

Dear Reader:

Pharmaceutical and vaccine research and development increasingly promise new therapies and preventions for infectious diseases, including HIV/AIDS, as well noncommunicable diseases, such as cancers, arthritis, heart disease, mental disorders and diabetes. Over 100 HIV/AIDS medicines are in development, including more than 10 vaccines. There are also more than 700 medicines in development for diseases important to a globally aging society – diabetes, arthritis, etc.

For the pharmaceutical industry to invest the billions of dollars, Euros, yen, etc. in these highly risky health care solutions, intellectual property protection is essential. However, patent and trademark protections are not the entire story. This paper corrects for the relative lack of attention given to another important component essential for continued therapeutic progress – the protection of critical information generated by painstaking analysis in the drug and vaccine development process. International treaties, including TRIPS, recognize this area of intellectual property rules; and this paper expands the discussion of data exclusivity rules and implementation.

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ENCOURAGEMENT OF NEW CLINICAL DRUG DEVELOPMENT: THE ROLE OF DATA EXCLUSIVITY

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I. Introduction

The discovery of a new pharmaceutical compound or vaccine is not sufficient to bring a safe and effective product to the market for use by patients. Rather, the public reaps the benefits of an innovative drug or vaccine only after relevant data, generated in extensive preclinical and clinical trials, demonstrate the drug's safety, quality and efficacy to the satisfaction of regulatory authorities.

The generation of such proprietary data involves a considerable amount of time and expense; the entire drug development process from discovery to marketing takes an average of 10 years and costs, on average, \$500 million in industrialized countries.

The protection of test data is a legally required and economically necessary component of the intellectual property package that serves to provide incentives for the development of innovative pharmaceutical products. The Agreement on Trade-Related Intellectual Property Rights (the "TRIPs Agreement") specifically recognizes the "protection of undisclosed information" as being a category of intellectual property subject to protection. Article 39.3 of the TRIPs Agreement provides that:

"Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural 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."

The intellectual property right reference in Article 39.3 is commonly referred to as "data exclusivity" in the U. S. and "data protection" or "regulatory data protection" in the European Union. Throughout this article, these terms are used interchangeably.¹ Data exclusivity is an independent intellectual property right and should not be confused with the protection provided by other rights, especially patents. It provides the holder with specific rights, namely that the data generated by the holder may not be referred to or used by another person or company for a specific period of time. It does not prevent another company from generating the data. Thus, the right is quite limited in the first instance. However, it has been considered to be of critical importance by countries to provide the necessary incentives for companies to generate the necessary data that accompanies registrational packages for medicinal products.

¹ See glossary of relevant terms in Annex I.

II. Background

1) Definition of the issue

In order to demonstrate a drug's efficacy and safety for its intended therapeutic use, it is necessary for the originator of the drug to conduct extensive testing on animals and humans in pre-clinical and clinical trials as well as toxicology, manufacturing feasibility and other scientific studies. The results of these tests and studies, which are proprietary, are contained in a registration dossier that is submitted to governmental authorities to obtain marketing approval for the drug.

The generation of this confidential registration data involves a very substantial amount of time and expense for the originator; the entire drug development process from discovery to marketing may take as long as fifteen years and cost, on average, \$500 million in industrialized countries. The registrational data are provided to the authorities in confidence and are not meant to be referred to by third parties. If these data were immediately available to third parties, there would be no incentive for a company to generate these data in the first instance, unless the investment in terms of both time and costs were protected by another means. In many instances, a patent will cover the pharmaceutical product at issue. However, more and more compounds which are not patent protected (for whatever reason) are being developed and thus data exclusivity in some instances is the only available intellectual property protection right. It is important that governments protect the confidentiality of these data against its unauthorized use or disclosure in order to protect the proprietary interests of scientists and others and to maintain the economic incentives for further pharmaceutical research and development.

