Northwestern Journal of International Law & Business

Volume 24
Issue 1 *Fall*

Fall 2003

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I. INTRODUCTION

At the onset of the Uruguay Round, many developed countries protected "undisclosed information" that was developed or acquired by enterprises and used to gain advantages over competitors. These countries varied widely in their approaches to protecting this undisclosed information. For example, countries following English jurisprudence generally provided a separate branch of law based on the common law. Others provided some protection in different branches of their law, including em-

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The views set out in this paper are those of the authors, not those of Sidley Austin Brown & Wood LLP or its clients.

ployment law, contract law, tort law and unfair competition law. These countries used significantly different nomenclature for undisclosed information, including trade secrets, know-how, proprietary information and confidential business information.

By contrast, many developing countries did not effectively protect undisclosed information, or failed to protect it at all. As a consequence, information dishonestly acquired in a country with protection could be exploited with impunity in these developing countries. In one widely publicized case that prompted a serious trade dispute, extremely valuable technical information about General Electric's process for making synthetic diamonds was wrongfully acquired in the United States and then used in South Korea.[1] Some countries went so far as to affirmatively require or facilitate disclosure of valuable undisclosed information. Coca-Cola Co., for example, allegedly withdrew from the Indian market when Indian authorities sought disclosure of the secret formula for its syrup.[2]

One explanation for such great differences in the level of protection offered for undisclosed information was the lack of clear international standards for such protection. The only multilateral treaty that addressed this issue even indirectly was the Paris Convention for the Protection of Industrial Property ("Paris Convention").[3] Article 10*bis* of the Paris Convention requires all countries of the Paris Union[4] to provide all nationals of the Union with effective protection against unfair competition, and this protection must be provided on a "national treatment" basis pursuant to Paris Article 2. The term "unfair competition" is defined as "any act of competition contrary to honest practices in industrial or commercial matters,"[5] and three examples of such acts are listed in the Paris Article 10*bis*(3).[6] While it is clear

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[1] *See* Edward T. Pound, *Papers Show GE Employed Big Guns in Industrial Diamond Market Struggle*, Wall St. J., May 4, 1992, at A7D.

[2] *See* Suman Dubey, *After 16-Year Dry Spell, Coca-Cola Co. Will Bring 'the Real Thing' Back to India*, Wall St. J., Oct. 22, 1993, at A9E.

[3] Stockholm Act, July 15, 1967, *reprinted in* G.H.C. BODENHAUSEN, GUIDE TO THE APPLICATION OF THE PARIS CONVENTION FOR THE PROTECTION OF INDUSTRIAL PROPERTY, AS REVISED AT STOCKHOLM IN 1967 (1968) [hereinafter Paris Convention], *available at* http://www.wipo.org/treaties/ip/paris/index.html.

[4] The Paris Convention provides that "[t]he countries to which this Convention applies constitute a Union for the protection of industrial property." Subsequent articles employ the phrases "a country of the Union" and "countries of the Union" to describe parties to the Convention, rather than using more modern terms such as "contracting parties" or "member states." *See id.*, at art. 1. As of July 15, 2003, 164 States were countries of the Union. A list of these States is available at http://www.wipo.org/treaties/ip/paris/index.html.

[5] Paris Convention, *supra* note 3, at art. 10*bis*(2).

[6] *Id.* at art. 10*bis*(3) states as follows:

The following in particular shall be prohibited:

that countries of the Union must, at a minimum, prohibit the listed acts—acts that do not directly relate to undisclosed information—it is not clear from the Paris Article 10*bis* what other acts must be prohibited.

After the last revision of the Paris Convention in 1967, Professor Bodenhausen[7] attempted to provide more clarity regarding the obligations of Article 10*bis* in the following passages from his *Guide*:

> What is to be understood by "*competition*" will be determined in each country according to its own concepts: countries may extend the notion of acts of unfair competition to acts which are not competitive in a narrow sense....
>
> Any act of competition will have to be considered unfair if it is contrary to *honest practices in industrial or commercial matters*. This criterion is not limited to honest practices existing in the country where protection against unfair competition is sought. The judicial or administrative authorities of such country will therefore also have to take into account honest practices established in international trade.
>
> If a judicial or administrative authority of the country where protection is sought finds that an act complained of is contrary to honest practices in industrial or commercial matters, it will be obliged to hold such act to be an act of unfair competition and to apply the sanctions and remedies provided by its national law. A wide variety of acts may correspond to the above criteria.[8]

Despite this explanation by Professor Bodenhausen, there remained no consensus on the scope of protection required by the Paris Article 10*bis*. Some maintained that misappropriation of undisclosed information lawfully held by another was an act of unfair competition with very significant economic consequences. Thus, they contended that countries of the Paris Union were required to prohibit such misappropriation. In contrast, others argued that use of information, absent criminal acts in its acquisition, was not "unfair." Moreover, they argued that protection of undisclosed information was not "industrial property" nor was it unfair competition within the meaning of the Paris Article 10*bis*. In any event, there was no effective method within the Paris Convention for adjudicating the meaning of the

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1. all acts of such a nature as to create confusion by any means whatever with the establishment, the goods, or the industrial or commercial activities, of a competitor;
2. false allegations in the course of trade of such a nature as to discredit the establishment, the goods, or the industrial or commercial activities, of a competitor;

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

[7] Professor Bodenhausen was the Director of the United International Bureaux for the Protection of Intellectual Property (BIRPI), the predecessor organization of the World Intellectual Property Organization, at the time of the Diplomatic Conference in Stockholm in 1967, which led to revision of the Paris Convention.

[8] BODENHAUSEN, *supra* note 3, at 144 (footnote omitted).

provision and enforcing the results of the adjudication.[9] Consequently, there was no effective multilateral standard for protecting undisclosed information, including undisclosed test and other data provided to regulatory authorities as a condition for obtaining marketing approval.[10]

To eliminate confusion about the appropriate interpretation of the Paris Article 10*bis*, and to prevent the distortion of trade through greatly different rules in this area, the negotiators of the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS") agreed to Article 39, which states as follows:

Section 7: Protection of Undisclosed Information

Article 39

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

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

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

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

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

3. Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except

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[9] The Paris Convention provides that countries of the Paris Union may request the International Court of Justice to resolve disputes related to the interpretation of the Convention. Historically, however, countries of the Union did not use this method of dispute settlement for several reasons. First, some countries of the Union took the reservation provided in the second paragraph of that Article and were not subject to this dispute settlement procedure. Second, disputes were not initiated against the remaining countries in the Union that did not take the reservation largely because there was no mechanism for enforcing a judgment of that Court. *See* Paris Convention, *supra* note 3, at art. 28(1)

[10] This protection for test and other data submitted to obtain marketing approval is often referred to as "data protection" or as "data exclusivity."

where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.[11]

Thus, TRIPS Article 39.1 clarifies that effective protection from unfair competition includes protection of undisclosed information. Negotiators gave holders of undisclosed information the right to protect it directly, and provided specific standards for this protection in TRIPS Article 39.2. Moreover, they identified a specific type of undisclosed information required by governments, certain test and other data, and set forth additional requirements in TRIPS Article 39.3 for the protection of that information by governments under the Paris Article 10*bis*.

This article provides a comprehensive analysis of the origins, purpose and scope of protection for test and other data required by TRIPS Article 39.3. Through this analysis, which looks to the ordinary meaning of the provision in proper context in the same manner as would a WTO dispute settlement panel or the WTO Appellate Body, we conclude that Article 39.3 provides protection against the unjust or unfair application or conversion of certain test and other data to make a profit or to obtain a benefit. Such protection must be provided long enough to allow the originator to at least recoup its investment in data production.

Part II provides a brief overview of the pharmaceutical drug approval process and the substantial investments that pharmaceutical companies must make to collect the test and other data required by governments. Part III discusses the evolution of data protection laws in the United States and European Community which served as precursors to the international protection required by TRIPS Article 39.3. Part IV explains the important benefits arising from adequate data protection for consumers in both developed and developing countries. Part V reviews the negotiating history of TRIPS Article 39.3. Parts VI, VII, VIII and X then analyze the requirements of TRIPS Article 39.3 in the same manner as would a WTO dispute settlement panel or the WTO Appellate Body. Part IX provides a detailed analysis of a recent decision of the Canadian federal courts related to data protection, and the erroneous interpretation by those courts of NAFTA Article 1711, the more detailed counterpart to TRIPS Article 39.3. Finally, Part XI briefly discusses the countries that have adopted specific legislation or entered into agreements that require data protection.

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[11] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization [hereinafter WTO Agreement]; Annex 1C, § 7 art. 39, 33 I.L.M. 1197-1225 (1994) [hereinafter TRIPS Agreement].

II. DEVELOPMENT OF "TEST AND OTHER DATA" AND THE DRUG APPROVAL PROCESS

Most governments regulate the marketing of pharmaceutical products, as well as agricultural chemical products (*e.g.*, insecticides, fungicides), to ensure that they are safe and effective, but governments as a rule do not test these products for safety and effectiveness in their own laboratories. Instead, they require those who wish to market these products to submit evidence that their products are safe and effective. The amount of evidence required varies from government to government, and depends on whether the active ingredient in the product was previously approved in connection with a similar product. Some governments (*e.g.*, the United States, European Community, Japan) require the submission of an extensive amount of data to prove conclusively that the benefits of using the product outweigh any possible side-effects, even if the product was approved by another government.[12]

In contrast, other governments (*e.g.*, Argentina[13]) require the submission of substantially less data if other governments approved the identical product. Most governments require less evidence that a product is safe and effective if they have previously approved a similar product with the same active ingredient.[14]

In any event, the ability to market a pharmaceutical product worldwide depends on obtaining approval from the most exacting governments. Thus, the developer of a pharmaceutical product containing a new active ingredient has no choice but to conduct the extensive tests to obtain the data necessary to prove that the benefits of using the product outweigh the risks. As a practical matter, without this data, no pharmaceutical product with a new active ingredient would be marketed anywhere in the world.

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[12] Each country has statutes and regulations that govern the marketing of pharmaceuticals, and many publish information on their approval processes. Publications by the U.S. Food and Drug Administration (U.S. "FDA") are some of the most readily accessible and understandable for those not familiar with the regulatory processes. *See, e.g.*, Dixie Farley, *Benefit vs. Risk: How FDA Approves Drugs,* FDA CONSUMER MAGAZINE, Dec. 1997 – Jan. 1998, at 6, *available at* www.fda.gov/fdac/special/newdrug/benefits.html (last visited Oct. 18, 2003); *Drug Approval Application Process*, *available at* http://www.fda.gov/cder/regulatory/applications/default.htm (last visited Oct. 18, 2003). For information on the regulatory procedures in Europe and Japan, respectively, see also European Agency for the Evaluation of Medicinal Products, *at* http://www.emea.eu.int (last visited Oct. 18, 2003); Japanese Pharmaceutical Manufacturers Association, *Contributing to Society by New Pharmaceuticals*, *at* http://www.jpma.org.jp/12english/ (last visited Oct. 18, 2003).

[13] *See* Argentine Law on Data Confidentiality, CODE CIVIL 24,766 art. 4.

[14] *See* U.S. FDA, Abbreviated New Drug Application (ANDA) Processfor Generic Drugs, *at* http://www.fda.gov/cder/regulatory/applications/ANDA.htm (last visited Oct. 18, 2003).

Once developers identify a promising new active ingredient, they test a product containing that active ingredient in animals. This is referred to as "pre-clinical" testing. Test and other data are generated regarding whether the product causes side effects when used in healthy animals, and whether the product provides therapeutic benefits when used in sick animals. Most new active ingredients do not successfully complete pre-clinical testing.[15]

Based on the pre-clinical data of these products, developers then construct plans (or protocols) for testing the products in humans.[16] Health authorities generally review the pre-clinical data and the proposed plans. If they deem the plans to be safe, the health authorities permit and monitor the human testing, called "clinical" trials, necessary to generate the data proving the product is safe and effective in humans. Clinical trials can take many years to complete and are very expensive to conduct.[17]

Not only must the developer prove that the new active ingredient is safe and effective, but it must also show that the process used to manufacture the product reproduces the tested product safely and consistently and that the manufacturing facilities meet basic safety requirements. To do so, the developer must generate additional data.

This process results in the generation of the equivalent of thousands of pages of raw data for the pre-clinical, clinical, and manufacturing trials.[18] Charts and graphs summarizing the data are also prepared to put the raw data into perspective.

Once the developer collects sufficient data, they are incorporated into a "data package" or "dossier" that is submitted to the health authorities for review. Only a fraction of the products that undergo clinical trials are approved by the health authorities.[19]

Although the data package or dossier is submitted to regulatory authorities, developers do not generally disclose the data to the public. Some limited information such as general data about lack of side effects may be included in a patent application to indicate that the product involves an "inventive step" and has an "industrial application" (also called "utility"). Developers do not, however, submit the raw data that is necessary to prove

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[15] Michelle Meadows, *The FDA's Drug Review Process: Ensuring Drugs are Safe and Effective*, FDA CONSUMER MAGAZINE, July-Aug. 2002, at 19, *available at* http://www.fda.gov/fdac/features/2002/402_drug.html (last visited Oct. 18, 2003).

[16] *Id.*

[17] *Id.*

[18] Anecdotally, the court in *Bayer Inc. v. Attorney General of Canada*, discussed *infra* Part IX, noted that the submission to the Canadian Minister of Health related to the drug in question "ran to some 366 volumes of description, test data and other information, and includes the results of clinical tests conducted over 8 years and involving 2,200 patients." Bayer Inc. v. Attorney General of Canada, [1998] 84 C.P.R. (3d) 129.

[19] Joseph A. DiMasi, *Risks in New Drug Development: Approval Success Rates for Investigational Drugs*, CLINICAL PHARMACOLOGY & THERAPEUTICS, Vol. 69, No. 5, at 297 (May 2001).

safety and effectiveness for the regulatory approval process in connection with a patent application.[20] Developers sometimes include general data in promotional materials to reinforce the conclusions of health authorities that the products are safe and effective. Again, they do not generally release raw data or specific information about the test data. Thus, the data necessary to prove that a new product is safe and effective is not normally publicly released by the developers and is not publicly available information in the normal course of business.

