

**PROTECTION OF DATA SUBMITTED FOR THE  
REGISTRATION OF PHARMACEUTICALS:  
IMPLEMENTING THE STANDARDS OF THE TRIPS  
AGREEMENT**

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## FOREWORD

The South Centre published in October 2000 a study by Carlos Correa entitled *Integrating Public Health Concerns into Patent Legislation in Developing Countries*. Second edition of the study was issued in September 2001, and the French and Spanish translations were published, also in 2001. The study, which was prepared with the collaboration of the World Health Organization, has been given wide circulation in the developing countries and has been found very useful by them in dealing with public health and patent legislation in the context of TRIPS implementation.

The current study by Carlos Correa entitled *Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the TRIPS Agreement* is continuation of the same work, focusing in depth on the specific issue of marketing approval protection under the TRIPS Agreement and its interpretation, an issue of major practical importance for the developing countries. The World Health Organization has agreed to co-publish this study.

As the earlier study, the current study was produced with the support of the Rockefeller Foundation. The author benefited from an extensive discussion on data protection issues with Prof. Jerome Reichman, whose valuable inputs the author wishes to acknowledge. The author also wishes to acknowledge the support from WHO, which organized a consultation meeting in New York, on 22 October, 2001 to review the draft of the study, at which participated Alfred Engelberg, Trevor Cook, Jim Keon, James Love, Jerome Reichman, Robert Weissman and German Velasquez. The author is thankful for the comments received during this meeting. He is also grateful for the comments by Octavio Espinosa (WIPO), in his personal capacity, Adrian Otten (WTO) and Jayashree Watal (WTO). The text was edited by Robert Weissman.

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## **EXECUTIVE SUMMARY**

1. As a condition for registering pharmaceutical products, national authorities normally require registrants to submit data relating to drugs' quality, safety and efficacy ("test data"), as well as information on the composition and physical and chemical characteristics of the product. A particularly important issue is the direct or indirect use of the data for subsequent registration of products similar to those originally registered.
2. The World Trade Organization's Trade Related Aspects of Intellectual Property Agreement (TRIPS), Article 39.3, requires member countries to establish protections for submitted test data. But this requirement is in fact narrowly drawn, and countries maintain substantial flexibility in implementation. The public interest in limiting protections for data is to promote competition, and to ensure that data protections do not become the means to block the timely entrance of generic competitors to off-patent drugs. Generic competitors drive down price, thereby promoting greater accessibility of medicines.
3. Article 39.3 requires governments to provide protection to marketing approval data only under certain conditions. Test data must be protected if national authorities require its submission. Article 39.3 does not require protection be given to already public data. Protection is required only for new chemical entities. Members have considerable discretion in defining "new," and may exclude applications for second indications, formulations and dosage forms. And, prior to granting protection, national regulatory authorities may request the applicant to prove that the information for which protection is sought is the result of significant investment.
4. Article 39.3 requires countries to protect against "unfair commercial use" of marketing approval data. Countries have con-

siderable discretion to define “unfair” in the context of their own national laws and culture. Use by the government to assess the efficacy and toxicity of a pharmaceutical or agrochemical product is not a commercial use subject to Article 39.3. Granting marketing approval to a second entrant, based on the second product’s similarity to a previously approved first product, is not a proscribed “use” under Article 39.3. These interpretations are supported by United States and Canadian Supreme Court decisions interpreting national laws.

5. Countries can meet their obligations to protect against “unfair commercial use” under Article 39.3 by barring “dishonest” uses of test data. This would require, for example, proscribing situations in which a competitor obtains the results of testing data through fraud, breach of confidence or other “dishonest” practices, and *uses* them to submit an application for marketing approval for its own benefit. It would also apply in cases where the government provides access to undisclosed testing data in order to provide an advantage to a firm which did not produce them or share their cost.
6. Countries are not obligated under Article 39.3 to confer exclusive rights on the originator of marketing approval data.
7. The pharmaceutical industry and some countries have argued for much broader coverage of Article 39.3, and for a requirement that countries confer exclusive rights on originators of marketing approval data. But these positions are not well grounded in either the text or negotiating history of TRIPS. TRIPS negotiators specifically considered and rejected language requiring grants of exclusive rights to test data.

## INTRODUCTION

As a condition for registering pharmaceutical products, national authorities normally require registrants to submit data relating to a drug's quality, safety and efficacy as well as to its physical and chemical characteristics. A particularly important issue is third parties' use of the data for subsequent registration of products similar to those originally registered.

In some jurisdictions, the data submitted for the registration of pharmaceutical (and agrochemical products), are subject to a *sui generis* system of protection, based on a temporary right to the exclusive use of such data by the first applicant (generally the company that developed a new product). In such a system, other companies (often "generics" manufacturers) cannot rely on the data submitted by the first applicant for the purpose of registering a similar product for commercial use. The rationale for this exclusivity model is to permit the originator of data to recover the investments made for their development. The underlying assumption is that, without such protection, private firms would have no incentive to bear the considerable costs of producing the required data.