However, because of a concern for avoiding repetitive tests and trials on animals and human, governments have sought to limit the originator's proprietary data rights. Therefore, the U. S. and the EU have acknowledged the right of data protection for a certain fixed period of time. After the period has expired, reference to the data is permitted by generic companies. This compromise is viewed as protecting the investment of the originator, while at the same time preventing unnecessary repetitive tests and trials. Arguably, if a country had no data protection law at all, then the data submitted as part of a registrational package should never be permitted to be referred to by a generic company.

The period of data exclusivity is not fixed by the TRIPs Agreement. Earlier drafts of the TRIPs Agreement provided a minimum five year period of

protection. However, this specific minimum time frame was removed from the final version. The time period must be sufficient to protect the originator's investment.

Given the substantial amount of time and resources that is dedicated to obtaining marketing approval and the fact that the data generated in such testing are proprietary and only disclosed by the originator when required by governmental authorities to obtain marketing approvals, governments should be required to protect the data against "unfair commercial use." That is, governments should be required not to disclose nor rely on these data for the marketing approval of generic copies of the pharmaceutical product without the prior approval of the originator for a fixed period of time. Furthermore, governments should be required to protect the data that they receive in a manner that will enable the originators to enforce their rights in every country in the world

2) Patents versus Data Exclusivity

As opposed to a patent right, which gives the right holder the right to exclude others from making, using, selling, offering for sale, or importing the patented product, the protection that governments must accord proprietary test data does not, per se, exclude the copier from running its own tests and submitting the results to the regulatory authorities. Assuming the absence of any intervening patents, a generic alternative may still receive marketing approval, provided that the generic manufacturer conducts its own pre-clinical and clinical trials and independently seeks marketing authorization by the regulatory bodies.

While data exclusivity and patents are the two most critical and, hence, relevant intellectual property rights for the pharmaceutical industry, they are distinct forms of protection; protection of one right is neither dependent on the other nor linked to the other in any intrinsic way and any linkage between the two contravenes TRIPs. The distinctive character of each intellectual property right is reflected in the structure of the TRIPs Agreement, which assigned each right to a separate, parallel section in Part II of the Agreement, Standards concerning the availability, scope and use of intellectual property rights.

3) "Considerable Effort" : The logic for requiring data exclusivity

TRIPs Article 39.3 on the protection of undisclosed information contains the logic for requiring protection by governments of registration data. This article recognizes the "considerable efforts" involved in originat-

ing the data; links the protection provided to the data to that “considerable effort” and declares, in essence, that any failure by the government to provide the required protection is “unfair commercial use” of the data. This article relates the protection of the data to the value of the data per se and not to the value of the product or the product in support of which the data were provided to the governments.

While WTO members are obligated to provide protection to proprietary data at a level that is commensurate with their obligations under Article 39.3 of the TRIPS Agreement, many countries—both developed and developing—fail to do so. Some countries do not provide any protection at all for proprietary registration data; other countries provide some protection, but not at the level required by TRIPS Article 39.3; while still others have the statutory basis for the protection but do not enforce the data exclusivity.

4) Protection in the United States, the EU and Switzerland

Most developed countries protect data that are submitted to the regulatory authorities. In practice, abbreviated applications for regulatory approval by subsequent applicants cannot be filed in the United States for five years after the originator’s approval. In the EU, Directive 65/65 provides a period of data protection of either 6 or 10 years depending on the Member State at issue. The larger Member States provide 10 years, while the smaller provide only 6 years. However, for products which are approved through the centralized procedure, Regulation 2309/93 provides a 10 year period of data protection (see Article 13.4). During this period of time, no applications that seek to rely on the originator’s data may be approved by the regulatory authorities.

While “paper dossiers” (which rely on published scientific literature to demonstrate the efficacy, quality and safety of the competitive drug) are permitted under Directive 65/65, they may only be filed for a drug with an “established medicinal use,” which the European Court of Justice has indicated would normally be met only after at least one decade. This loophole has now been closed by Commission Directive 1999/83 (which amends Directive 75/318) and provides that a minimum period of not less “than one decade from the first systematic and documented use of that substance as a medicinal product in the EU” is required for a finding of “well established medicinal use.”