Extensive testing directly translates into extensive costs for generating the data necessary to obtain approval of each new active ingredient. To make matters worse, developers must also recover the costs of generating the data associated with products that were abandoned in pre-clinical or clinical trials or were not approved by the health authorities. Estimates of costs vary widely, but studies by the Tufts Center for the Study of Drug Development indicate that the costs of developing a new drug was $US 54 million in 1976 (in 1976 dollars), $US 231 million in 1991 (in 1991 dollars), and $US 802 million in 2002 (in 2002 dollars).[21] These studies demonstrated that a significant portion of the costs were associated with developing test and other data, and that the cost of generating such data has been especially significant over the last twenty five years.[22]

III. PROTECTION FOR TEST AND OTHER DATA BEFORE THE URUGUAY ROUND

In the years preceding the Uruguay Round, the high cost of obtaining the necessary test data caused several serious problems for developers and consumers. First, if the projected sales of a particular product were low (*e.g.*, drugs for rare diseases) and the projected costs of developing the product and of conducting the tests to obtain the necessary data were high, enterprises often did not undertake the necessary research, conduct the tests or market that product. Even if products were developed but projected sales were low,[23] enterprises often did not conduct the necessary tests to market

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[20] Most materials prepared by industrial property offices do not expressly state items that are *not* required in an application. Guidelines prepared by the U.S. Patent and Trademark Office, for example, illustrate what must be provided to fulfill the "utility" requirement. These guidelines do not suggest the deposit of raw data. *See* U.S. PTO, *Revised Interim Utility Guidelines Training Materials, available at* www.uspto.gov/web/menu/utility.pdf (last visited Oct. 18, 2003).

[21] *Backgrounder: A Methodology for Counting Costs for Pharmaceutical R&D*, Tufts Center for the Study of Drug Development, *at* http://csdd.tufts.edu/newsevents/recentnews.asp?newsid=5 (last visited Oct. 18, 2003).

[22] *Id.*

[23] For example, products initially thought to treat common ailments can be found during pre-clinical trials to be ineffective in the treatment of those diseases, but effective in the

the products. In short, the technology to treat certain diseases or conditions may have been available, but its use was not approved. Few developing countries encountered this first problem directly, given that such products were rarely created in those countries.

Second, the requirement that competitors of the originator of a product duplicate the safety and efficacy tests initially performed by the originator represented a significant market entry barrier that added costs for consumers, without providing any new information about the safety or efficacy of the product. Some developing countries attempted to resolve this second problem by permitting competitors to rely on the data presented by the originator to show that their products were safe and effective, rather than requiring duplicative tests. By doing so, they expected to increase competition for products containing a specific active ingredient, and hoped that such competition would result in lower prices for that product. These countries, however, rarely provided any mechanisms for originators to recoup their costs of developing the test data. Instead, they relied on incentives from the developed countries to ensure that originators developed the necessary data, given that data required in developing countries were also required in developed countries.

These problems also existed in developed countries and were considered extensively. The solutions reached in the United States were very different and far more complex than the solution applied in some developing countries. These solutions, however, set a precedent for other developed countries and had a significant effect on the negotiations related to undisclosed information during the Uruguay Round.

A 1982 report by a committee of the U.S. Congress found that there were only 34 drugs, often called "orphan" drugs, marketed in the United States to treat rare, but well-known, diseases such as muscular dystrophy, ALS (Lou Gehrig's Disease), and Huntington's disease.[24] Although the government, academia, and the private sector had developed many more orphan drugs, those drugs had not been tested because the potential market was not sufficient to justify the significant expenses involved in testing.[25] Moreover, the report found that patent protection was often not available to provide a means of recouping the costs associated with testing these drugs. In fact, the U.S. Congress found that patent protection, even when it was available, was not sufficient to promote the testing of orphan drugs in some instances.[26]

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treatment of rare diseases. Also, some biologics could be known to have therapeutic properties but remain untested. *See infra* notes 24-40.

[24] H.R. REP. NO. 97-840, pt. 1, at 7 (1982), *to accompany* H.R. 5238.

[25] *Id.*

[26] *Id.*; *see also* H.R. REP. NO. 99-153, at 3 (1985), *to accompany* H.R. 2290 (1985).

To increase the supply of drugs to treat rare diseases, the U.S. Congress enacted legislation entitled the Orphan Drug Act[27] which contained several measures to encourage the private sector to commercialize such drugs. One of the most important measures in the Act was the provision of a seven-year period of exclusive marketing rights for those companies that provide the extensive test and other data necessary to obtain marketing approval for an orphan drug.[28] During this exclusive marketing period, developers are expected to recoup their investment in obtaining test and other data.

Almost two years after the enactment of the Orphan Drug Act, the U.S. Congress examined other important issues related to the availability of drugs in the U.S. market, and adopted a number of groundbreaking provisions in the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Act").[29] Like some developing countries, the U.S. Congress decided to permit competitors to rely on test and other data submitted by the originator of a product,[30] eliminating unnecessary testing by competitors, which translates into unnecessary costs for consumers. The critical difference from the approach taken by the developing countries, however, was the recognition by the U.S. Congress that the complete rescission of the requirement for test data would be unfair and would give competitors a "free ride" allowing them to provide the product at a lower cost than the originator. This, in turn, would jeopardize the ability of the originator to recoup the costs of generating the test data, and would reduce the incentives for the originator to generate the necessary test data to market the product, particularly for products that were not patented.[31]

Hence, following the rationale of the Orphan Drug Act, the Hatch-Waxman Act prohibits competitors from relying on the data submitted by the originator for a five-year period after approval of the product associated with the data, if the product contains an active ingredient that had not been previously approved by the U.S. Food and Drug Administration.[32] After the

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[27] Pub. L. 97-414, 96 Stat. 2049 (1983) (codified as amended in scattered sections of 21 U.S.C., 26 U.S.C. and 42 U.S.C.).

[28] Orphan Drug Act, § 2(a) (codified at 21 U.S.C. § 360cc (2003)).

[29] Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended in scattered sections of 15 U.S.C., 21 U.S.C., 28 U.S.C., and 35 U.S.C.); *see, in particular*, Hatch-Waxman Act, § 101, 21 U.S.C. § 355 (1984).

[30] It should be noted that while competitors may rely on or refer to the data submitted by the originator, neither competitors nor the public may examine or review that data. The data remain "undisclosed."

[31] Effective patent protection, if available, may provide an opportunity to recoup the cost of generating the data. Patent protection is not available for all products, however. Some important products are based on naturally occurring substances and, as a result, are not patentable subject matter. In some cases, the patent expires before or shortly after the product is launched because of the lengthy time required to conduct the necessary tests.

[32] 21 U.S.C. § 355(c)(3)(D)(ii) (effective for drugs approved after Sept. 24, 1984).

expiration of this period, competitors are permitted to rely on the showings and data submitted by the originator of the product, if these competitors can show that their products are bioequivalent to the approved product.[33] Alternatively, competitors could independently obtain the necessary data before the end of the five-year period. In this manner, competitors are not required (although they have the option) to spend considerable resources to prove again that a particular drug is safe and effective, but originators are given an opportunity to recoup their investment in developing the drug and the associated test data that is needed to show that the product is safe and effective.

Noting the success of these measures in the United States, the Council of the European Community adopted a measure in 1986 similar to the Hatch-Waxman Act.[34] In adopting this measure, the Council noted that "experience has shown that it is advisable to stipulate more precisely the cases in which the results of pharmacological and toxicological tests or clinical trials do not have to be provided with a view to obtaining authorization for a proprietary medicinal product which is essentially similar to an authorized product, while ensuring that innovative firms are not placed at a disadvantage."[35] To accomplish this, the Directive waived the requirement to submit the data from those tests and trials when the product for which approval was sought was "essentially similar" to a product approved more than six years before, or ten years before if the product was considered to be a "high-technology medicinal product."[36] In other words, the Directive prohibited reliance on the data of others for a period of six to ten years.

More than ten years later, the European Parliament and Council adopted a Regulation to promote the development of orphan drugs.[37] The Regulation noted that "some conditions occur so infrequently that the cost of developing and bringing to the market a medicinal product to diagnose, prevent or treat the condition would not be recovered by the expected sales

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[33] *See, e.g.*, 21 U.S.C. § 355(j)(2)(A)(iv) (2003).

[34] Council Directive 87/21/EEC 1987 O.J. (L 15) 36-37 (amending Council Directive 65/65/EEC). This Directive amended Point 8 of Article 4 of Directive 65/65/EEC governing approval of medicinal products by waiving the requirement to submit data resulting from pharmacological and toxicological tests and clinical trials if (1) the applicant received permission to use the data of another; (2) the applicant submitted publicly available material in lieu of data; or (3) the mentioned time periods had elapsed. *See* Directive 87/21/EEC, art. 1.1. Directives 65/65/EEC and 87/21/EEC are no longer in force, having been superseded by Council Directive 2001/83/EC of the European Parliament and of the Council of November 2001 on the Community code relating to medicinal products for human use, which now governs approval of human medicinal products. Council Directive 2001/83/EC 2001 O.J. (L 311) 67. Article 10 of Directive 2001/83/EC now incorporates the requirements of Article 4 of Directive 65/65/EEC.

[35] Council Directive 87/21/EEC, *supra* note 34, at 1, cl. (2).

[36] *Id.* at art. 1.1(a)(iii) (Art. 1.1, however, states that Member States are at liberty not to apply the 6-year period beyond the date of expiration of a patent protecting the original product).

[37] Council Regulation on Orphan Medicinal Products 141/2000, 2000 O.J. (L 18/1) 1.

of a medicinal product; the pharmaceutical industry would be unwilling to develop the medicinal product under normal market conditions; these medicinal products are called 'orphan[s].'"[38] The Regulation also stated that it was necessary to provide additional incentives in the market to promote the development of orphan drugs, and that these incentives should be applied "at the Community level in order to take advantage of the widest possible market and to avoid the dispersion of limited circumstances."[39] One of the incentives is to grant specified orphan drugs with ten years of market exclusivity, as provided in Article 6 of the Regulation.[40]

Over time, these measures have been referred to collectively as data protection laws, given that they were intended to a large degree to promote the generation of test data. The developed countries sought to incorporate the principles of these data protection laws into the TRIPS Agreement.

IV. BENEFITS OF PROTECTING TEST AND OTHER DATA

Before proceeding with a detailed interpretation of the scope of data protection mandated by TRIPS Article 39.3, it is important to examine the underlying purpose of providing such protection. It is not within the scope of this article, however, to provide an exhaustive economic justification for providing the right to exclusive use of data submitted to obtain marketing approval. Instead, the following discussion demonstrates, based on the practical effects of domestic data protection laws and a basic understanding of economic incentives, that the right to exclusive use of test data may provide significant benefits to consumers in developed and developing countries, even if it initially precludes some "price" competition.[41]

As discussed in Part III *supra*, the Orphan Drug Act in the United States provided exclusive rights to market an orphan drug if the innovator submitted the necessary safety and efficacy data. The Act led to dramatic benefits for consumers. Within three years of its enactment, 54 more orphan drugs were under development and testing—far more than the total number of orphan drugs in the market on the date of enactment.[42] Within five years, development had started on 179 new orphan drugs and 20 addi-

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[38] *Id.* at 1, cl. (1).

[39] *Id.* at 1, cl. (3).

[40] The major differences between "market exclusivity" provided by Council Regulation 141/2000, *supra* note 37, and "data exclusivity" provided in Council Directive 87/21, *supra* note 34, is that (1) the term for market exclusivity is ten years in all Member States instead of six years in some; and (2) marketing approval for the second orphan drug would not be granted, even if independently generated data or publicly available data are provided, until the lapse of the term of protection.

[41] It should be noted that most pharmaceutical drugs compete with other patented or unpatented products. As a result, there will be "price" competition for many new products associated with protected data, even if they are subject to a patent.

[42] H.R. REP. NO. 99-153, *supra* note 26, at 3.

tional drugs had been approved.[43] As of January 2001, a total of 212 orphan drugs had been approved, with another 855 drugs as candidates for development.[44]

Similarly, the prohibition on reliance on the data submitted by others, provided by the Hatch-Waxman Act in the United States, spurred the development and testing of new active ingredients. This is particularly true for those products that were not eligible for effective patent protection, such as TAXOL®, a very effective product for treating cancer.

It would be an error to suggest that the incentives to obtain data in developed countries are sufficient to encourage development of all data necessary to prove that a product is safe and effective in all countries, and to fully compensate the originator for its efforts. Such reasoning leads to the erroneous conclusion that it is not necessary for developing countries to protect data against unfair commercial use. This suggestion is very simplistic.

Besides the inability of consumers to afford pharmaceutical products, one of the most significant problems for developing countries is the lack—at any cost—of products or formulations of products directed at diseases or conditions that are not normally found in developed countries, *e.g.*, malaria and many tropical diseases. Incentives based solely on sales in developed countries will not encourage the creation and testing of these products when there is no market for them in the developed countries. As a result, much-needed products will be created and tested only if there are sufficient incentives in developing countries for private enterprises, or substantial philanthropic initiatives for development of such products or a combination of both. Data protection is one incentive that can be offered by those developing countries that do have markets for pharmaceutical products.[45] The more countries that offer such incentives, the greater the likelihood that enterprises will engage in research and testing of products to treat conditions in the developing world.

Even if the disease or condition is found in developed countries, the markets in developed countries may not be sufficient to warrant research and testing for all products for treating the specific disease or condition. For example, a disease could affect only a small number of people in developed countries, but a large number in developing countries. In this case, the markets in developed countries alone would not always justify the expenses associated with research and testing. Thus, effective data protection in all relevant countries—both developed and developing—would be particularly

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[43] *Id* at 4.

[44] Thomas Maeder, *Adopting Orphan Diseases*, RED HERRING, Jan. 22, 2001.

[45] Market-based incentives will not benefit countries where poverty essentially eliminates the market, such as some countries in sub-Saharan Africa. Thus, most enterprises do not seek to obtain patents in those countries and do not attempt to sell products in those countries.

important, as it would be only the *combined* market power of consumers in all of these countries that would create the proper incentives.

This may become an increasingly significant problem given recent technological advances that have led to a situation in which greater benefits from research and testing are possible when the research is concentrated on specific variations of diseases or sub-categories of diseases, rather than undertaken with a disease generally. For example, it now appears possible to treat prostate cancer successfully in many patients through medication.[46] To achieve the same level of success for other types of cancer, separate products may have to be developed, even if they are based on the same scientific principles as the new treatment of prostate cancer. Each product will have to be created and tested. In time, products will become more and more "specialized," and potential markets, even in the developed countries, will shrink. Again, it is possible that the technology to treat diseases more effectively may be available, but ability to obtain marketing approval may not.

It could be argued that the current terms of data protection provided by some countries for certain chemical entities might be too long. One concern is that the term of protection may be longer for some products than justified by the amount of effort expended in testing those products. Yet, it would be administratively difficult to determine a term of protection for each set of test or other data associated with a particular product, just as it would be difficult to set each patent term to recover the cost of developing the particular invention covered by the patent.