In other countries, however, health authorities are permitted to rely on data submitted by the first applicant to process and approve third parties' subsequent applications for a similar product,<sup>1</sup> subject to evidence that its physico-chemical attributes are equivalent to those of the first applicant's product. This approach emphasizes that the registration of products should not erect barriers to otherwise legitimate competition. It holds, instead, that the registration system should promote price competition and access to more affordable medicines.

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<sup>1</sup> In some cases, national authorities are allowed to rely on the registration made in a foreign country to approve subsequent applications.

The issue of data protection is especially relevant for off-patent products as well as for products, such as biologicals, that are often difficult to patent. In cases where the product is patented, the patent holder can, in principle, exclude *any* competition during the lifetime of the patent -- a period of exclusion which will generally run longer than that afforded by data protections. Data protection rules are of particular importance to many developing countries that until recently did not provide patent protection for pharmaceuticals (and to those under the transitional periods of the WTO's TRIPS Agreement, which still do not provide pharmaceutical patent protection). In these countries, there is a large pool of unpatented pharmaceutical products. Data protection systems could, if they provided exclusivity, become a partial substitute for patent protection in these cases and nullify, in practice, the transitional periods granted to developing countries.

Before the entry into force of the TRIPS Agreement, countries had considerable latitude to determine rules for the protection of test data. The Agreement introduced the first *international* standard on the subject, as contained in its Article 39.3.<sup>2</sup> But the Agreement is not a "uniform law" -- it only establishes broad parameters for national rules. An important question is the extent to which the Agreement allows WTO Member countries freedom to apply different approaches for the protection of test data protection and, in particular, the extent to which a competitive model -- i.e., protection without exclusivity -- is compatible with the minimum standards set forth in Article 39.3.

To properly interpret Article 39.3, the Vienna Convention on the Law of the Treaties instructs that the ordinary meaning and context of the terms used, and the object and purpose of the treaty

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<sup>2</sup> The full text of Article 39.3 reads: "Members, when requiring as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use."

must be carefully considered. The history of the negotiation is also an important complementary element for interpretation (Article 31 (2) of the Vienna Convention).

The first section of this paper describes the different stages of drug development and the testing required for marketing approval of new pharmaceutical products. The second section discusses the rationale for test data protection. The third section examines the conditions, established by Article 39.3 of TRIPS, under which protection must be given to marketing approval data. The fourth section examines the concept of “unfair commercial use” of data -- the conduct proscribed by Article 39.3. The fifth section examines the legal means that States may adopt to provide protection against commercial use. The sixth section offers a brief analysis of the negotiating history of Article 39.3, which provides the backdrop for interpretation of the TRIPS Agreement’s data protection obligations. A final, concluding section assesses the obligations on countries to provide marketing approval protection under the TRIPS Agreement, and reviews the flexibilities available to Member countries.



## **I. DATA REQUIRED FOR THE REGISTRATION OF PHARMACEUTICALS**

The development of a *new* drug involves different stages, during which a variety of data are produced.

The “discovery” stage involves the synthesis or isolation of new chemicals. Initial screening tests determine whether the new chemicals possess sufficient biological activity to be worthy of further investigation. The nature of pharmaceutical research has changed dramatically in the last twenty years with the application of the “rational drug design” method and the use of combinatorial chemistry. With discovery by design, scientists use knowledge about the causes of human disorders, the properties of drug compounds, and their action in the human organism to conceptualize the structure of an “ideal” molecule that is expected to restore the altered equilibrium. Laboratory chemists then search for substances whose molecular structures match as closely as possible the theoretical model (Gambardella, 1995, p. 23). This methodology reduces the cost of the “discovery” stage, but does not eliminate the need for bioassay, animal and other tests of the new drugs.

Once a promising new chemical is identified, its non-toxicity and efficacy must be confirmed. The testing procedures involve different stages and phases (see Box 1).

On the basis of the results of these tests, national authorities can assess whether to grant marketing authorization for a new chemical entity. All the safety and efficacy tests must normally be completed before the authority approves the product. The authority may also require additional clinical tests. In 1980, the duration of these studies varied from about 1 to 7 years and averaged slightly less than 3 years. This period has been significantly reduced since then (Raggett, 1996, p. 26).

### **Box 1** **Testing new drugs**

#### ***Preclinical Stage***

In the preclinical stage, the new chemical entity (NCE) is tested in animals to assess its pharmacodynamic, pharmacokinetic and toxicological profile. Results of these tests are studied carefully before tests in human beings are carried out.

#### ***Safety and Efficacy Testing***

The types of tests, the procedures to be used, and the standards to be met to demonstrate safety and efficacy may vary among therapeutic classes and even among drugs for use within a therapeutic class. This stage includes different phases.

In *Phase I* chemical testing, a small group of healthy volunteers receive dosages of the investigational drug for a short period of time. The primary purpose is to look for evidence of toxicity or unexpected undesirable reactions, and to study the bioavailability and pharmacokinetics of the NCE/drug applied to patients.