In most larger European countries, new chemical entities approved by the national regulatory authorities (the alternative approval process to the

use of the centralized procedure) receive ten years of data exclusivity. As a result of a recently-enacted revision to the Intercantonal Convention on the Control of Medicines, Switzerland now provides ten years of market exclusivity for New Chemical Entities (NCE).

a) In Brief: the Obligation to Provide Data Exclusivity

There appears to be a United States-EU-Swiss consensus that protection of registration data against “unfair commercial use,” as reflected in TRIPS Article 39.3, requires governments to prevent reliance, by regulatory authorities or third parties, on the data for the marketing of subsequent versions of the drug during the period of exclusivity without the originator’s consent. Where the two regions differ is over the length of the period of data exclusivity. While the United States has a five year period, the EU has a six or ten year period, and Switzerland has a ten year period.² [A key difference is also that the US gives (shorter) protection to new indications but the EU does not]. The five year period in the United States is not sufficient for recouping the huge investment of money and time for developing new pharmaceutical products.

b) Data Exclusivity as a Governmental Function

Protection of registration data, through the data exclusivity that results from non-reliance on the data, is a governmental function.³ The authorities may not consider an application for a marketing authorization during the period of data protection. An application relying upon a third party’s data may only be submitted after the period of data protection has expired. In the EU, where the periods of data protection differ, the European Commission has made it clear in its “Commission communication on the Community marketing authorization procedures for medicinal products, 1998

² For a country without any tradition of protecting test data, the five to ten year periods of data exclusivity may not be enough and may be undercounting the actual length of time that the data should be protected. The periods of time cited for the United States, the EU and Switzerland assume that the data will not be disclosed or relied upon by the regulatory body before the originator of the data receives the marketing approval for the new product. It is critical that any enumeration of the periods of data exclusivity that are required by Article 39.3 include the time after the data is provided but before the marketing approval is granted. As a general rule, this will add three to four years to the five to ten year period cited as the practice in the United States and the EU.

³ With the proliferation of freedom of information acts, which provide for the public release of governmentally-held information, it is critical that regulatory bodies not disclose proprietary data submitted by originators. At the time of a drug’s marketing approval in the US, the Food and Drug Administration compiles a Summary Basis for Approval, which contains conclusionary data and non-proprietary information and is publicly available under the US Freedom of Information Act. Similarly disclosed information is available in Europe. Disclosure of proprietary information in such documents would call into question the protection required under TRIPS Article 39.3.

C 229/4, at C229/13” that “if the [data] protection period in the concerned Member State is longer than in the reference Member State, mutual recognition in the concerned Member State is not possible before the expiry of the 10-year period.” (page C 229/13).

Thus, while governments are only required to provide the legal environment in which the patent holder may enforce his right against an infringer, it is another matter with respect to the protection of registration data. It is the government, through its regulatory agencies, and not the originator of the data, that has the responsibility for preventing copiers taking advantage of proprietary data during the period of data exclusivity.

Governments of most developing countries do not protect registration data and freely rely on the data that the pioneer drug companies provide in order to facilitate the expeditious marketing of generic copies of the pioneer drugs. However, this approach may remove the incentive of an innovator to launch in a particular market.

III. Commercial and Economic Rationale for Test Data Confidentiality

As briefly noted above, the generation of the data necessary for the original marketing approval requires a very substantial investment of time, expertise, resources and money. The originators of the drug must be given an opportunity – and the incentive – to recoup the enormous costs involved in generating such data before a competitor is permitted to rely on those data for the approval of the generic alternative.

For example, research-based pharmaceutical companies in the United States invested \$21.8 billion in R&D in 1998, a 10% increase over 1997. With forty percent of these R&D expenditures going to pre-clinical functions and thirty percent going towards completing the Phase I, II, and III clinical trials required by the FDA, seventy percent of all R&D expenditures in the United States go to gain regulatory approval.