In addition, if the term of protection significantly exceeds the period necessary to recover the costs of obtaining the data, market forces will apply to counter the effect of protection. This is especially true in the case of data protection because, unlike with patents, a competitor can enter the market based on independently developed data (except for orphan drugs, which are generally protected through a period of market exclusivity). For example, suppose that a product contains a new chemical entity that must be shown to be safe and effective, and the new chemical entity ("the second product") has similar characteristics to a product that was approved earlier ("the first product"). The amount of data necessary to show that the second product is safe and effective may be far less than the amount of data necessary to prove that the first product was safe and effective. Further suppose that the term of protection gives the originator of the data associated with the first product a reasonable opportunity to recoup expenses related to data development. It would then appear, at first glance, that the same term

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[46] Jocelyn Uhl, *New Prostate Cancer Drug Delays Progression of Advanced Disease*, Office of Communications and Public Affairs of Johns Hopkins Medical Institutions, May 14, 2001, *at* http://www.hopkinsmedicine.org/press/2001/MAY/010514.htm (last visited Oct. 18, 2003).

would be longer than necessary for the originator of the data associated with the second product to recoup investments, assuming that the same sales potential existed for both products. In the case of the second product, this effect is countered by the fact that the barrier to market entry faced by the competitors is also much lower because there is less data to be prepared and submitted for approval. Thus, the competitor can more likely justify independent generation of the data and enter the market before the period of protection expires.

It could also be suggested that, as a matter of principle, the term of protection should be shorter in developing countries than in developed countries. The basis for this suggestion apparently could be the belief that developed countries should shoulder most of the costs of generating safety and efficacy data because they are richer. Shorter terms in developing countries, however, also reduce the incentives to generate data for conditions found predominately in developing countries with markets. Moreover, the poorer a country is, the less flexibility an enterprise has in setting the price of a product in that country, which further reduces the ability to recover costs of developing test data. As a consequence, the proportion of costs already paid in poorer countries is generally less than what is paid in the developed countries—even if the term of protection is the same.

V. NEGOTIATING HISTORY OF TRIPS ARTICLE 39

As early as 1987, participants in the Uruguay Round Negotiating Group[47] who were responsible for intellectual property issues formally circulated proposals that outlined standards for protection.[48] Over the next two years, discussion of these standards stimulated the refinement of these proposals and the circulation of alternative proposals by other participants.[49]

In early 1990, the European Community introduced a comprehensive proposal in treaty language followed shortly by proposals in treaty language from the United States, Switzerland, a group of developing countries and Japan. In its proposal, reproduced *infra* in Table 1, the European Community suggested that certain test data be protected against "unfair exploita-

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[47] DANIEL GERVAIS, THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS 10 (1998); JAYASHAREE WATAL, INTELLECTUAL PROPERTY RIGHTS IN THE WTO AND DEVELOPING COUNTRIES ch. 2 (2001).

[48] Office of the United States Trade Representative in Geneva, *United States Proposal for Negotiating on Trade Related Aspects of Intellectual Property Rights*, MTN.GNG/NG11/W/14 (Oct. 20, 1987), *available at* http://www.ictsd.org/dlogue/2002-04-19/Kuanpoth.pdf (last visited Oct. 18, 2003); Switzerland, *Suggestion by Switzerland for Achieving the Negotiating Objective*, MTN.GNG/NG11/W/15 (Oct. 26, 1987). These appear to be the first formally circulated proposals.

[49] The Secretariat published a list of working documents that includes these proposals and refinements. GATT Secretariat, *List of Documents*, MTN.GNG/NG11/W67/Rev.1 (Mar. 30, 1990). Many of the proposals, however, are not available on the WTO document database.

tion" for a reasonable period of time.[50] Presumably, this proposal reflected the protection required by Council Directive 87/21/EEC, discussed *supra*. The United States submitted a proposal, also reproduced *infra* in Table 1, to prohibit any use of the data that would affect the "commercial or competitive benefits of the government or of any person other than the right-holder *except* with the right-holder's consent" and to protect the data against disclosure, with several limited exceptions.[51] Presumably, the U.S. proposal reflected data protection provisions of the Orphan Drug Act and/or the Hatch-Waxman Act. The Swiss suggested that governments be prohibited from using the data for "commercial purposes,"[52] as also shown in Table 1. The proposals from the group of developing countries[53] and from Japan[54] did not contain provisions related to data protection.

TABLE 1

Proposals Circulated to Negotiating Group 11 in 1990

European Community MTN.GNG/NG11/W/68	United States MTN.GNG/NG11/W/70	Switzerland MTN.GNG/NG11/W/73
Article 28 In the course of ensuring effective protection against unfair competition as provided for in Article 10*bis* of the Paris Convention - (b) Contracting parties, when requiring the publication or submission of test or other data, the origination	*Article 33* Exceptions (1) Contracting parties which require that trade secrets be submitted to carry out governmental functions, shall not use the trade secrets for the commercial or competitive benefit of the government or of any person other than the right-holder *except* with the	*Article 243. Exceptions* (1) Proprietary information submitted to a government agency for purposes of regulatory approval procedures such as clinical or safety tests, shall not be disclosed without the consent of the proprietor, except to other governmental agencies if necessary to protect human, plant or

[50] European Community, *Draft Agreement on the Trade-Related Aspects of Intellectual Property Rights*, MTN.GNG/NG11/W/68 (Mar. 29, 1990) (proposed Annex II, Part 2G, Article 28).

[51] United States, *Draft Agreement on the Trade-Related Aspects of Intellectual Property Rights*, MTN.GNG/NG11/W/70 (May 11, 1990) (proposed Annex J, Part 2G, Article 33).

[52] Switzerland, *Draft Amendment to the General Agreement on Tariffs and Trade for the Protection of Trade-Related Intellectual Property Rights*, MTN.GNG/NG11/W/73 (May 14, 1990) (proposed Part V, Section 2G, Article 243).

[53] Argentina et al., *Communication from Argentina, Brazil, Chile, China, Colombia, Cuba, Egypt, India, Nigeria, Peru, Tanzania and Uruguay*, MTN.GNG/NG11/W/71 (May 14, 1990).

[54] Japan, *Main Elements of a Legal Text for TRIPS*, MTN.GNG/NG11/W/74 (May 15, 1990).

of which involves a considerable effort, shall protect such efforts against unfair exploitation by competitors. The protection shall last for a reasonable time commensurate with such efforts, the nature of the data required, the expenditure involved in their preparation and shall take account of the availability of other forms of protection.	right-holder's consent, on payment of the reasonable value of the use, or if a reasonable period of exclusive use is given the right-holder. (2) Contracting parties may disclose trade secrets to third parties, only with the right-holder's consent or to the degree required to carry out necessary government functions. Wherever practicable, right-holders shall be given an opportunity to enter into confidentiality agreements with any non-government entity to which the contracting party is disclosing trade secrets to carry out necessary government functions. (3) Contracting parties may require right-holders to disclose their trade secrets to third parties to protect human health or safety or to protect the environment only when the right-holder is given an opportunity to enter into confidentiality agreements with any non-government entity receiving the trade secrets to prevent further disclosure or use of the trade secret.	animal life, health or the environment. Governmental agencies shall not be entitled to use the information for commercial purposes. They may disclose it only with the consent of the proprietor or to the extent indispensable to inform the general public about the actual or potential danger of a product. (2) Disclosure of any proprietary information to a third party, or other governmental agencies, in the context of an application for obtaining intellectual property protection, shall be subject to an obligation to hear the applicant and to judicial review. Third parties and governmental agencies having obtained such information shall be prevented from further disclosure and commercial use of it without the consent of the proprietor.

In July 1990, a composite text of an agreement was prepared by the Chairman of the Negotiating Group.[55] This Chairman's Consolidated Text contained three alternative formulations for describing the protection to be afforded to test data submitted to governments. Not surprisingly, the three alternatives generally followed the submissions of the European Community, United States, and Switzerland, as shown in Table 2.

[55] Chairman's Report to the GNG, *Status of Work in the Negotiating Group: Chairman's Report to the GNG*, MTN.GNG/NG11/76 (July 23, 1990).

TABLE 2

Chairman's Consolidated Text
MTN.GNG/NG11/76
(All text was [bracketed].)

Alternative 3Aa (European Community)	Alternative 3Ab (United States)	Alternative 3Ac (Switzerland)
3Aa PARTIES, when requiring the publication or submission of test or other data, the origination of which involves a considerable effort, shall protect such efforts against unfair exploitation by competitors. The protection shall last for a reasonable time commensurate with such efforts, the nature of the data required, the expenditure involved in their preparation and shall take account of the availability of other forms of protection.	3Ab.1 PARTIES which require that trade secrets be submitted to carry out governmental functions, shall not use the trade secrets for the commercial or competitive benefit of the government or of any person other than the right holder except with the right holder's consent, on payment of the reasonable value of the use, or if a reasonable period of exclusive use is given the right holder. 3Ab.2 PARTIES may disclose trade secrets to third parties, only with the right holder's consent or to the degree required to carry out necessary government functions. Wherever practicable, right holders shall be given an opportunity to enter into confidentiality agreements with any non-government entity to which the PARTY is disclosing trade secrets to carry out necessary government functions. 3Ab.3 PARTIES may require right holders to disclose their trade secrets to third parties to protect human health or safety or to protect the environment only when the right holder is given an	3Ac.1 Proprietary information submitted to a government agency for purposes of regulatory approval procedures such as clinical or safety tests, shall not be disclosed without the consent of the proprietor, except to other governmental agencies if necessary to protect human, plant or animal life, health or the environment. Governmental agencies may disclose it only with the consent of the proprietor or to the extent indispensable to inform the general public about the actual or potential danger of a product. They shall not be entitled to use the information for commercial purposes. 3Ac.2 Disclosure of any proprietary information to a third party, or other governmental agencies, in the context of an application for obtaining intellectual property protection, shall be subject to an obligation to hear the applicant and to judicial review. Third parties and governmental agencies

	opportunity to enter into confidentiality agreements with any non-government entity receiving the trade secrets to prevent further disclosure or use of the trade secret.	having obtained such information shall be prevented from further disclosure and commercial use of it without the consent of the proprietor.

Intense negotiations followed the introduction of the Chairman's Consolidated Text with the goal of reaching agreement in as many areas as possible before the Ministerial Conference that was to take place in Brussels in December 1990. With regard to data protection, the following text was prepared for the Ministerial:

> 4A PARTIES, when requiring, as a condition of approving the marketing of new pharmaceutical products or of a new agricultural chemical product, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall [protect such data against unfair commercial use. Unless the person submitting the information agrees, the data may not be relied upon for the approval of competing products for a reasonable time, generally no less than five years, commensurate with the efforts involved in the origination of the data, their nature, and the expenditure involved in their preparation. In addition, PARTIES shall] protect such data against disclosure, except where necessary to protect the public.[56]

This provision reflected concepts and nomenclature found in the proposals of the European Community, Switzerland, and the United States. Specifically, it required Members to protect data against unfair commercial use—in addition to protection against disclosure. It appears that the drafters chose the term "unfair commercial use" in order to integrate the concepts of the three proposals and to encompass the level of protection required in the second sentence. By contrast, the developing countries objected to any protection for data other than protection against disclosure.[57]

Unfortunately, the negotiators in Brussels were not able to resolve a number of very difficult issues unrelated to intellectual property. As a result, negotiations were not concluded at the Brussels Ministerial. One year later, the Director General of the GATT, Arthur Dunkel, tabled a text that he believed to be the most widely acceptable text for an agreement in areas under consideration during the Round. This text, called the Dunkel Text, contained the present text of TRIPS Article 39.3 (except for technical conforming amendments).

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[56] GATT Secretariat, *Draft Final Act Embodying the Results of the Uruguay Round of Multilateral Negotiations*, MTN.TNC/W/35 Rev.1 (Dec. 3, 1990).

[57] WATAL, *supra* note 47, at 199.

In short, the Dunkel Text retained the concept that a form of protection in addition to protection from disclosure must be provided by Members, and retained the phrase "unfair commercial use" that was created to encompass the concepts in the proposals of the European Community, Switzerland, and the United States. The Dunkel Text, however, did not specify the form that this protection must take, as did the bracketed text presented to the Ministers at Brussels. Therefore, it would be logical to conclude that the term "unfair commercial use" encompasses "unfair exploitation" as suggested by the European Community, and the use of the data of another for commercial purposes as suggested by Switzerland and the United States. Given that the more detailed requirements related to this protection were deleted, it can be concluded that Members are free to choose how to protect the data as long as they protect such data against all unfair commercial uses.

One commentator provides an explanation for the deletion of the express prohibition on reliance that is consistent with the meaning of "unfair commercial use":

> United States negotiators agreed to drop the non-reliance language, because they viewed the phrase as no more than "belts and suspenders"; that is, the accepted definition at the time of "protection against unfair commercial use" included non-reliance for a fixed period of time for new chemical entities and the second phrase was, therefore, not needed.[58]

VI. NATURE OF PROTECTION REQUIRED BY TRIPS ARTICLE 39.3

A. Relationship to the Paris Convention

TRIPS Article 39.1 requires Members to protect certain undisclosed data in accordance with TRIPS Article 39.3 "[i]n the course of ensuring effective protection against unfair competition as provided in Article 10*bis* of the Paris Convention (1967)." For WTO Members, this provision essentially adds "unfair commercial use" and "disclosure" of certain test and other data to the list of examples of prohibited acts of unfair competition in Paris Article 10*bis*. Consequently, this brings TRIPS Article 39.3 into the Paris *acquis*, and, therefore, other provisions of the Paris Convention will apply independent of TRIPS Article 2.1 (which incorporates, by reference, various provisions of the Paris Convention). For example, the protection provided for undisclosed information must be in accord with the national treatment provisions of the Paris Article 2. In addition, individuals may be able to enforce the obligations in TRIPS Article 39.3 directly in a Member,

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[58] *See* JACQUES J. GORLIN, AN ANALYSIS OF THE PHARMACEUTICAL-RELATED PROVISIONS OF THE TRIPS (INTELLECTUAL PROPERTY) AGREEMENT 48 (1999).

even absent a statute directly implementing that Article, to the extent that the Paris Convention is self-enforcing in that Member.[59]

The connection provided by the TRIPS Agreement between the Paris Article 10*bis* and TRIPS Article 39.3 may also impose obligations on countries of the Paris Union that are not TRIPS Members. Professor Bodenhausen states in his *Guide*, with regard to the Paris Article 10*bis*, as follows:

> Any act of competition will have to be considered unfair if it is contrary to *honest practices in industrial or commercial matters*. This criterion is not limited to honest practices existing in the country where protection against unfair competition is sought. The judicial or administrative authorities of such country will therefore also have to take into account honest practices established in international trade.[60]

By virtue of TRIPS Article 39, the 146 Members[61] of the WTO agree that unfair commercial use and disclosure of certain test and other data constitute unfair competition within the meaning of the Paris Article 10*bis*. Given that Members constitute the majority of countries in the world, it would appear that those acts have been "established in international trade" as dishonest practices and acts of unfair competition. Thus, it follows from the commentary of Professor Bodenhausen that all countries of the Paris Union must now also consider these acts as contrary to honest practices, and impose the protection required by TRIPS Article 39.3.

