulations are used to ensure that disclosure of commercially sensitive data pertaining to pharmaceutical products that are submitted to the government for obtaining marketing approvals are not misappropriated.

However, the United States, along with the Members of the European Commission, has been insisting that adequate protection to undisclosed data can only be provided by ensuring that the fixed period of protection is allowed. Countries that have not been following this interpretation have been either threatened with trade retaliation using unilateral means, as in the case of the United States, or by invoking the WTO Dispute Settlement Mechanism. The following section discusses this issue.

4. Disputes on the issue of data exclusivity

Disputes on data exclusivity have been initiated using both unilateral means as well as the multilateral mechanisms. Unilateral action has been more prevalent with the United States continuing with its practice of identifying countries that violate intellectual property rights using the Special 301 provisions of its Trade Act of 1988. As regards the multilateral process, the sole case that has come to light is the one concerning United States and Argentina.

The details of the disputes are discussed below.

4.1 Argentina

The first dispute on Article 39.3 of the TRIPS Agreement was brought before the Dispute Settlement Body by the United States against Argentina in May 1999[5]. While initiating this dispute the United States maintained that the regime of intellectual property protection that Argentina had adopted in fulfilment of its TRIPS obligations was, among other things, not providing adequate protection to undisclosed test data. The main point of contention of the United States was that while prior to August 1998, the Government of Argentina provided a ten-year term of protection against unfair commercial use for undisclosed test data or other data submitted to Argentine regulatory authorities in support of applications for marketing approval for agricultural chemical products, it had stopped this practice thereafter. This followed the issuance in 1998 of Regulation 440/98, which revoked the earlier regulations.

Regulation 440/98 was brought into the statute books for giving effect to Law No. 24.766, which was enacted in December 1996. This law concerned the approval or authorization for commercialisation of, for example, a pharmaceutical product. This type of information is related to the composition and the production process of a medication that is about to be commercialised. This stage comes after the patent has been issued. This authorization may require that certain information pertaining to the efficacy of the product be made available to the local health authority. The law protects this information from "[a]ny dishonest commercial use and shall not be disclosed". However, under Article 5 "similar products" can be approved or authorized by the "local sanitary authority" once the original product has been registered in Argentina (or the United States, which is the other country relative to this analysis). In this case an "abbreviated procedure" is implemented. According to this article, if someone has a "similar product" to one that has already been registered in the Argentine Republic (or in the United States or other country mentioned in Annex I), that person can rely and use the "tests", that had to be performed, to obtain the authorization for commercialisation. In other words, the party that has performed extensive tests and research trusts the confidential information to the corresponding health authority in order to authorize the product; that information, however, can also be used by others requiring authorization for a similar or identical product. The article ends by stating that "The approval of the registration or of the authorization for commercialisation by the local administrative authority under the procedures established in this article for similar products does not imply the use of the confidential information protected under this law". This constituted one of the main complaints of the United States towards insufficient Argentine protection of intellectual property rights in the pharmaceutical field. The big pharmaceutical manufacturers also opposed this concept. The main objection to the law was the "similarity" concept contained in the text, which permits utilizing an inverse formula (to the original one) to arrive at the pharmaceutical product. This was viewed as protecting local Argentine laboratories because it permits the registration of a similar drug, not necessarily identical, to another that is already on the market. Foreign drug manufacturers in Argentina argued

[5] Switzerland joined the consultations subsequently. A subsequent dispute was brought by the United States before the Dispute Settlement Body in June 2002. The European Communities and Switzerland also joined the consultations.

that there should be very precise proof in order to determine that when someone tries to register a medication similar to another that he is not using the same production process than the inventor of the drug. The problem was exemplified during the "transition period" in which Argentina did not issue patents for pharmaceutical products.

The following example illustrates the United States´ concern in this area. When Pfizer, the first company to introduce Viagra, obtained the marketing authorization from the relevant government authority (ANMAT) several local companies came up with requests for marketing "similar products". Since there were no pharmaceutical patents issued at the time, a company could copy Viagra and at the same time it could easily obtain authorization to commercialise it relying on the original companies´ information through the "similarity" provision contained in the law. Local companies were required however to demonstrate to the ANMAT their capability of producing a medication similar to the one that Pfizer produced. The concern expressed by the United States and pharmaceutical companies as to this law during the transition period is well founded.

Some studies have pointed out that the situation as regards protection to owners of drug patents against misappropriation of their data and other confidential information has changed since patent protection on new products started to be granted in October 2000[6]. This is because even though another company could use the information to obtain approval for commercialisation of a "similar drug", it would not be able to legally produce the product without the corresponding license and royalty payment. The Argentine patent law would in effect at this time protect the product by granting a patent for it. This above-mentioned point has also been emphasised by the European Generics Manufacturers Association (EGA). The high level of intellectual property protection and the wide application of patents would make exclusivity provisions quite unnecessary, opines EGA[7].