A new drug costs, on average, \$500 million and requires as long as 15 years to develop, if preclinical and clinical trial phases are taken into account. Only three out of ten drugs introduced in the United States from 1980 – 1984 had returns higher than their average after-tax R&D costs. Comprehensive drug testing in the clinical trial stage alone can cost \$150 million or more for a single medication, and only 10% - 20% of drugs ever clear the full set of pre-clinical and clinical trials. In stark contrast, a man-

ufacturer of a generic alternative, if it is not required to generate its own test data to gain marketing approval, needs only to invest \$1 million to launch a competitor drug, as long as it can demonstrate bioequivalency.⁴

When the later applicant receives the benefit of the data generated by the originator without any investment on its part, the originator is placed at a significant commercial disadvantage. Such a situation undermines the investment potential existing even in countries with strong and effective patent protection, since the results of the originator's tests are immediately available to competitors at no cost. In addition, the burden is placed entirely on the originator to pursue any patent rights; under the data protection scenario, a product is only considered for marketing approval once the period of data protection has passed. Given the imbalance between the cost to the originator of gaining marketing approval for its drug and the copier's cost of coming on to the market, the research-based industry would have a reduced incentive, without such protection, to engage in the important R&D activities that will ultimately benefit patients through the availability of new and innovative drug therapies.

The incentive for developing new drug therapies that is provided by a period of data exclusivity is especially critical when the new drug therapy is not patentable. For example, had generic copies of TAXOL[®], (paclitaxel), Bristol-Myers Squibb's anti-cancer drug, which did not have any patents on its active ingredient, been able to be approved immediately, BMS would not have had any incentive to incur the extensive costs (estimated at well in excess of \$500 million) to develop, test and bring TAXOL to market.

The fact that both patent protection and data exclusivity provide incentives reflects the dual nature of the drug development process.

- Without the period of market exclusivity provided by a patent, the research-based industry would not have any incentive to undertake the research leading up to the discovery of the innovative drug therapy.
- Without data exclusivity, the originators of the innovative drug would be placed at an unfair commercial disadvantage when compared to their generic competitors, who do not face similar costs of meeting the mandated requirements set by regulatory bodies for drug approval.

⁴ Bioequivalency between a generic and a pioneer drug is demonstrated by the bioavailability of the two products. Bioavailability is the extent and rate at which the body absorbs the drug. Scientists measure the time it takes the generic drug to reach the bloodstream. The generic drug must deliver the same amount of the active ingredient in the same time period as the pioneer drug in order to be bioequivalent.

The distinctiveness of the two incentives is recognized in the United States and the European Union, where patent protection and data exclusivity provide, side-by-side, incentives to discover new drug therapies and to undertake the extensive testing required to bring them to market.

IV. Current State of Data Protection

Many developed and developing countries currently fail to provide data exclusivity along the lines mandated by Article 39.3 of the TRIPS Agreement. The forms of the noncompliance range from the total absence of protection to provisions and practices that limit the effective scope of the protection. The following are examples of these practices:

1) Absence of data protection

Countries such as South Africa, Brazil and Israel currently do not have any laws on their books that provide protection for proprietary registration data. Notwithstanding that Articles 78 and 79 of Decision No. 344 of the Andean Pact provide for the protection of registration data, the individual member countries, such as Bolivia, Colombia, and Ecuador, do not provide such protection in their legislation.

2) Linkage of the period of data exclusivity to the life of the underlying patent

Spain links data exclusivity to the life of the underlying patent for the product for which marketing approval is being sought. Linkage of the period of data exclusivity to the life of the underlying patent violates TRIPS obligations, since nowhere in Article 39.3 is there any linkage of the protection for trade secrets to any of the other protections found in Part II of the TRIPS Agreement. Indeed, trade secret protection is entirely independent of other protection and it is not permitted to link the two.