The incorporation of TRIPS Article 39.3 into the Paris *acquis* does not mean that *generalized* national laws aimed at preventing unfair competition or the misappropriation of undisclosed information are sufficient to fulfill the obligations of the Member. This basic principle was explained by the WTO Appellate Body in *India—Patent Protection for Pharmaceutical and Agricultural Chemical Products*, which found that India was required to provide a "sound legal basis" for implementing its specific TRIPS obligations (*i.e.*, TRIPS Article 70.8).[62] Thus, the Appellate Body found that some regulatory or statutory provisions were necessary to ensure that inven-

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[59] The ability to enforce TRIPS Article 39.3 directly through the Paris Convention may also depend on the extent to which the country of the Paris Union has waived sovereign immunity.

[60] BODENHAUSEN, *supra* note 3, at 144.

[61] There were 146 Members of the WTO as of April 4, 2003. *See* World Trade Organization, *What is the WTO?, at* http://www.wto.org/index.htm (follow link to *What is the WTO*) (last visited Oct. 18, 2003); *See also* World Trade Organization, *Accessions, at* http://www.wto.org/index.htm (follow links to *The WTO, Accessions*) http://www.wto.org/English/thewto_e/acc_e/acc_e.htm (as of Nov. 30, 2003, there were working parties for the accession of 27 countries).

[62] WTO Appellate Body, India—Patent Protection for Pharmaceutical and Agricultural Chemical Products, WT/DS50/AB/R (adopted Jan. 16, 1998).

tors obtained a right that could be enforced at a future date.[63] It seems unlikely that general unfair competition or misappropriation laws, especially in "civil law" countries, would contain sufficient specificity to ensure submitters of data that governments were required to prevent "unfair commercial use" of undisclosed test and other data. Specific statutes, regulations, or decrees are required to establish a "sound legal basis" for this protection.

B. Data Protection as an Obligation of the Government

A government does not comply with its TRIPS obligations by simply providing a private right of action for victims of unfair commercial use of the test and other data covered by TRIPS Article 39.3. TRIPS Article 39.3 specifically provides that "*Members . . . shall protect* such data against unfair commercial use" and "*Members shall protect* such data against disclosure."[64] Read literally, the ultimate obligation to protect the data is clearly on the government of the Member, and not on the victim or originator of the data.

This obligation in TRIPS Article 39.3 is not satisfied by simply shifting the burden of protection to the submitter of the data by providing the submitter with a private right of action against natural or legal persons for actions related to unfair commercial use or disclosure of the submitted data. If the drafters of the TRIPS Agreement had intended the obligation to be fulfilled by the creation of such a private right, they would have expressly required Members to give submitters a private right of action.

For example, TRIPS Article 39.2 requires Members to provide those persons who lawfully control undisclosed information with the right to initiate an action against those who exploit the information without consent in a manner contrary to honest commercial practices. Like TRIPS Article 39.2, TRIPS Articles 11, 14, 16, 22, 23, 25, 28, and 36 contain provisions that require Members to create private rights of action. By contrast, like TRIPS Article 39.3, TRIPS Articles 1, 2, and 9, for example, require direct action by the Member. From a review of these Articles, it is clear that the drafters of the TRIPS Agreement understood the difference between requiring the creation of a private right of action, and requiring a Member to fulfill an obligation directly. Consequently, it is clear that the phrase "Members shall" in TRIPS Article 39.3 was purposefully included to clarify that the creation of a private right of action was not enough, and that a Member must be prepared to act on its own.[65]

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[63] *Id.*

[64] TRIPS Agreement, *supra* note 11, at art. 39.3 (emphasis added).

[65] Alternatively, the drafters could have required both a private right of action and direct action by the government of the Member, but limited the direct action requirement to in-

VII. CONDITIONS THAT TRIGGER PROTECTION FOR TEST AND OTHER DATA UNDER ARTICLE 39.3

Under TRIPS Article 39.3, each Member is required at a minimum to protect data that meet all of the following five criteria:

- The data were submitted as a condition for obtaining marketing approval for a product in that Member.
- The product for which marketing approval was sought was a pharmaceutical or agricultural chemical product.
- The product for which marketing approval was sought contained a new chemical entity.
- The data were undisclosed at the time of submission.
- The generation of the data required considerable effort.

Given the construction of this provision, it appears to be "inclusive" and Members are not permitted to impose additional requirements as a condition for protecting the data, pursuant to TRIPS Article 39.3.[66]

Pursuant to TRIPS Article 1.1, Members are permitted to protect other data, such as data submitted in connection with an orphan drug product, regardless of whether that product contains a new chemical entity.[67] Similarly, Members may also protect data that do not meet the characteristics defined in Article 39.3.

A. Interpretative Principles

The terms used in TRIPS Article 39.3 are not defined in the Agreement. To interpret the meaning of an undefined term, the WTO Appellate Body and dispute settlement panels have applied the first paragraph of Article 31 of the Vienna Convention on the Law of Treaties ("Vienna Article 31"), which provides: A treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose. [68]

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stances where a Member's legislation so permits, as they did in TRIPS Articles 22.3 and 23.2. TRIPS Agreement, *supra* note 11, at arts. 22.3, 22.2.

[66] Dr. Gorlin notes "According to the principal U.S. TRIP[S] Negotiator, Mike Kirk, whenever the negotiators wanted to make exceptions to a right, they spelled out that exception together with the right. If the right did not have an exception tied to it, then the negotiators did not intend that there be any other exceptions for that right." *See* GORLIN, *supra* note 58, at 19.

[67] TRIPS Article 1.1 states that Members "may, but shall not be obliged to, implement in their law more extensive protection than is required" by the TRIPS Agreement, provided that such additional protection does not contravene other provisions of the Agreement. TRIPS Agreement, *supra* note 11, at art. 1.1.

[68] Vienna Convention on the Law of Treaties, May 23, 1969, 1155 U.N.T.S. 331; *See, e.g.*, WTO Dispute Panel Report on Canada—Patent Protection of Pharmaceutical Products, WT/DS114/R, para. 7.13 (adopted Apr. 7, 2000) [hereinafter WTO Report on Canada-

Where necessary to determine the ordinary meaning of a particular word, panels and the Appellate Body have often relied on dictionary definitions.[69]

Article 32 of the Vienna Convention allows for supplementary means of interpretation in limited circumstances, and states as follows:

> Recourse may be had to supplementary means of interpretation, including the preparatory work of the treaty and the circumstances of its conclusion, in order to confirm the meaning resulting from the application of article 31, or to determine the meaning when the interpretation according to article 31:
>
> (a) leaves the meaning ambiguous or obscure; or
>
> (b) leads to a result which is manifestly absurd or unreasonable.

Thus, the negotiating history, discussed supra in Section 5 of this article, becomes especially relevant for purposes of interpreting provisions pursuant to Vienna Article 32.

B. Submission

TRIPS Article 39.3 requires, at a minimum, that Members protect data submitted as a condition for obtaining marketing approval. The TRIPS Agreement, however, does not expressly limit protection to data submitted directly to the government of the Member providing protection. To illustrate, a Member could require the submission of otherwise protectable data to an independent research facility for analysis, rather than requiring submission to a government entity. In such a case, the Member would never physically acquire or retain the data. Read literally, TRIPS Article 39.3 requires the Member to protect data submitted to that research facility because that Article does not specify to whom the data must be submitted. It demands protection when the Member requires the data to be submitted; regardless of to whom the data must be submitted. As a policy matter, it would be illogical to place a requirement to protect data on a Member, and then allow a Member to avoid that requirement by simply delegating certain functions from it to a non-governmental entity.

Similarly, some Members condition approval of pharmaceutical products on the prior approval in one of a specified group of countries, rather

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Pharmaceutical Products]; WTO Dispute Panel Report on United States—Section 110(5) of the United States Copyright Act, WT/DS160/R, DSR 2000: VIII, 3769, para. 6.43 (July 27, 2000) [hereinafter WTO Report on United States-Section 110(5)].

[69] *See, e.g.*, WTO Report on United States-Section 110(5), *supra* note 68, at paras. 6.108-6.110; WTO Appellate Body Report on Canada—Term of Patent Protection, WT/DS170/AB/R, para. 65 (adopted Oct. 12, 2000) [hereinafter WTO Appellate Body Report on Canada-Patent Protection]; WTO Appellate Body Report on United States—Section 211 Omnibus Appropriations Act of 1998, WT/DS176/AB/R, paras. 137, 172, 187, & 215 (Feb. 1, 2002) [hereinafter WTO Appellate Body Report on United States Section 211].

than requiring submission of the data to a government entity in their own territory or to their designated agent. In such cases, Members are, in fact, requiring submission of otherwise protectable data for approval, albeit indirectly. In other words, but for the submission of test data to another country, these Members would not approve sale of the product in their territories. The countries in the group upon which certain Members rely for reviewing test data are essentially agents of the Members—agents to which the countries require submission of test data. Therefore, it follows that those Members must protect the data, even though the data were submitted to a different country.

C. Pharmaceutical or Agricultural Chemical Products

Members must, at a minimum, protect test and other data related to "pharmaceutical [and] agricultural chemical products." The TRIPS Agreement does not contain a definition of that phrase. Most Members, however, have legislation to regulate the marketing of these products, and will define what constitutes those products broadly in that legislation to ensure the health and safety of their constituents.

Members are not required to protect data for products that are not considered to be pharmaceutical or agricultural chemical products, but may elect to do so. To illustrate, some Members may require the submission of test data to obtain approval to market certain purely industrial chemicals, such as dyes or detergents that could contain new chemical entities. Members would not be required pursuant to TRIPS Article 39.3 to protect undisclosed information related to these products, but Members are permitted to protect it pursuant to TRIPS Article 1.1.

D. New Chemical Entity

Members also must, at a minimum, protect test and other data related to pharmaceutical and agricultural chemical products containing a "new chemical entity." The TRIPS Agreement does not define the phrase "new chemical entity." Following the practice of panels and the Appellate Body of interpreting a phrase pursuant to Vienna Article 31,[70] one finds that the word "new," depending on context, ordinarily means "not existing before," "of a kind now first invented or introduced; novel," or "now known, experienced, used, etc. for the first time."[71] Consequently, pursuant to Vienna Article 31, it is necessary to analyze on a case-by-case basis how the word "new" is used in the context of the TRIPS Agreement to determine its proper interpretation. A review of the TRIPS Agreement reveals that in

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[70] *See supra at* Part VII(A).

[71] THE NEW SHORTER OXFORD ENGLISH DICTIONARY, vol. II 1912 (1993) [hereinafter OXFORD DICTIONARY].

some instances, the word is intended to mean experienced or used for the first time, but in others it is intended to mean "novel" in the patent sense.

TRIPS Article 39.3 protects data and products involved in the marketing approval systems, rather than as such data relate to the patent systems. Consequently, the word "new" in this context refers to the status of a chemical entity within the marketing approval system, not with respect to the state of the art or "novelty" in the patent sense. This conclusion is further supported by state practice[72] and the fact that the word "new" is frequently used to refer to the status of a chemical entity or a product vis-à-vis the marketing approval systems of various countries. For example, the term "new" is used in connection with the phrase "chemical entity" to refer to chemical substances that have not been subject to marketing approval in the United States.[73] Likewise, the term "new" is used in connection with the word "drug" in the United States to refer to requests for marketing approval for products not previously approved.[74] Moreover, in the European Union, the term "new" was used in connection with "proprietary medical products" in Council Directives 87/21/EEC[75] and 65/65/EEC,[76] in force during the negotiation of the TRIPS Agreement, to denote status within the marketing approval system.[77] Also, the term "new" is used in connection with "drug" and "drug submission" in chapter 870, section C.08.002.1 of Canada's Food and Drug Regulations to denote status within the marketing approval system. The word "new" does not mean "novel" in the patent sense in any of these legal instruments.

Looking to other provisions in the TRIPS Agreement, TRIPS Article 70.7 refers to the introduction of "new matter" into applications for protection, including patent applications. The term "new" in this provision, just as in TRIPS Article 39.3, refers to the status of the information within the application vis-à-vis the filing date of the application, without regard to

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[72] WTO panels, in considering "subsequent practice" when interpreting a treaty pursuant to Vienna Article 31(3), have looked to state practice for guidance. *See, e.g.*, WTO Report on United States-Section 110(5), *supra* note 68, at ¶ 6.55 ("In our view, state practice as reflected in the national copyright laws of members before and after 1948, 1967, and 1971, as well as of WTO Members before and after the date that the TRIPS Agreement became applicable to them, confirms our conclusion about the minor exceptions doctrine.").

[73] The U.S. Food and Drug Administration defines a "new chemical entity" as "a drug that contains no active moiety that has been approved by [the] FDA in any other application submitted under . . . the [Federal Food, Drug, and Cosmetic] [A]ct." 21 C.F.R. 314.108 (2003).

[74] 21 U.S.C. § 355 (2000).

[75] Article 1, amending Council Directive 65/65/ECC, art. 4.

[76] Council Directive 65/65/ECC, art. 4.

[77] Directives 65/65/EEC and 87/21/EEC were superseded by Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use. Council Directive 2001/83/EC, 2001 O.J. (L311) 67. The new Directive does not use the term "new."

whether the information was found in the state-of-the-art as of the filing date of application. This is consistent with the normal usage of the term "new matter," which is understood to be information introduced into an application after the filing date of that application to amend or correct an application.[78] Thus, the term "new," as used in TRIPS Article 70.7, is not synonymous with "novelty."

In contrast, TRIPS Articles 27.1 and 34.1 specifically relate to inventions and their status within the state-of-the-art.[79] There, the word "new" is a term-of-art in the patent area and refers to whether an invention is within the state-of-the-art at a given time. There is no reason to assume that the term used in the context of determining patentability would be used identically in provisions for determining whether test data should be protected.