These arguments notwithstanding, the United States Trade Administration continues to target Argentina as a “priority watch country” for its shortcomings in the patent law, which include failure to protect confidential test data submitted to government regulatory authorities for pharmaceuticals. With the United States maintaining this view, the dispute with Argentina on the latter’s fulfilment of its TRIPS commitments has remained unresolved as regards protection afforded to confidential test data. Argentina, thus, remains under intense pressure from the United States to introduce a data protection regime, in a manner that a few similarly placed countries have done in the recent past.[8]

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6 Hernan L. Bentolila, “Lessons from the United States Trade policies to convert a “Pirate”: The case of pharmaceutical patents in Argentina, George Washington University Law School, 2002.

7 EGA Position Paper, Data Exclusivity: A major obstacle to innovation and competition in the EU pharmaceutical sector, December 2000.

8 A mutually agreed solution to the two disputes involving the United States and Argentina on patent protection for pharmaceuticals was notified in June 2002. The notification, however noted the following: “The Parties will continue consultations to assess the progress of the legislative process of approval of items 4, 5 and 6 of this notification, 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

4.2 Other Potential Disputes

In its recent "Special 301" submission, the PhRMA has commented that "time has come for the US Government to consider the launch of a WTO dispute settlement case on data exclusivity." According to PhRMA, "the simplest and most straight-forward case might be against a WTO Member that does not provide any data exclusivity at all"[9].

This view of the PhRMA seems consistent with the position enumerated by the USTR in its 2002 Special 301 Report, which indicated that the "United States is actively considering the initiation of new WTO cases for later this year or early next year against certain WTO Members that appear not to be in compliance with their TRIPS obligations". The issue that the USTR indicated would be closely monitored in this context is protection of confidential test data.

Among the countries that were put on the "priority watch list" in 2002, India, Hungary and Israel were identified as those in which protection of exclusive test data was not adequate. The USTR had indicated that in case of India and Hungary, all options, including WTO dispute settlement, would be used to "resolve outstanding TRIPS compliance concerns" that the United States had vis-à-vis these countries.

This position taken by the USTR becomes even more serious in light several developments that were seen in the recent past concerning data exclusivity. Two of these developments would be mentioned briefly in the following section.

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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." See WTO, Argentina – Patent Protection for Pharmaceuticals and Test Data Protection for Agricultural Chemicals (WT/DS171)/ Argentina – Certain Measures on the Protection of Patents and Test Data (WT/DS196), 22 June 2002.

9 "Enforcing Data Exclusivity", PhRMA "Special 301" Submission, March 2003.

5. Recent Developments Concerning Protection of Data

The United States and the European Union were both involved in significant initiatives to put data exclusivity on a firm pedestal through legislative action.

The major development involving the United States took place in the process for evolving the Free Trade Area of the Americas (FTAA). As has been visualised, the FTAA would be a significant economic grouping comprising of the middle-income economies of the Americas. A recent draft Agreement of the FTAA was finalised towards the end of 2002[10], which provides for a TRIPS plus regime of intellectual property protection. Section 10 of the proposed FTAA Agreement on TRIPS defines a framework for the protection of undisclosed information. This framework provides protection to undisclosed information for a period of at least five years from the date of approval granted to the party submitting such information. Additionally, if data pertaining to a patented product were protected the term of data protection would not be altered even if the patent term expires earlier. In other words, the patent holder would be able to get extended term of protection on the data pertaining to the product in question.

The development that could have inimical consequences for the generic industry relates to the decision of the European Parliament to enforce a ten-year data exclusivity period in all the Member States of the Union. As was mentioned in the foregoing, the European Commission allows the Member States to provide for data exclusivity periods from 6 to 10 years from the first marketing of the product, or of 6 years maximum dependent on the term of patent protection of the relevant product[11]. An amendment to the European Parliament and Council Directive on the Community code relating to medicinal products for human use that was proposed by the European Parliament in October 2002 includes provisions that have far reaching implications for data exclusivity[12].

Article 10(1) of Directive 2002/83/EC is proposed to be amended with the inclusion of the following additional provision: "The marketing authorization of a generic medicinal product can be granted only after ten years have elapsed from the first authorisation of the reference medicinal product. A generic medicinal product authorised pursuant to this provision cannot be manufactured or placed on the market until ten years have elapsed from the first authorisation of the reference medicinal product. In the case of a biosimilar medicinal product, pre-clinical tests and clinical trials shall be necessary"[13]. A further amendment is proposed thus: "The ten-year period referred to [above] shall be extended to ***a maximum*** of eleven years if, during the first eight years of those ten years, the marketing authorisation holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorisation, are held to

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10 Free Trade Area of the Americas – Draft Agreement, Chapter on Intellectual Property Rights, November 2002.

11 EU Directive 2001/83/EC.

12 European Parliament, Community code relating to medicinal products for human use, P5_TA-PROV(2002)0505, 23 October 2002.

13 European Parliament, Community code relating to medicinal products for human use, P5_TA-PROV(2002)0505, 23 October 2002, Amendment 34.

bring a significant clinical benefit in comparison with existing therapies"[14]. This decision by the European Parliament, which extends the period of market exclusivity that a holder of a patented medicine would enjoy by a considerable period of time, would thus be able to snuff out competition from the generic manufacturers quite effectively.