3) Springboarding

Canadian regulatory authorities accept applications for marketing approval of generic copies that rely on the originator's data before the period of data exclusivity expires. Even though the product appears on the market after the period of data exclusivity expires, the review of the dossier occurs during the period of data exclusivity. This practice is a violation of the TRIPS obligation not to rely on the originator's data during the period of data exclusivity.

4) Vague and questionable definitions of data exclusivity

Singapore curtails the five-year period of data exclusivity by starting protection from the date of filing of the originator's pharmaceutical product, rather than from the date of its marketing authorization, which is the standard practice in the United States and the EU. Beginning the count from the date of filing is illogical, since the originator does not reap any commercial benefit from the data exclusivity when its product is awaiting marketing approval and, thus, is not on the market. The effective period of data exclusivity provided in Singapore is thus curtailed by nine to fifteen months.

In addition to its "springboarding" policies, Canada interprets the definition of "reliance" in a strictly literal manner. On November 3, 1998, Justice Evans in *Bayer Inc. v. Attorney General of Canada and Minister of Health*, supported the Government of Canada's contention that if the authorities in the Ministry of Health do not physically open the dossier, then reliance has not occurred. Judge Evans further compounded the problem when he stated that "a period of five years is a long time to grant a de facto monopoly for a drug that is not protected by a patent," thereby confusing the two separate intellectual property rights and erroneously equating patent protection with the period of data exclusivity.

5) Nullification of existing law

Korea had a data exclusivity law on its books but, in May 1997, deleted part of the law that had specified that data on "efficacy" and "domestic use" were required for generic drug applications submitted within the six-year re-examination period. Local clinical trial data or proof of bioequivalency is now no longer needed for a copier drug to enter the Korean market, thereby negating the value of the six-year re-examination period.

6) Permitting on the market "similar" copies of originator drugs that were either approved for marketing abroad or in the country

The Government of Argentina, which previously did not have any statutory protection for registration data, took a step backwards when it passed a data exclusivity law in December 1996, legitimizing the reliance on the originator's registration data submitted to the Argentine public health authorities for use by producers of similar products. Argentina provides for an expedited marketing authorization of a "similar" drug when the originator drug has already been marketed in Argentina or in a number of other (developed) countries. Argentina reportedly will permit the mar-

keting of the generic copy if a certificate of free sale can be provided from abroad for the originator drug.

Argentina claims that such use of certificates of free sale to approve the marketing of a generic copy of the originator's drug does not constitute reliance on the originator's data. A recently enacted law in Israel permits the importation and marketing of any drug that is "similar" to a drug that is already registered in Israel.

7) Unauthorized disclosure of proprietary data embodied in the registration dossier

While TRIPS Article 39.3 permits the disclosure of the data, it only does so if the disclosure is accompanied by steps to ensure that the data are protected against "unfair commercial use." The countries of Eastern and Central Europe, in preparation to join the European Union, are attempting to converge their marketing regulatory requirements with those of the European Union. With the exception of the Czech Republic, these countries are demanding full access to the registration dossiers of the originator drugs, without providing any guarantee that the data will be protected from disclosure. Slovenia reportedly does not take any safeguards to protect registration dossiers against disclosure to generic copiers.⁵

8) Requirement to disclose test data without taking measures to protect confidentiality

Although Japan precludes the issuance of any second approval without full clinical and non-clinical data for six years after the originator's approval, it is not for the purpose of protecting the data but to confirm, during the re-examination period, the efficacy and safety of the approved new drug.

In addition, the Japanese Ministry of Health and Welfare ("MHW") intends to publish a "Summary Basis of Approval" after the approval of each new pharmaceutical product. As the "Summary Basis of Approval" includes all necessary information for examination of such new products by MHW, with a total length of 500 pages or more, the scope of this publication will be significantly greater than the FDA's SBA and the European "Summary of the Product Characteristics", which are about 40-50 pages in

⁵ As part of the *acquis communautaire*, Slovenia has decided to link the period of data exclusivity to the life of the underlying patent for the product for which marketing approval is being sought. This violates the TRIPS Agreement. The new data protection law provides a period of six years of data protection from either the initial approval in the EU or Slovenia.

length. Given that a data protection law is not available in Japan, this wide-ranging publication gives rise to doubts about this policy being in compliance with TRIPS.