Some commentators have erroneously suggested that the word "new" as used in TRIPS Article 39.3 may be interpreted in the same manner as it is in provisions related to patents, such as Articles 27.1 and 34.1.[80] They contend that "new" is a term-of-art in the patent laws that is synonymous with "novel," and that, consequently, Article 39.3 refers to a chemical entity that was not found within the state-of-the-art, presumably at the time of submission. Therefore, they argue, only data related to products with chemical entities that were not publicly known before the submission of the data would be eligible for protection. Under this flawed interpretation, Members would not be required to protect data related to products containing naturally occurring substances, even if the medical or agricultural use of the substance was not known prior to submission. Furthermore, Members would not have to protect data associated with products containing man-made chemical entities that were known before submission, even if no medical or agricultural use was publicly known before submission of the data.

This interpretation is untenable. First, as explained *supra*, such an interpretation is not consistent with the use of the word "new" within the context of the provision. Moreover, the purpose of the protection required by

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[78] *See* Article 7(3) *Draft Substantive Patent Law Treaty*, WIPO Document SCP/7/3, Mar. 6, 2002, *at* http://www.wipo.org/search/en/ (search *WIPO Document SCP/7/3*) (last visited Oct. 19, 2003).

[79] TRIPS Article 25 requires Members to protect "new and original" designs. In this Article, it appears that "new" is also used in the sense of "novel." *See* TRIPS Agreement, *supra* note 11, at art. 25.

[80] Carlos Correa, *Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the TRIPS Agreement,* 16 (2002), *at* http://www.southcentre.org/publications/protection/protection.pdf (last visited Oct. 19, 2003) [hereinafter Correa, *Protection of Data*]; Carlos Correa, *Unfair Competition under the TRIPS Agreement: Protection of Data Submitted for Registration of Pharmaceuticals*, 3 CHI J. INT'L L. 69, 74 (2002) [hereinafter Correa, *Unfair Competition*]; *see also* GERVAIS, *supra* note 47, at 187 (noting that some may wish to interpret "new" in the patent sense, but that this interpretation has practical difficulties).

TRIPS Article 39.3 is to eliminate acts of unfair competition that discourage the marketing of safe and effective pharmaceutical and agricultural chemical products. It violates this purpose and defies logic to encourage introduction only of recently invented products, and to discourage simultaneously the entry of safe and effective products derived from naturally occurring substances, or of substances that were known to the public but not previously marketed as pharmaceutical or agricultural chemical products.

E. Undisclosed at the Time of Submission

TRIPS Article 39.3 provides that "Members, when requiring . . . the submission of undisclosed test or other data, . . . shall protect such data." Read literally, Members must attach protection to the data if the data were undisclosed at the time of submission. Technically, there is no express permission to cease protection if the data are disclosed after submission. As a practical matter, protection by Members against disclosure may be irrelevant if a third party discloses the data. Protection against unfair commercial practices, however, may still be relevant. This issue will be discussed further *infra* Part VIII(A).

F. Considerable Effort

Members are required, at a minimum, to protect data which the origination thereof required "considerable effort." Again, the term "considerable effort" is not defined in the Agreement.

Following the approach of WTO panels and the Appellate Body of interpreting words pursuant to Article 31 of the Vienna Convention,[81] one finds that the ordinary meaning of "considerable" is "worthy of consideration or regard; of consequence" or "worthy of consideration by reason of magnitude; somewhat large in amount, extent, duration."[82] The ordinary meaning of "effort" is "exertion or striving, physical or mental; a vigorous attempt" or "the result of any concentrated or special activity."[83] Therefore, it is likely that the term "considerable effort" would be interpreted to mean the concentrated or special activities, physical or mental, that are extensive in scope or duration. The conduct of the tests needed to amass the data required by health authorities would normally fall within this interpretation of the phrase "considerable efforts."

It is also important to note that TRIPS Article 39.3 applies to data the "*origination* of which involves a considerable effort."[84] The requirements of most health authorities for test data are similar, and the data generated to

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[81] *See supra* Part VII(A).

[82] OXFORD DICTIONARY, *supra* note 71, at vol. I 485.

[83] *Id.* at 787.

[84] TRIPS Agreement, *supra* note 11, at art. 39.3 (emphasis added).

comply with requirements of one Member may often be used for submissions to authorities in other Members. The "considerable effort" criterion is required only with respect to the origination of the data—not to activities such as reformatting and translating data in one submission for use in others. Thus, a Member cannot deny protection against unfair commercial use and disclosure on the grounds that there was no "considerable effort" because the submission merely included data used in submission to other Members.

VIII. PROTECTION AGAINST UNFAIR COMMERCIAL USE

If test and other data meet the five criteria discussed *supra* in Part VII, Members must protect the data from "unfair commercial use." That phrase is not defined in the Agreement. As detailed herein, TRIPS Article 39.3, when interpreted pursuant to the principles followed by WTO dispute settlement panels and the Appellate Body, requires WTO Members to provide protection against the unjust or unfair application or conversion of such test and other data to make a profit or obtain a benefit. Application or conversion of this test data by someone other than the originator is unfair or unjust at a time before the originator has been able to at least recoup the investment made to produce the data.

Interpreting the phrase according to Article 31 the Vienna Convention on the Law of Treaties,[85] one begins with the ordinary meaning. The ordinary meaning of "unfair" is "not equitable, unjust; not according to the rules, partial."[86] "Commercial" means "engaged in commerce; of, pertaining to, or bearing on commerce" or "interested in financial return rather than artistry; likely to make a profit; regarded as a mere matter of business."[87] Finally, "use" means an "action of using or state of being used; application or conversion to some purpose" and "ability to be used, especially for a particular purpose; usefulness; advantage."[88]

Synthesizing these definitions, a panel or the Appellate Body would likely conclude that the phrase "unfair commercial use" of test data was intended to mean the unjust application or conversion of the data for the purpose of making a profit or other business benefit.

Thus, if a Member, at the request of a competitor of the originator of data, relied on data submitted by the originator in a manner that benefits the competitor, this would constitute an application or conversion of the data that helps the competitor to make a profit. Similarly, reliance by a Member on the data, absent a specific request by the competitor to rely on the data,

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[85] *See supra* Part VII(A).

[86] OXFORD DICTIONARY, *supra* note 71, at vol. II 3482.

[87] *Id.* at vol. I 451.

[88] *Id.* at vol. II 3531.

also would be considered an application of the data designed to allow the competitor to make a profit. Both are "commercial uses" of the data.

This leaves the question of whether such reliance is to be considered "unjust" or "unfair". Given the requirement of Vienna Article 31 to interpret provisions within their context, it is likely that the term "unjust" would be evaluated in light of the "considerable effort" expended by the originator to generate the data. Thus, acts that deprive the originator of the opportunity to recover at least the resources expended in the considerable effort would appear to be unjust. For example, any reliance on the data by a competitor before the originator has had the opportunity to recoup the resources associated with the considerable efforts to develop the data would be unjust; it would give the competitor a "free ride" on the investment made by the originator. Moreover, it would put the free rider in a better market position than the entity that invested in bringing a new product to market because of the substantial savings in fixed costs that comes from not having to develop test data.

Each phrase in an agreement must be interpreted in light of the context in which it is used. Moreover, when interpreting a particular phrase in one provision, it is likely that panels would give similar interpretations to analogous phrases used *in similar contexts* elsewhere in the TRIPS Agreement. For example, a panel interpreted the phrase "conflict with a normal exploitation of the work" in TRIPS Article 13, which relates to copyright protection, to mean "uses . . . [that] enter into economic competition with the ways the right holders normally extract economic value from the right to the work . . . and thereby deprive them of significant or tangible commercial gains."[89] Similarly, a panel interpreted the phrase "unreasonably conflict with the normal exploitation of the patent" in TRIPS Article 30, regarding limitations to exceptions to patent protection, as preventing "all forms of competition that could detract significantly from the economic returns anticipated from a patent's grant of market exclusivity."[90] Thus, it is reasonable to conclude that the term "unfair" in the context of TRIPS Article 39.3 would also be interpreted in light of commercial consequences, and would, therefore, be interpreted to prohibit reliance. Moreover, there is no indication that a competitor must acquire the data through a dishonest practice to constitute unfair commercial use. As the Government of New Zealand stated shortly after the TRIPS Agreement entered into force:

> 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

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[89] WTO Report on United States-Section 110(5), *supra* note 68, at para. 6.183.

[90] WTO Report on Canada-Pharmaceutical Products, *supra* note 68, at para. 7.55.

> 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 this is, in New Zealand's view, "unfair commercial use". In effect, the regulatory authority is giving a 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.[91]

TRIPS Article 39.3 does not specify how the protection should be provided, nor does it specify a term of protection. Members could protect data by prohibiting reliance directly on the data for a period of time, as is required by the North American Free Trade Agreement (NAFTA).[92] Also, they could grant exclusive marketing rights to products associated with the data for a specific period of time. There may be other forms of protection that would fulfill the obligations of Members under TRIPS Article 39.3. The European Commission supports this understanding:

> 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 commercial 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—systems to non-reliance over a reasonable period do not appear to exist.[93]

In some instances, WTO dispute settlement panels will use supplementary materials such as the negotiating history of a provision or ordinary practice at the time of conclusion of a treaty to confirm an interpretation of the ordinary meaning of the provision, to the extent permitted under Vienna Article 32.[94] Vienna Article 32 also provides that recourse may be had to such supplementary means of interpretation when the effort to determine the ordinary meaning of a provision pursuant to Vienna Article 31 "(a) leaves the meaning ambiguous or obscure; or (b) leads to a result which is manifestly absurd or unreasonable."

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[91] Government of New Zealand, Presentation at the APEC Seminar on the TRIPS Agreement on Protection of Undisclosed Information and Control of Anti-Competitive Practices, (May 17-19, 1995).

[92] North American Free Trade Agreement, Dec. 17, 1992, Can.-Mex.-U.S., art. 1711, 32 I.L.M. 605, 675 [hereinafter NAFTA].

[93] Commission Publication on Questions on TRIPs and Data Exclusivity: An EU Contribution, (2001).

[94] WTO Report on United States-Section 110(5), *supra* note 68, at paras. 6.43-6.46; WTO Report on Canada-Pharmaceutical Products, *supra* note 68, at paras. 7.13 - 7.15.

It is unclear whether a panel would consider supplementary information in attempting to define the term "unfair commercial use." If it did, the panel would find that the term "unfair commercial use" was first used in the following [bracketed] text presented to the Ministerial Conference in Brussels in December 1990:

> 4A PARTIES, when requiring, as a condition of approving the marketing of new pharmaceutical products or of a new agricultural chemical product, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall [protect such data against *unfair commercial use*. Unless the person submitting the information agrees, the data may not be relied upon for the approval of competing products for a reasonable time, generally no less than five years, commensurate with the efforts involved in the origination of the data, their nature, and the expenditure involved in their preparation. In addition, PARTIES shall] protect such data against disclosure, except where necessary to protect the public.[95]

This provision reflected concepts and nomenclature found in earlier proposals of the European Community, Switzerland, and the United States, as discussed *supra* Part V. Specifically, it would have required Members to protect data against unfair commercial use—in addition to protection against disclosure. It appears that the drafters chose to call the protection "unfair commercial use" in an attempt to integrate the concepts in the three proposals.

It was this version, without the second sentence and with some format changes, that became TRIPS Article 39.3. Article 39.3 did not specify the form that this protection must take, as did the bracketed text presented to the Ministers at Brussels. It did, however, retain the concept that a form of protection beyond just protection from disclosure must be provided by Members. The article also retained the phrase "unfair commercial use" that was created to encompass the concepts in the proposals of the European Community, Switzerland, and the United States. Therefore, it would be logical to conclude that the term "unfair commercial use" encompasses "unfair exploitation" as suggested by the European Community, or the use of the data of another for commercial purposes as suggested by the Swiss and the United States. Thus, the ordinary meaning of the phrase "unfair commercial use"—the unjust application or conversion of the data to make a profit or to obtain a benefit—is consistent with the negotiating history of the provision. The fact that the more detailed requirements related to this protection were deleted demonstrates that Members are free to choose how to protect the data, as long as they protect the data against all unfair commercial uses.

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[95] Draft Final Act Embodying the Results of the Uruguay Round of Multilateral Negotiations, TNC/W/35 Rev.1, (Dec. 3, 1990) (emphasis added).

In a statement made shortly after entry into force of the TRIPS Agreement in 1995, the General Counsel's Office of the United States Trade Representative provided the following interpretation of "unfair commercial use" in light of the negotiating history:

> TRIPS 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 the logic and the negotiating history of the provision.[96]

In contrast, one commentator notes that the deletion of the express prohibition on reliance from the Brussels text during the negotiations was one of the factors that has given rise to the view by some Members that unlimited reliance on the data of others is permitted under TRIPS Article 39.3.[97] She also notes that these Members protect test data against disclosure, but do not protect the data from unfair commercial use (*i.e.*, they permit reliance on the data of others).[98] This practice, however, violates TRIPS Article 39.3, which contains an express requirement to protect certain test data from unfair commercial use. Panels and the Appellate Body have been very reluctant to interpret provisions in a manner that leaves them without meaning and that makes them redundant.[99] Therefore, a Member would not likely prevail in dispute settlement by arguing that Members are required to protect data only from disclosure. Moreover, it is likely that a panel would find a Member to be inconsistent with TRIPS Article 39.3 unless that Member provided some form of protection against unfair commercial use that differed from protection against disclosure.

This interpretation best satisfies the fundamental purpose of data protection—to provide incentives to bring new drugs and agricultural products to market.

TRIPS Article 39.3 does not specify the length of the period during which a Member must provide protection against unfair commercial use. Given the structure of TRIPS Article 39.3, protection against commercial use must commence when the associated data are submitted and must be provided as long as the use is "unfair."[100] It follows that the use would be

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[96] The Protection of Undisclosed Test Data in Accordance with TRIPs Article 39.3, Office of the General Counsel, U.S. Trade Representative, (1995) (unattributed paper for submission in bilateral discussions with Australia in May 1995).

[97] WATAL, *supra* note 47, at 199.

[98] *Id.* at 200.

[99] *See, e.g.*, WTO Appellate Body Report on United States Section 211, *supra* note 69, at para. 338.

[100] Some TRIPS Articles expressly permit Members to limit the period of protection required by the Agreement, *e.g.*, Article 12 (copyright), Article 18 (trademark protection), Article 26.3 (design protection), Article 33 (patent), and Article 38 (integrated circuit

unfair during the period necessary for the submitter to recover at least the costs of the "considerable efforts." To date, Members that have followed this approach have provided protection for a set period of years that they deem permit the opportunity to recover investments. Typically, the period is five to ten years counted from the date of approval of the product for which the data is associated, depending on the Member and depending on the level of effort.[101]

With respect to the relationship between test and other data related to chemical entities and possible patent protection for those same chemical entities, there is nothing either explicit or implicit in the TRIPS Agreement that requires or allows for any linkage between the term of data protection, on the one hand, and the term of a related patent, on the other. These are two distinct types of intellectual property, covered by distinct sections of the TRIPS Agreement; patents are covered by Section 5 of Part II of the Agreement, while undisclosed information (including test and other data) is covered by Section 7 of Part II. In instances where there is a relationship between the different intellectual property rights sections of the TRIPS Agreement, this relationship is explicitly stated. For example, with respect to the relationship between geographical indications (Section 3) and trademarks (Section 2), various articles of the geographical indications section directly discuss the relationship between these two different types of intellectual property (*i.e.*, Articles 22.3, 23.2, 24.5, and 24.7). There is no such relationship between the patent section (Section 5) and the undisclosed information section (Section 7). They are independent of one another and, consequently, the terms of each type of intellectual property are also independent of one another.