Yet another development of considerable significance is the proposed sui generis system for the protection of databases that the WIPO has proposed (see Annex for a detailed discussion). The draft of the proposed treaty was placed before the WIPO Members in 1996 and after lying dormant for most of the intervening period, the database treaty is again being considered quite actively in the WIPO forum.

The parallels between the attempts to extend intellectual property rights to confidential test data and the introduction of sui generis protection of databases is what makes the later development significant in the context of the present discussion. Two issues stand out. The first pertains to the scope of protection, which in both cases is related to the fact that considerable investments have been made for the generation of the data for which protection is being sought. By so doing, the proponents of protection of data have, for the first time, argued that they are interested in using the system of intellectual property protection not for protecting creations of the human mind, but investments.

The second issue is that the system that has been proposed by the WIPO to protect databases would be able to provide protection to the owners of databases in perpetuity. While a 15/25-year period of protection is proposed in the first instance, the period of protection can be extended if "substantial change resulting from the accumulation of successive additions, deletions, verifications, modifications in organisation or presentation, or other alteration, which constitute a new substantial investment" is carried out.

These developments indicate that considerable changes are afoot globally in the realm of data protection, the ramifications of which can be quite considerable on the generic industry. The strengthening of the regimes for protection of test data pertaining to pharmaceuticals in both the European Union and United States is a pointer to the increased conflicts that would be seen in the ensuing phase. As was mentioned in an earlier discussion, the PhRMA has advised the United States Trade Administration to initiate cases against the "offending" countries in the WTO, and this quite clearly is the immediate threat that countries like India would have to contend with.

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[14] European Parliament, Community code relating to medicinal products for human use, P5_TA-PROV(2002)0505, 23 October 2002, Amendment 35.

Annex

Sui Generis Protection of Databases

The proposed sui generis protection of databases is particularly significant given the fact that large corporate interests have developed in Western Europe and the United States in the production of databases. The EU Directive of 1996 on database protection lent support for these arguments. The EU initiative in turn was given a further direction by the WIPO when it brought the proposal for the sui generis protection of databases the same year.

The main elements of the databases treaty proposed by the WIPO are as flows:

Scope of Protection

In the first instance, it proposes to protect any database that represents substantial investment in the collection, assembly, verification, organisation or presentation of the contents of the database. Secondly, protection is proposed to be given to a database regardless of the form or the medium in which the database is embodied, and regardless of whether or not the database is made available to the public. The scope of protection of databases so defined fundamentally alters the principles on which the system of intellectual property protection is sought to be established. Intellectual property rights, by their very nature, should entail protection given to products of human ingenuity and not physical investment as is proposed in the databases treaty. In all forms of intellectual property, for them to qualify for statutory protection, certain standards are set to test the contribution of the human mind, but in case of the proposed treaty such standards have been dispensed with. At the outset, therefore, the proposed treaty makes it abundantly clear that what it seeks is investment protection rather than intellectual property protection.

Rights of the Database Owner

All pervasive rights are being proposed for the owners of databases. The rights holder would be free to authorise or prohibit the extraction or utilisation of the contents of databases. Alongside granting such rights, the member countries to the proposed treaty are allowed to provide only limited exceptions to or limitations of the rights subject to these exceptions not Aaffecting the legitimate interests of the right holders.

Terms of Protection

The term of protection of the databases has been so defined that the owner of given database can extend the protection in perpetuity. This has been made possible through a three-tiered period of protection that has been proposed. In the first instance, a 15 or 25-year protection has been proposed for any database qualifying for protection. Any database thus protected can claim another 15 or 25-year period of protection if it is made public before the expiry of the earlier period of protection. In other words, a given database can enjoy a period just less than 15 or 25 years of protection while kept not been disclosed to the public and a further period of 15 or 25 years when it is made available to the public. But what makes the period of protection run into perpetuity is the third level in the proposed term of protection of databases. It is provided that Aany substantial

change to the databases, either qualitatively or quantitatively, including any substantial change resulting from the accumulation of successive additions, deletions, verifications, modifications in organisation or presentation, or other alteration, which constitute a new substantial investment, shall qualify the database resulting from such investment for its own term of investment". This implies that periodic revision of protected databases, which can be seen as constituting a "substantial change" to its original form, would require a fresh term of 15 or 25 years to be given to it and this can be rolled over into perpetuity. Thus, what the proposed database treaty seeks is to provide absolute monopoly over any given set of information that a database may be used to protect, which is completely antithetical to the efficient functioning of the markets.

Application in Time

This provision complements the term of protection by proposing to extend to all the existing databases, the provisions of the databases treaty. In other words, all the databases which were available to the public at large before the adoption of the proposed treaty would qualify for protection once the databases treaty is in place. Here again, the proposed treaty marks a departure from the established norms of intellectual property protection. When any invention or a literary work has entered public domain, protection cannot be extended to such intellectual property in the same form as it has existed, but in the databases treaty, this requirement has been dispensed with. The rights of the owners of databases are sought to be enhanced further by limiting the operation of entities that may have been involved in reproducing these databases while they were not protected. It has been provided that such reproduction would be allowed only for two years after the databases have been brought under the purview of protection.