Furthermore, a “Freedom of Information Act” is to be implemented in Japan from 1 April 2001. Since the Japanese Freedom of Information Act will require the widest range of publication in the world, the Act will give rise to serious doubts about its being TRIPS-compliant, unless it is properly applied.

V. Conclusion

Data exclusivity is an independent intellectual property right and should not be confused with the protection provided by other rights, especially patents. Countries with the leading research-based pharmaceutical industries recognize the strong incentive provided by data exclusivity and have taken steps to ensure that the proprietary registration data that companies are required to submit to gain marketing approval are protected against unfair commercial use and disclosure.

The protection of data embodied in the “non-reliance/non-disclosure” concept is time-related – data exclusivity should be provided for at least ten years from the originator’s marketing approval. This time frame is evident from the negotiating history of the TRIPS Agreement and the current practice of countries with leading research-based pharmaceutical industries, such as the European Union and Switzerland.

The obligation to protect registration data against “unfair commercial use” is incumbent upon governments, not the originators of the data. Since January 1, 2000, all WTO member countries – with the exception of only the least developed countries – have been required not only to have TRIPS-compliant protection for proprietary registration data but also to enforce effectively this protection.

As described above, many countries currently either fail to provide such protection or the protection that they provide falls below the levels required by TRIPS. Only with a clear understanding of the data exclusivity issue and a concerted effort by governments, will industries, such as the pharmaceutical industry, that are required to provide registration data to governments have the assurances that their extensive efforts to research, develop and bring new, innovative products to market will not be subject to unfair commercial use.

Glossary of Relevant Terms

The concept of “data exclusivity” is sometimes confused with the concepts of “data privacy” and “trade secrets or business confidential information.” The following brief definitions may help to alleviate that confusion:

1. *Exclusivity of Registration Data* – period of non-reliance and non-disclosure that a government must provide to pharmaceutical registration data. Pharmaceutical registration data are the proprietary data generated by scientific research conducted to demonstrate the efficacy and safety of new medicines and submitted to regulatory authorities for marketing approval.

2. *Data Privacy* – individually-identifiable information, e. g., medical background and personal health data, that may not be disclosed or transferred inappropriately without the explicit or implicit authorization of the individual. Unlike registration data, which applies only to those industries such as the pharmaceutical and agro-chemical industries, data privacy applies to all industries.

3. *Trade Secrets or Business Confidential Information* – information deriving its value from not being known to the public, competitors or other parties who may gain benefits from its disclosure or use. To receive protection as a “trade secret,” business confidential information must be secret, have commercial value because it is secret and have been subject to reasonable steps taken under the circumstances to keep it secret.

SECTION 7: PROTECTION OF UNDISCLOSED INFORMATION (TRIPS)**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 below and data submitted to governments or governmental agencies in accordance with paragraph 3 below.
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:
 - is secret in the sense that it is not, as a body or in the precise configuration 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.
3. Members, when requiring, as a condition of approving the marketing of a pharmaceutical or of agricultural or 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 when necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.

* 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.