In many cases, the test data will relate to a chemical entity that cannot, for a variety of possible reasons, be patented. For example, the chemical entity may be based on naturally occurring substances and, therefore, be deemed unpatentable. In addition, if an inventor of an otherwise patentable chemical entity does not meet the formal requirements for patentability (including, for example, avoidance of the "on sale" and "public use" bars in the United States), then the chemical entity will not be entitled to patent protection. In all of these instances, it is even more important that incen-

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protection). The drafters, however, did not specify the term length for other types of protection required by the TRIPS Agreement, *e.g.*, geographical indications (Section 3 of Part II) and undisclosed information (Section 7 of Part II). (Article 24.9, however specifically states a condition in which protection for geographical indications is no longer necessary but does not include a specific minimum term.) Thus, if the drafters intended to permit Members to limit the term of protection for geographical indications (other than in Article 24.9) and undisclosed information while the conditions for obtaining protection were met, they would have inserted a provision expressly providing the authority to limit the period of protection.

[101] Submitters cannot recover these costs during the time between the submission of the data and approval to market the product. As a result, that time is not included in the calculation of the period necessary for recovery of costs.

tives be provided for the development of test and other data necessary to bring new drugs and agricultural chemical products to market, as there is no potential to profit from a patent.

Even in instances where there is a related patent, the term of data protection may not be linked to the patent term. Whether or not there was an underlying patent does not determine what term for data protection is necessary to prevent "unfair commercial use." For example, it may be necessary to develop the data required to market a new pharmaceutical drug after the related patent has already expired. Without data protection at that point, the incentive to develop this data, and to bring a new (now-unpatented) drug to market, would severely diminish. This is especially true for a person that works to produce test data and to market a new drug, but who never had rights to the now-expired patent.

It should be noted that TRIPS Article 39.3 only requires that the data be undisclosed as of the date of submission. There is no express condition that the data remain undisclosed after submission in order to maintain protection. Thus, protection against unfair commercial use must still be provided for the period necessary to recover costs even if the data are disclosed to the public. In fact, the second sentence of TRIPS Article 39.3, although unclear, does confirm that unfair commercial use is to be prevented in some cases where the data have been disclosed.

Moreover, if the purpose of TRIPS Article 39.3 is to provide an incentive to develop safety and efficacy data, it would violate that purpose to condition such protection on the continued undisclosed nature of the data. Submitters of data would not know if the protection were to last for days or years, because some intervening event beyond their control could cause the protection to lapse. For example, suppose that a health authority accidentally disclosed test data. The submitter would lose all protection. Similarly, the submitter would lose protection if someone obtained the data legally or illegally, and deliberately disclosed it. In such situations, the submitters would not be able to recover the resources they expended, and would not be able to depend on protection of their data.

IX. *BAYER V. ATTORNEY GENERAL*

Neither the WTO Appellate Body nor a WTO dispute settlement panel has interpreted the phrase "unfair commercial use" as found in TRIPS Article 39.3. Moreover, the authors are not aware of any reported decisions of national courts that interpret TRIPS Article 39.3.[102] The decision by a Ca-

[102] At least one commentator asserts that the statements made by the United States Supreme Court, before the initiation of the Uruguay Round, in *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986 (1984) support the suggestion that reliance on the data of others is not "unfair commercial use." *See* Correa, *Protection of Data, supra* note 80, at 33. In *Ruckelshaus,* the Court decided issues related to the constitutionality of provisions of the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"). The 1978 version of FIFRA provided ten years

nadian trial court in *Bayer Inc. v. Attorney General of Canada,*[103] affirmed by an appellate court,[104] however, interprets a Canadian regulation that implements paragraphs 5 through 7 of NAFTA Article 1711, the more detailed counterpart to TRIPS Article 39.3. As will be discussed, the interpretations of the regulation by the trial and appellate courts are seriously flawed and raise questions about the consistency of Canadian law with paragraph 6 of NAFTA Article 1711 and TRIPS Article 39.3.

A. Background

In general, Canada requires that those who manufacture a "new drug"[105] obtain permission from the Ministry of Health before marketing that drug in Canada. Accordingly, the manufacturer must file a "new drug submission" (NDS)[106] that includes data from pre-clinical and clinical tests to show that the product is safe and effective. If a "new drug," however, is similar to a product that was already approved for marketing in Canada, the

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of data exclusivity and prohibited disclosure of data in applications submitted after October 1, 1978 to obtain marketing approval of pesticides. That version also protected data presented in applications submitted between 1969 and the effective date of the 1978 version. No protection was provided for data submitted before 1969. Monsanto argued that any reliance by competitors on data considered to be trade secrets by Monsanto, or disclosure of that data, was a "taking" of property without compensation which was prohibited by the Fifth Amendment of the United States Constitution. The Court disagreed. To determine whether a law is a "taking" of property and not merely "regulating" the use of property, the Court opined that it must ascertain whether the law interferes with "reasonable investment-backed expectations" of the property owner. After review of the FIFRA provisions governing data submitted after October 1, 1978, the Court found that the statute provided a ten-year data exclusivity period, *after* which Federal officials could rely on the data to approve applications for similar pesticides by competitors. The Court stated that reliance on data *after the ten-year exclusivity period* did not interfere with a reasonable investment-backed expectation of Monsanto because Monsanto knew when it filed its application containing data that those data could be relied upon by a competitor after expiration of the term of protection. Moreover, the Court found that FIFRA outlined when data could and could not be disclosed. Therefore, as Monsanto knew the conditions of disclosure upon application, the Court found that there was no interference with reasonable investment-backed expectations and no taking due to disclosure by the Environment Protection Agency. The Court also reviewed the FIFRA provisions governing data submitted between an earlier revision of the statute in 1972 and October 1, 1978, as well as provisions governing data submitted before 1972. For various reasons, the Court found that those provisions did not lead to a taking under the Fifth Amendment. International obligations were not an issue in *Ruckelshaus*. Consequently, it is inappropriate to interpret the opinion in *Ruckelshaus* to exclude reliance on data from the scope of "unfair commercial use" pursuant to TRIPS Article 39.3.

[103] *Bayer Inc. v. Attorney General of Canada et al.*, 84 C.P.R. (3d) 129, (Fed. Ct., Trial Div. 1998) [hereinafter *Bayer I*].

[104] *Bayer Inc. v. Attorney General of Canada, Apotex Inc. et al., Intervenors*, 87 C.P.R. (3d) 293, (Fed. Ct. of Appeal 1999) [hereinafter *Bayer II*].

[105] Food and Drug Regulations, C.R.C. 1978, ch. 870, sec. C.08.001(c).

[106] C.R.C. 1978, ch. 870, sec. C.08.002.

requirement to submit an NDS is waived, and the manufacturer of the subsequent "new drug" is required to file only an "abbreviated new drug submission" (ANDS) that proves the subsequent product is bioequivalent to the first approved product.[107]

Canada is a Party to the NAFTA, of which paragraph 5 of Article 1711[108] requires protection of certain test and other data against disclosure in the same manner as required by TRIPS Article 39.3. Paragraph 6 of NAFTA Article 1711 requires Parties to prohibit, for a specified period, a person from relying on test and other data submitted by another without authorization of the submitter.[109] As discussed, "reliance" on the data of another is a form of "unfair commercial use" also prohibited by TRIPS Article 39.3. The term "unfair commercial use", however, could encompass acts other than "reliance" such that the scope of protection required by the TRIPS Agreement is broader than that required by NAFTA.

To implement paragraphs 5 and 6 of NAFTA Article 1711, the Canadian Government, in 1995, promulgated chapter 870, section C.08.004.1(1) of the Food and Drug Regulations, which follows:

> C.08.004.1(1) Where a manufacturer files a new drug submission, an abbreviated new drug submission, a supplement to a new drug submission or a supplement to an abbreviated new drug submission for the purpose of establishing the safety and effectiveness of the new drug for which the submission or supplement is filed, and the Minister *examines* any information or material filed with the Minister, in a new drug submission, by the innovator of a drug

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[107] C.R.C. 1978, ch. 870, sec. C.08.002.1.

[108] NAFTA Article 1711.5 states as follows:

> If a Party requires, as a condition for approving the marketing of pharmaceutical or agricultural chemical products that utilize new chemical entities, the submission of undisclosed test or other data necessary to determine whether the use of such products is safe and effective, the Party shall protect against disclosure of the data of persons making such submissions, where the origination of such data involves considerable effort, except where the disclosure is necessary to protect the public or unless steps are taken to ensure that the data is protected against unfair commercial use.

NAFTA, *supra* note 92, at art. 1711.5.

[109] NAFTA Article 1711.6 states as follows:

> Each Party shall provide that for data subject to paragraph 5 that are submitted to the Party after the date of entry into force of this Agreement, no person other than the person that submitted them may, without the latter's permission, rely on such data in support of an application for product approval during a reasonable period of time after their submission. For this purpose, a reasonable period shall normally mean not less than five years from the date on which the Party granted approval to the person that produced the data for approval to market its product, taking account of the nature of the data and the person's efforts and expenditures in producing them. Subject to this provision, there shall be no limitation on any Party to implement abbreviated approval procedures for such products on the basis of bioequivalence and bioavailability studies.

NAFTA, *supra* note 92, at art. 1711.6.

> that contains a chemical or biological substance not previously approved for sale in Canada as a drug, and the Minister, in support of the manufacturer's submission or supplement, *relies* on data contained in the information or material filed by the innovator, the Minister shall not issue a notice of compliance in respect of that submission or supplement earlier than five years after the date of issuance to the innovator of the notice of compliance or approval to market that drug, as the case may be, issued on the basis of the information or material filed by the innovator for that drug.[110]

Thus, to be subject to the five-year right to exclusive use of the safety and efficacy data provided by the Regulation, the Minister must (1) rely on that data in the submission of another and (2) examine that data in connection with the submission of the other.

In the case at issue, Bayer filed a new drug submission requesting a "notice of compliance" (marketing permission) for an unpatented drug X to treat disease X. The NDS included "366 volumes of description, test data and other information, and include[d] the results of clinical tests conducted over 8 years and involving 2,200 patients."[111]

According to an affidavit presented to the trial court, representatives from Bayer met with officials from the Canadian Ministry of Health, and asked if the Minister of Health would deny requests for marketing approval for drug X from competitors within a five-year period after the approval of drug X, as specified in Regulation section C.08.004.1(1).[112] The officials did not "take the view" that the Minister was required to refuse such requests by competitors.[113] Consequently, Bayer posed a series of questions to the trial court, asking the court to interpret Regulation section C.08.004.1(1) and its applicability to requests for marketing approval of the drug X.[114]

B. General Discussion by the Trial Court

The trial court expressed its surprise at Bayer's request for a five-year period of exclusivity for the data submitted in connection with drug X, noting that the purpose of the Regulation was to "ensure that drugs marketed in Canada are safe and effective" and "to produce . . . a more cost effective process for the approval of generic drugs."[115] Such a period of exclusivity, it opined, would run counter to the goal of cost reduction.

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[110] C.R.C. 1978, ch. 870, section C.08.004.1(1) (emphasis added).

[111] *Bayer I*, *supra* note 103, at 133, ¶ 9.

[112] *Id.* at 136, ¶ 18.

[113] *Id.*

[114] *Id.*

[115] *Id.* at 139, ¶ 27.

The court's reasoning is flawed. If these were the only purposes of the Regulation, as the trial court implies, then there would be no reason for Regulation section C.08.004.1 to ever create a right to the exclusive use of the data. Therefore, the court must have ignored at least one additional purpose for the Regulation. That purpose, of course, is the promotion of the introduction of new and more effective drugs in the Canadian market. The failure of the trial court to recognize this purpose and its preoccupation with lowering costs resulted in the misinterpretation of the Regulation and the NAFTA.

In addition, the trial court was surprised at Bayer's request because it reasoned that the suggested five-year period of exclusive use of data would be a right "normally conferred with respect to products that are protected by a patent."[116] This statement is predicated on a misunderstanding, one shared by the appellate court.[117] It is well-established that products are often protected through a combination of both patents and protection from unfair competition in the form of misappropriation of trade secrets such as know-how or associated data. It is also well-established that enterprises commonly license these rights together.

Moreover, some products are not protected by patents but are effectively protected only through unfair competition, *e.g.*, the formula for Coca Cola®. Thus, a "patents-only" regime is not a normal situation as suggested by the trial court. Products normally would be subject to protection from misappropriation of the associated know-how and data, whether or not they are protected by patents.

Beyond the example of patents and unfair competition protection, it is common for several types of intellectual property to protect aspects of a single product. For example, some designs are subject to protection under both the copyright and industrial design laws.[118] Food and agricultural products can be protected using geographical indications and trademarks.[119] The TRIPS Agreement and the NAFTA generally require protection to be granted for each type of intellectual property right if the specified criteria are fulfilled.[120] Thus, Members and Parties must allow the right holders to simultaneously protect products using, for example, the copyright and industrial design laws, or geographical indications and trademarks, if the criteria in the Agreements for obtaining protection are met and there is no conflict among the various intellectual property rights, as defined by the TRIPS Agreement or the NAFTA. Similarly, right holders must be able to

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[116] *Id.*

[117] *Bayer II*, *supra* note 104, at 299, ¶¶ 16 - 17.

[118] *E.g.*, lamps with designs on the bases.

[119] For example, in France, some sparkling white wines are protected by the use of a geographical indication "champagne" as well as house marks such as Moet et Chandon®, Veuve Clicquot®, *etc.*

[120] *See* TRIPS Agreement, *supra* note 11, at pt. II; NAFTA, *supra* note 92, at ch. 17.

acquire and enjoy patent protection as well as protection for undisclosed data related to a single product. Again, the *normal* situation allows for the coexistence of two or more types of rights in the same product, not the preference of patents over another type of right.