Nature of Obligations under TRIPS Article 39.3

The TRIPS Agreement, which was negotiated as part of the Uruguay Round of trade negotiations in the GATT, the predecessor organization to the World Trade Organization (WTO), was the first international intellectual property agreement to include obligations for the protection of trade secrets, especially the proprietary data submitted by innovators to governments.⁶

Observers have come to realize the growing commercial significance of the incentives provided by a period of data exclusivity for products that were not under patent protection, either because the new chemical entities did not meet the novelty test for a patent from the outset and were, therefore, not patentable or because the chemical entities involved new uses of products whose patents may have expired. Another contributing factor to the emergence of data exclusivity is the expiration of the transition period for TRIPS implementation by the developing countries and the countries of Central and Eastern Europe that are in the process of transformation from centrally-planned into “market, free-enterprise” economies. On January 1, 2000, these countries were obligated to have implemented Article 39.3 together with the rest of the TRIPS Agreement, and any failure to do so exposes them to WTO dispute settlement. Even those countries that will be permitted by the TRIPS Agreement to delay until January 1, 2005 the application of the TRIPS patent obligations to pharmaceutical products--e. g., India, Argentina, and Egypt--were required, as of January 1, 2000, to have their proprietary data protection at the level mandated by the TRIPS Agreement.

Article 39.3 requires a WTO member state to protect registration test data submitted to regulatory authorities against “unfair commercial use and disclosure,” except when necessary to protect the public, or unless it can ensure that the data are protected against unfair commercial use. Article 39.3 contains two obligations: protection against disclosure and protection against unfair commercial use. The Office of the General Counsel of USTR defines these two obligations in the following manner:

⁶ Although the NAFTA Agreement was concluded in 1992, prior to the completion of the TRIPS Agreement, TRIPS Article 39.3 appeared in its final form in the Dunkel text of the TRIPS Agreement, which appeared in December, 1991. Similarly, while the OECD Council Recommendation concerning the Exchange of Confidential Data on Chemicals was adopted prior to the Dunkel Text -- on July 26, 1983 -- it was only a recommendation to the OECD member states and not a binding international instrument.

... With regard to the first requirement, test data must be protected against disclosure to the public (or even within the government) unless such disclosure is necessary for public safety or unless steps are taken to ensure that the data are protected against unfair commercial use.

With regard to the second requirement... TRIPS Agreement negotiators understood it [the term “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.⁷

A similar understanding of the obligation to protect “against unfair commercial use” was contained in a paper presented by New Zealand at the APEC Seminar in 1995:

Defining ‘unfair commercial use’ can only properly be done by reference to the context of the complete provision, i. e. the purpose behind the provision. In the light of this we interpreted Article 39.3 as meaning that there is a restriction on the use which regulatory authorities can make of original data they hold in order to approve subsequent applications for approval of generic medicines, animal remedies or pesticides. In other words, where undisclosed information is provided to a regulatory authority by an applicant so that the authority can approve the applicant’s product, if this information is then used by the authority to approve the product of a second applicant that is, in New Zealand’s view, ‘unfair commercial use.’ In effect, the regulatory authority is giving commercial advantage to the second applicant in that the applicant does not have to generate the data which was required of the first applicant. This can be a significant economic saving.⁸

The negotiating history of TRIPS Article 39.3 supports “non-reliance on the originator’s data for a particular period of time” as the definition of the obligation to protect the data against “unfair commercial use.” Early drafts of the agreement had specified a period of time during which governments should not rely on such data for the approval of competing products without the consent of the originator of the data. For example, the draft of November 23, 1990 contained the obligation that, “... the data may not be

⁷ “The Protection of Undisclosed Test Data in Accordance with TRIPS Article 39.3,” unattributed paper which was drafted by the Office of the General Counsel of USTR for submission in bilateral discussions with Australia, May 1995.

relied upon for the approval of competing products for a reasonable time, generally no less than five years...”

The obligations in Article 39.3 apply to “new chemical entities.” “New chemical entity” is a regulatory concept and should not be confused with the “novelty” requirement of a patent. Drug regulatory agencies, such as the U. S. FDA and the national agencies in Europe, define a “new chemical entity” as a new compound with no prior approval as a drug, that has undergone full development and testing, and is proven to be safe and effective. “New chemical entity” status does not relate to the time when the active ingredient was first discovered or synthesized.

⁸ *Protection of Undisclosed Information and Control of Anti-Competitive Practices*, APEC TRIPS Seminar: 17-19 May 1995, Presentation by New Zealand.