It should be noted that the European Community[121], Japan[122], and the United States[123] all protect pharmaceutical products in the manner that was requested by Bayer and rejected by the Canadian courts. That is, they provide for the exclusive use of data for a fixed period of time of at least five years, and they maintain that that such protection is required by the TRIPS Agreement. In addition, the European Community, Japan, and the United States provide for "market exclusivity" for orphan drug products[124]—stronger protection than the right to exclusive use of the data.[125] Both the right to exclusive use of the data and market exclusivity are available even if the qualifying products are also subject to protection under patents. The possibility for coexistence of the rights to exclusive use of pharmaceutical data, on the one hand, and patent rights, on the other, in what collectively represents the vast majority of the worldwide market for pharmaceutical products dispels any representations that exclusive use of data is not *normal* in light of the availability of patents.

C. Question of Reliance

The trial court was asked to determine if the issuance of a marketing approval based on an abbreviated new drug application for drug X would constitute "reliance" on data submitted by the innovator, as the term is used in Regulation section C.08.0004.1. Bayer argued that the only information available to the Minister about the safety and efficacy of drug X was provided by Bayer. Therefore, any approval of a drug X without independently generated data would be based on or "rely upon" data submitted by Bayer. The Attorney General responded that the Minister of Health reviews only the information in the abbreviated new drug application and does not "refer to the material previously filed by the innovator."[126]

The trial court essentially found that the Minister would have to rely "indirectly" on the data submitted by the innovator to approve an abbrevi-

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[121] Council Directive 87/21/EEC *supra* note 34, at art. 1.

[122] Japanese Pharmaceutical Affairs Law, Article 18-3.

[123] *See supra* notes 28 & 29 and accompanying text.

[124] *See supra* notes 28, 34 & 37. In Japan, protection for orphan drugs is required by the Notice of the Director General of the Pharmaceutical Affairs Bureau (1985) and the Orphan Drug Regulation (1993) according to a study conducted for the European Parliament, *available at* http://www.europarl.eu.int/stoa/publi/167780/default_en.htm (last visited Oct. 19, 2003).

[125] "Market exclusivity" prevents another from obtaining marketing approval based on independently generated data, while the "right to exclusive use of the data" does not.

[126] *Bayer I,* supra note 103, at 141, ¶ 32.

ated new drug application.[127] Nevertheless, the trial court refused to interpret the Regulation to apply to indirect reliance on the data of the innovator and, consequently, refused to invoke the period for exclusive use of the data submitted by Bayer to obtain approval of drug X. In the opinion of the trial court, such an interpretation would broaden the meaning of the term "relies" and would be inconsistent with the intended purpose of the regulatory scheme.[128] In short, the trial court interpreted the word "rely" to mean physically "review" or "examine." This view was expressly affirmed by the appellate court.[129]

The reasoning of the trial and appellate courts was flawed in several important ways. First, the word "rely" in this context in the English language means "depend *on* or *upon* with full trust or confidence; be dependent *on*."[130] Reliance does not mean "review" or "examination." But for the fact that Bayer provided sufficient data to obtain marketing approval for drug X, an abbreviated new drug application could not be approved. Therefore, the Minister directly "depends" or "relies" on Bayer's data. There is no "indirect" dependence or reliance.

Second, given the lack of adverbs, the plain or literal reading of the Regulation is that any reliance, whether direct, indirect, tacit, express, *etc.*, would trigger the creation of a right to the exclusive use of the data. Read literally, the Regulation includes the concept of "indirect" reliance, and the trial and appellate courts essentially removed it from the literal meaning of the Regulation.

Third, the only justification for removing the concept of indirect reliance would be that it was inconsistent with the overall regulatory scheme. The trial court attempted to justify the removal on this ground, but failed. The court again noted that the purpose of the Regulation is to reduce the cost of drugs. Therefore, it claimed that providing the right to the exclusive use of the data would add costs and run counter to the regulatory intent. The trial court failed to appreciate, however, that one of the key purposes of the Regulation is to encourage the testing and entry of new drugs into the market. Indeed, the right to the exclusive use of data is consistent with one of the purposes of the Regulation, and the concept of indirect reliance is consistent with the overall regulatory scheme. It cannot be eliminated from the Regulation.

The trial court cited an example from the Regulatory Impact Analysis Statement[131] indicating that the right to the exclusive use of data may extend beyond the patent term and, thus, the products of the innovator could

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[127] *Id.* at 141 - 42, ¶¶ 33 & 37.

[128] *Id.* at 141 - 42, ¶¶ 34-37.

[129] *Bayer II, supra* note 104, at 296 - 298, ¶¶ 7-14.

[130] OXFORD DICTIONARY, *supra* note 71, at vol. II 2539.

[131] C. Gaz., Part II, vol. 129, No. 18, 2497-2502 (1995).

be protected for a period longer than patent protection.[132] From this example, the trial court inferred that the regulatory intent is limited to providing the right to the exclusive use of the data to innovators who have patents on the regulated product.[133] While the example is correct, the inference from the trial court is not. The situation described in the Statement is merely an "example" of the effects of the protection required by the Regulation. It is not a definition of the right to exclusive use of the data or the exclusive application of the right. Thus, the application of Regulation section C.08.004.1 certainly should not be limited to data associated with patented products based simply on this example.

The appellate court also refers to the Regulatory Impact Analysis Statement to support its interpretation.[134] Specifically, the Statement explains that if the Minister finds the submission from a second entry manufacturer to be insufficient to demonstrate safety and efficacy of the product, the Minister will notify the second entry manufacturer.[135] It further states that if that manufacturer supplies additional data, the Minister may grant marketing approval immediately; if not, the Minister will "rely" on the data of the innovator and will delay approval of the product for five years.[136] The appellate court inferred that this portion of the Statement is intended to clarify that the Minister has the discretion to directly examine data in relation to an abbreviated new drug submission, and that absent such examination, there would be no reliance.[137]

It appears, though, that this part of the Statement was intended to ensure that those second entrants who did *not* file abbreviated new drug submissions would have the opportunity to provide additional safety and efficacy data to prevent implementation of the 5-year period of exclusive marketing rights for the innovator's drug.[138] Those entrants filing abbreviated new drug submissions would never provide information about the

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[132] *Bayer I, supra* note 103, at 141 - 42, ¶ 36 - 37.

[133] *Id.* at 142, ¶ 36.

[134] *Bayer II, supra* note 104, at 296 - 97, ¶ 10 - 11.

[135] *Id.* at 296 - 97, ¶ 10.

[136] *Id.*

[137] *Id.* at 297, ¶ 11.

[138] When reviewed in its entirety, the authors did not find the Regulatory Impact Analysis to shed light on interpretation of the Regulation. Many statements, including those cited by the courts, give rise to various conflicting interpretations. Also, the Statement introduces the concept of "collateral use" – a concept not found in the Regulations and not defined in the Statement – to describe the contents of the Regulations. This merely confuses rather than clarifies the intent of the drafters. Finally, we note the sentence "This alternative, to establish regulatory requirements specific to second-entry drugs, is consistent with practices in the United States, Europe and many other developed countries" (p. 2498). Clearly, the interpretations of the Regulations by the courts in *Bayer* are not consistent with practice in the United States and Europe that preclude reliance and examination during a fixed period of time.

safety and efficacy of the product, but instead provide only bioequivalency and bioavailability data; consequently, there would be little point in examining the innovator's submission. Thus, it does not appear that this part of the Statement applies to applicants who filed abbreviated new drug submissions. Instead, such applicants automatically elect to receive the five-year waiting period for marketing approval in lieu of submission of safety and efficacy data.

Again, the trial and appellate courts failed to appreciate that one of the purposes of the Regulation is to encourage the testing and marketing of new and more effective pharmaceutical products. If the inferences of the trial court were correct, only innovators holding patents would receive the benefits of the right to exclusive use of the data—a group that already has some incentives to test and market new products. By contrast, benefits of the Regulation would be denied to those who have no patent incentives, such as those wishing to market products based on naturally occurring materials. Ironically, these are the groups of products with the greatest need for the incentives associated with data protection to provide the public with new and more effective pharmaceutical products. This simply is not a logical result, and is certainly not required by the test set forth in the Canadian Regulation.

In summary, the trial court erred in finding that approval of an abbreviated new drug submission would not constitute reliance on the data submitted by Bayer in its new drug application for the drug X.

D. "Examination of the Data" and Relationship to the NAFTA Obligations

The finding that approval of an abbreviated new drug submissions for drug X did not constitute "reliance" for purposes of Regulation section C.08.004.1(1) disposed of the action because one of the two requirements was not fulfilled. Nevertheless, the trial court analyzed the other requirement of the Regulation to determine if the review of an abbreviated new drug submission required "examination" of the data contained in Bayer's new drug submission.[139] In fact, it appears that officials rarely obtain and review copies of previous submissions of data from an innovator when evaluating abbreviated new drug submissions.[140]

Counsel for Bayer presented the trial court with several theories to explain why the term "examination" should not be interpreted literally. Specifically, Bayer argued that the Regulation was intended to implement paragraph 6 of NAFTA Article 1711, which did not permit Parties to condition the right to exclusive use of test data on the examination of that data, as literally required in the Regulation.[141] Therefore, Bayer suggested that the

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[139] *Bayer I, supra* note 103, at 142, ¶¶ 39 *et seq.*
[140] *Id.* at 142, ¶¶ 40.
[141] *Id.* at 144, ¶ 44.

term "examination" in the Regulation must be interpreted in a manner that is consistent with the NAFTA provision, such that the examination requirement could not be interpreted beyond the requirement for reliance.[142]

Counsel for the Minister responded that the Regulation was not ambiguous and that, consequently, it was inappropriate to consider interpretations other than the literal or plain meaning of the provision.[143] The trial court properly rejected the notion that it could not consider international obligations in interpreting the terms of the Regulation.[144] The trial court, however, erroneously interpreted paragraph 6 of NAFTA Article 1711 to permit Parties to condition the right to the exclusive use of test data on examination of that data.

Specifically, the trial court found that paragraph 6 of NAFTA Article 1711 did not apply to situations in which officials review abbreviated new drug submissions, reasoning that Canadian officials do not "rely" on the data of the innovator because they do not review that data.[145] The appellate court agreed.[146] The courts found that Canadian officials "relied" only on the bioequivalency and bioavailability studies provided in abbreviated new drug submissions, and not on the data submitted by the innovator.

The last sentence of paragraph 6 of NAFTA Article 1711, however, provides "[s]ubject to this provision, there shall be no limitation on any Party to implement abbreviated approval procedures for such products on the basis of bioequivalence and bioavailability studies." This means that there are no limitations *except* for those in paragraph 6. This sentence, and the phrase "[s]ubject to this provision," would not be necessary *unless* paragraph 6 actually did impose a limitation on the use of abbreviated approval procedures that require only bioequivalence and bioavailability studies. Thus, approval of such abbreviated applications must constitute "reliance" for purposes of NAFTA Article 1711.

Based on the last sentence of paragraph 6 of NAFTA Article 1711, the Counsel for the Minister stated that the drafters of Article 1711 did not intend to create a system that would impose a five-year delay in approving abbreviated new drug submissions.[147] Curiously, the trial court noted this sentence as significant but dismissed it stating "new drugs are being developed all the time, and 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."[148] While these

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[142] *Id.*

[143] *Id.* at 144, ¶ 45.

[144] *Id.* at 145, ¶ 47.

[145] *Id.* at 147, ¶ 55.

[146] *Bayer II, supra* note 104, at 297-98, ¶ 14-15.

[147] *Bayer I, supra* note 103, at 144, ¶ 46.

[148] *Id.* at 147, ¶ 57. This statement is internally inconsistent. If there were a new product to treat a symptom or disease introduced into the market every five years, then there would

statements make it clear that the trial court and the Counsel for the Minister were uncomfortable with an interpretation of paragraph 6 that provides exclusivity for data, it is unclear what, if any, relevance this has to a proper interpretation of an international agreement.

As mentioned *supra*, WTO dispute settlement panels and the Appellate Body interpret treaties pursuant to Article 31 of the Vienna Convention,[149] and often use dictionary definitions to determine the ordinary meaning of a provision.[150] NAFTA arbitral panels established pursuant to Chapter 20 of NAFTA also interpret treaties pursuant to the Vienna Convention.[151] Thus, they would find that "rely" means "depend on"[152]—not "review" as proposed by the courts. Indeed, review of abbreviated new drug submissions depends on the data of the innovator, even if officials do not review the data. Consequently, to approve an abbreviated new drug submission, officials necessarily "rely" on the data of the innovator in a new drug submission. The contrary interpretation of the trial court is incorrect.

The trial court also mistakenly opined that paragraph 6 of NAFTA Article 1711 precludes reliance on data only when a Party fails to protect the data under paragraph 5 of that article.[153] There is nothing in paragraph 6 to suggest that the requirement to prevent reliance is conditional. A plain reading of paragraph 5 suggests that the requirement to protect the *confidentiality* of data is waived or "condition[ed]" under two circumstances, one of which is the protection against "unfair commercial use." The use of different terms, "unfair commercial use" and "reliance", also suggests that paragraph 6 is not conditioned on the earlier paragraph.

The trial court stated that its conclusion is consistent with the requirement in paragraph 1 of NAFTA Article 1711 to provide persons with the ability to protect against the misappropriation of trade secrets.[154] Apparently, the trial court failed to appreciate the fact that, unless expressly linked, the paragraphs in a particular NAFTA article are related only so far

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be perhaps four or six products to treat every symptom or disease, albeit some more effective than others. The enterprise marketing the latest drug would have to price that drug in relation to the other drugs on the market. The cost differential would be limited to the difference in benefits between the new product and the older products. If the price exceeded the value of the benefits, consumers would not use the new product. Thus, enterprises would not be able to engage in "monopoly" pricing, and there would be no *de facto* monopoly. In reality, most products in the pharmacopoeia of any market are off-patent and off-data protection. Thus, they compete freely with products covered by patents or data protection.

[149] *See supra* Part VII(A).

[150] *See id.*

[151] *See, e.g., In the Matter of Cross-Border Trucking Services*, No. USA-MEX-98-2008-01, Final Panel Report, ¶ 220 - 222 (Feb. 6, 2001); *In the Matter of Tariffs Applied by Canada to Certain United States Origin Agricultural Products*, CDA 95-2008-01, Final Panel Report, ¶ 119-121 (Dec. 2, 1996).

[152] *See* OXFORD DICTIONARY, *supra* note 71.

[153] *Bayer I, supra* note 103, at 146, ¶ 54.

[154] *Id.*

as they are linked by the title of the article, or by creating general context for each other. For example, paragraph 1 of NAFTA Article 1705 clarifies that computer programs and certain compilations are literary works. In contrast, paragraph 5 of that Article relates to reproduction and translation rights. Similarly, as there is no language to expressly link paragraphs 1 and 6 of NAFTA Article 1711, the requirements are not linked except that they both generally relate to undisclosed information. Paragraph 6 is a completely separate requirement from paragraph 1.

It should also be noted that like TRIPS Article 39.3, paragraphs 5 and 6 of NAFTA Article 1711 place the obligation to protect test data directly on the Parties. As explained in connection with TRIPS Article 39.3, those paragraphs do not merely require Parties to provide persons with a right to protect their data.

Thus, the Canadian courts used flawed logic in analyzing the relationship between the Regulation and NAFTA Article 1711. It appears that the trial court essentially decided that NAFTA Article 1711 deals only with "reliance"—narrowly and incorrectly defined by the court to mean examination or review—instead of mere "dependence," as properly defined by the dictionary. The court found that since Canadian practice does not involve reliance, the NAFTA Article does not apply. This conclusion is, of course, erroneous given the flawed interpretation of the word "rely." In addition, it begs the real question. Paragraph 6 of NAFTA Article 1711 requires protection against "reliance," however defined. Moreover, that requirement is "inclusive," which means that a Party cannot impose additional requirements. Section C.08.004.1(1) of the Canadian Regulation purports to fulfill the obligations of paragraph 6, but adds the "examination" requirement. Regardless of the interpretation of the term "rely" vis-à-vis Bayer's situation, the Regulation appears to be inconsistent with paragraph 6 of NAFTA Article 1711.

E. Consistency with International Obligations

The Regulation, as interpreted by the *Bayer* courts, is inconsistent with the obligations of Canada under both the NAFTA and the TRIPS Agreement. It appears that pursuant to section C.08.004.01 of the Canadian Regulation, as interpreted by the *Bayer* decisions, the Minister is permitted to "rely" on the innovator's data, as the term is used in paragraph 6 of NAFTA Article 1711, without providing the right to exclusive use of the data required by that paragraph. In addition, it appears that the Regulation conditions the right to exclusive use of the data on the "examination" of the data, a condition that is not authorized by paragraph 6.

"Reliance" on test data, as the term is used in paragraph 6, is an "unfair commercial use" under TRIPS Article 39.3, as discussed earlier. Again, Regulation section C.08.004.1, as interpreted by the *Bayer* decisions, does not provide protection against such reliance.

X. PROTECTION AGAINST DISCLOSURE

In addition to the requirement that test data be protected against unfair commercial use, TRIPS Article 39.3 requires that Members prevent the disclosure of certain test data. As with protection against unfair commercial use, Members are required to protect against disclosure of test and other data as of the date that the data are submitted. No express term of protection is provided in the TRIPS Agreement. Therefore, protection against disclosure must be provided as long as the data remain "undisclosed."[155]

This requirement to protect data is subject to two exceptions: "where necessary to protect the public" or when "steps are taken to ensure that the data are protect[ed] against unfair commercial use." As for the first exception, there appear to be few instances where disclosure of such data would aid the public. As a preliminary matter, public discourse about this issue reveals that there is much confusion about the nature of the data submitted to obtain approval, its public availability, and the possible benefits of making the data public. The description by the court in the *Bayer* case of the over 300 volumes full of data, including raw data and summaries, provides an example of the large quantities of raw data that are sometimes involved.[156] By contrast, some countries do not require the physical submission of all of the data, but instead require summaries based on the raw data.

The test data are intended for use by health authorities in determining the safety and efficacy of pharmaceutical products. As such, these data appear to have little, if any, "scientific" value, as there is no evidence that they would assist researchers in improving existing pharmaceutical products. In fact, there appear to be only two uses of the data other than by the health officials.

First, competitors who wish to market a similar product could use the data to avoid generating their own safety and efficacy data, and would, thereby, achieve a commercial benefit from accessing the data. As noted earlier, countries are permitted under TRIPS Article 39.3 to allow others to rely on the data, but only after a period of time that allows an originator of data to recoup its investment in developing the data. This approach appears to balance the needs of innovators and competitors.

The second use of the test data would be to enable members of the public to review the data and "second guess" the decisions of health authorities. It is questionable whether most members of the public have the expertise to review the data, and there appears to be very little to be gained from encouraging them to do so.

Consequently, there are few, if any, public benefits to the disclosure of the test and other data submitted to health authorities.

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[155] *See supra* Part XIII(A).

[156] *Bayer I, supra* note 103 at 133, ¶ 9.

The meaning of the second exception to the requirement of Article 39.3 to prevent disclosure is unclear. The introductory phrase—"In addition"—indicates that the requirement to prevent disclosure is cumulative, and implies that both protection from unfair commercial use and protection from disclosure are required. Yet, the second exception appears to permit disclosure if protection against unfair commercial use is provided. Thus, in order to read the second exception in a manner that gives meaning to the disclosure prohibition, it must be interpreted as requiring a heightened level of protection against unfair competition before disclosure is permitted, relative to the level required by the first sentence of Article 39.3. In fact, instead of simply stating that a Member "shall protect such data against unfair commercial use," as does the first sentence, the second sentence requires that "steps are taken to *ensure* that the data are protected against unfair commercial use"(emphasis added). Interpreting this provision pursuant to Vienna Article 31, one finds that the word "ensure" means "guarantee, warrant," "secure, make safe, (*against, from*, a risk, *etc.*)," "make certain the occurrence of (an event, situation, outcome, etc.)," and "secure (a thing for or to a person)."[157] While it is unclear what "steps" must be taken to create this heightened level of protection where a submitter is guaranteed or warranted that unfair commercial use will not result, it seems that a government must implement additional regulations to benefit the originator of the data that would not be necessary if the data were not disclosed. Perhaps this would take the form of a much longer period of market or data exclusivity for the originator if the data are disclosed.

XI. NATIONAL LAWS

It is outside the scope of this article to detail the specific manner in which all WTO Members have implemented, or failed to implement, their obligations under TRIPS Article 39.3. Nevertheless, it is important to note that many countries have integrated data protection measures into their national laws, to the point where it appears that there is a trend towards incorporation of specific measures to protect test and other data. Whether or not these countries actually implemented these measures in a TRIPS-consistent manner is another question that is far more difficult to answer. For example, Part IX of this article discusses the way in which Canadian courts have failed to implement Canada's data protection obligations pursuant to the TRIPS Agreement and NAFTA, despite having adopted a relevant regulation. The following discussion provides examples of countries that enacted legislation, implemented regulations, or entered into other international agreements requiring protection of test and other data, but is not meant to be an exhaustive list of such countries.

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[157] OXFORD DICTIONARY, *supra* note 71, at vol. I 827.

As detailed *supra*, U.S. law had already provided for protection of test and other data associated with pharmaceutical products prior to the date of application of TRIPS Article 39.3 with respect to developed countries.[158] Similarly, the fifteen Member States of the European Communities were also required to provide for such protection in their national laws at that time by the *acquis communitaire*.[159] Since then, a significant number of countries have adopted national or regional regimes to protect test and other data from unfair commercial use and disclosure, or have entered into additional international agreements requiring such protection.

The International Federation of Pharmaceutical Manufacturers Association ("IFPMA") reports that the following countries have adopted specific legislation or entered into agreements containing specific obligations: Australia, Brazil, Bulgaria, Canada, China, Costa Rica, Czech Republic, Egypt, Estonia, Finland, Guatemala, Hungary, Iceland, Jordan, Korea, Latvia, Mexico, New Zealand, Norway, Panama, Poland, Romania, Singapore, Slovak Republic, Slovenia, and Switzerland.[160] IFPMA also noted that Andean Community Decision 486—effective in Bolivia, Colombia, Ecuador, Peru, and Venezuela—repeated the obligations of TRIPS Article 39.3 and expressly authorized Community Members to adopt national legislation to protect test and other data.[161] Moreover, IFPMA reported that Colombia and Venezuela entered into other international agreements requiring additional protection.[162] It should also be noted that Ecuador, a Member of the Andean Community, entered into a bilateral agreement with the United States that also mandates data protection.[163]

Certain countries, which have not been listed by IFPMA as having enacted specific national legislation to implement TRIPS Article 39.3, entered into other international agreements requiring data protection. For example,

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[158] *See* Pub. L. 97-414, *supra* note 27, and accompanying text; *see* Pub. L. 98-417, *supra* note 29, and accompanying text.

[159] *See* Council Directive 87/21/EEC 1987 O.J. (L 15), *supra* note 34, and accompanying text.

[160] *A Review of Existing Data Exclusivity Legislation in Selected Countries*, International Federation of Pharmaceutical Manufacturers Associations, Revised Version, 2002, up-dated May 14, 2003, *available at* http://www.ifpma.org. Note that Hong Kong was also listed, but is technically not a separate country.

[161] *Id.* at 18-20. Unlike the other countries of the Andean Community, Colombia has adopted an internal domestic measure in addition to the Community Decision. *Id.* at 7.

[162] Treaty of Group of Three (Colombia, Mexico and Venezuela). *Id.*

[163] Agreement Between the Government of the United States of America and the Government of Ecuador Concerning the Protection and Enforcement of Intellectual Property Rights, Oct. 15, 1993, art. 8, U.S.-Ecuador, TIAS 12679 (amended on July 28, 1995, TIAS 12679). (Note that in contrast to *Treaties in Force* published by the Department of State, the database maintained by the Department of Commerce states that this Agreement is not in force).

the United States has entered into bilateral agreements[164] requiring data protection with Albania,[165] Cambodia,[166] Mongolia,[167] Sri Lanka,[168] Vietnam,[169] and most recently Chile.[170] Lithuania[171] has also entered into a Europe Agreement that requires Lithuania to provide data protection. Cyprus and Malta, upon accession to the European Union on January 1, 2004, will have to comply with the *acquis communitaire* with respect to protection of test and other data.

XII. CONCLUSION

The negotiators of Article 39.3 of the TRIPS Agreement recognized the long-term benefits to the health and welfare of the citizens of all WTO Members that would result from proper data protection enforced by governments around the world. Such benefits naturally flow from the incentives that data protection provides for marketing new pharmaceutical and agricultural chemical products. For example, the data protection and marketing exclusivity created by the Orphan Drug Act in the United States has led to a dramatic growth in the number of orphan drugs available in the marketplace.

Developed and developing countries alike also recognize the potential short term costs that may result from data protection as a consequence of less competition and higher prices for certain drugs during specified periods

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[164] Copies of these Agreements are available at http://www.tcc.mac.doc.gov/ (link to *Trade Agreements*) (last visited Oct. 19, 2003) except for the Agreements with Vietnam and Chile. Agreement Between the United States of America and the Socialist Republic of Vietnam on Trade Relations, *available at* http://www.ustr.gov/regions/asia-pacific/text.pdf (last visited Oct. 19, 2003); Chile-United States Free Trade Agreement, *available at* http://www.ustr.gov/new/fta/Chile/final/index.htm (last visited Oct. 19, 2003).

[165] Agreement on Trade Relations between the Republic of Albania and the United States of America, May 14, 1992, U.S.-Albania, art. IX, subparas. 2(e)(iv)(1) & (2), TIAS 12454.

[166] Agreement between the United States of America and the Kingdom Of Cambodia on Trade Relations and Intellectual Property Rights Protection, Oct. 4, 1996, U.S.-Cambodia, art. XIX, para. 5.

[167] Agreement on Trade Relations Between the Government of the United States of America and the Government of the Mongolian People's Republic, Jan. 23, 1991, U.S.-Mongolia, art. IX, subpara. 2(f)(iv).

[168] Agreement on the Protection and Enforcement of Intellectual Property Rights Between the United States of America and the Democratic Socialist Republic of Sri Lanka, Sep. 20, 1991, U.S.-Sri Lanka, subpara. 2(e)(iv), TIAS 12436.

[169] Agreement Between the United States of America and the Socialist Republic of Vietnam on Trade Relations, July 13, 2000, U.S.-Vietnam, ch. 2, art. 9, paras. 5, 6.

[170] Chile-United States Free Trade Agreement, June 6, 2003, U.S.-Chile, art. 17.10(1) (As of this writing, it had not yet entered into force).

[171] Europe Agreement Establishing an Association between the European Economic Communities and their Member States, of the one Part, and the Republic of Lithuania, of the other Part, Feb. 20, 1998, art. 67(2) 1998 O.J. (L 051) 3, and associated Joint Declaration.

of protection. In agreeing to TRIPS Article 39.3, however, they demonstrated an understanding that the long-term benefits of data protection, in the form of greater availability of new products, far exceed these short-term costs. It is this calculation of net benefit, also reflected by NAFTA Article 1711.5, that the Canadian courts in *Bayer*, focusing exclusively on short-term costs, completely overlooked.

As detailed in Part IV of this article, data protection may, in some instances, be even more important in developing countries than in developed countries. For example, when diseases harm many people from developing countries with weak markets, but affect few, if any, people in developed countries, it will take the combined market power of all of these developing countries, including data protection by all of the governments of these countries, to encourage development and testing of new drugs. Therefore, it is especially important that developing countries, the citizens of which suffer from common maladies, all have policies that protect test data and encourage investment in other ways.

In this article, we have carefully analyzed the text of TRIPS Article 39.3 pursuant to the Vienna Convention in the same manner as would a WTO dispute settlement panel or the Appellate Body. Such analysis of the ordinary meaning of the terms in proper context leads to an understanding that Article 39.3 provides protection against the unjust or unfair application or conversion of certain test and other data to make a profit or to obtain a benefit. The protected data in a Member need not be related to a "novel" chemical entity, in the patent sense, but only to the application for marketing approval of any chemical entity that has not yet been subject to approval in that Member. The data must be protected regardless of the entity, or other government, to which a Member requires a data originator to submit its information. This protection must be provided at least as long as the use of such data would be unfair, allowing the originator of data to recoup at least the costs of data production. Reliance on the data, either directly or indirectly, before the originator's investment in data production was recouped would violate a Member's obligations under TRIPS Article 39.3. As demonstrated in Part IX, the interpretation by the Canadian court to the contrary, with respect to NAFTA Article 1711.5, was fundamentally flawed. Moreover, governments are prohibited from disclosing the data, except under very limited circumstances. This interpretation of TRIPS Article 39.3 is confirmed by the negotiating history, and in particular the manner in which the proposals of the United States, European Community, and Switzerland were combined in the Chairman's Text and Dunkel Text to create the current text of TRIPS Article 39.3.

Of course, the ordinary meaning of TRIPS Article 39.3 is not as clear as it might otherwise be, and the ambiguity is a consequence of difficult negotiations among very different countries. Nevertheless, when interpreting TRIPS Article 39.3, it is critical to keep in mind the fundamental purpose of data protection as a means to the end of creating a public good in the form

of new medications and other chemicals that will improve the health and standard of living of mankind.