*Phase II* of clinical testing has a similar purpose to phase I, but considering the therapeutic context. Its primary objective is to ascertain the effectiveness of the investigational drug.

*Phase III* clinical trials are conducted on a large number of patients; they often involve several hundred human subjects and are conducted for substantial periods. These tests are designed to determine the efficacy of the investigational drug and to uncover any unanticipated side effects that the drug may have, considering age and gender influence, drug interactions and specific dosage for different indications.

While the phase III trials are under way, long-term animal toxicity studies are undertaken to determine the effects of prolonged exposure and the effects on subsequent generations. The duration of the studies vary widely among therapeutic classes. For drugs that affect the reproductive system or that will be used over long periods of time, animal toxicity studies are typically expensive and lengthy.



In addition to test data, national authorities require information on the quantitative and qualitative composition and other attributes of the product, as well as on manufacturing methods.

Marketing approval is generally granted for a specific drug used for a specific therapy. Changing the composition of the drug, combining it with other drugs in a single product or selling the drug for a different therapeutic purpose requires new approval.



## II. THE RATIONALE FOR DATA PROTECTION

### A. Approaches to data protection

A basic element of data protection is the obligation imposed on third parties not to disclose the data; that is, to keep them confidential.

Some health specialists have argued against any concealment of data submitted for the approval of pharmaceuticals (Ollila and Hamminki, 1996, p. 169). In their view, non-disclosure contradicts the right of the public to be informed about the efficacy and safety of approved pharmaceuticals. According to this opinion, the concealment of data on clinical, pharmacological and toxicological experiments retards the development of knowledge, and poses risks that consumers of a drug may be injured unnecessarily. Since confidentiality prevents the scientific community from scrutinizing the scientific basis of a licensing decision, it is not possible to determine whether there is commercial bias in the information, or whether it meets high standards. Drug companies have an interest in not publishing research that is not favourable to their products, and may even try to hinder the publication of such studies (Dukes, 1996, p. 149).

Other experts emphasize that health authorities should be able to use and rely on registration data submitted for similar products, or on the existence of a prior registration elsewhere.<sup>3</sup> If the regulatory body is not free, when assessing a file, to use all the knowledge available to it, including data from other files and published information, a great deal of *repetitive* toxicological and clinical investigation will be

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<sup>3</sup> In this case, the authority bases its decision on the fact that a foreign country has granted registration, and on the proof of equivalence in terms of the physical and chemical characteristics and other relevant attributes of the product.

required, which will be wasteful and in the case of animal testing, ethically questionable (Dukes, 1996, p. 146).

According to this position, when the authorities already know the characteristics and effects of the product (due to the first registration), it is not rational from the society's point of view to duplicate tests to recreate existing information. All that the authorities need for the second application is confirmation that the second product is *similar* to the first product. How to prove similarity is a matter for national regulation; some countries require bio-equivalence and bio-availability tests, while others are satisfied with the proof of chemical similarity and prior registration.

This position is also grounded in the pro-competitive effects of low entry barriers for pharmaceutical products. If producers (particularly generics manufacturers) are obliged to repeat long and costly testing, competition will be reduced because of time delays and, more importantly, because some small and medium firms -- especially local firms in developing countries -- will lack the resources to undertake such testing. This reduces competition and the affordability of medicines that -- by definition -- are off-patent and, therefore, should be broadly available at the lowest possible price.

The research-based industry has, however, argued for stronger test data protection, using both equity and health policy arguments. The industry position argues that the manufacturer has invested, often heavily, in conducting tests and deserves a return on investment. Where patent law fails to provide protection (for example, because the patent on an active component is shortly to expire, or because the drug is based on a combination of known substances used in novel manner) data exclusivity is a necessary barrier to competitors rapidly producing and registering an exact copy of the drug.

In accordance with this view,

*“equity demands that protection be provided for data, which can cost the original submitter several million dollars to produce. Disclosing this data to the public or allowing its use by another applicant unfairly denies the compiler of the data the value of its efforts*

*and grants an economic advantage to later applicants for marketing approval, enabling them to avoid the cost of developing test data for their own products. Countries that allow such unfair advantages to later applicants discourage developers of new pharmaceuticals and agricultural chemicals from seeking to introduce their state-of-the-art products in the country's market. So, not only is such protection required by the TRIPS Agreement, it is both equitable and wise from a public and health policy standpoint"* (Priapantja, 2000, p. 4).

Finally, consumer groups such as the Trans-Atlantic Consumer Dialogue have proposed that, since data exclusivity is intended to protect investment, companies seeking data exclusivity should be required to disclose the amount actually invested. This would enhance transparency and allow the establishment of a relation between the actual investment and the protection provided (WHO, 2000, p. 40).

In the light of these contrasting approaches, a key issue is the extent to which, under the TRIPS Agreement, Member countries are obliged to provide exclusivity, and whether authorities can rely on the data from a prior registration or on a registration made in a foreign country.

## **B. National practices before TRIPS**

Companies originating data for the registration of new products have requested from national health authorities and generally obtained protection of submitted data against disclosure. Confidentiality is essentially intended to protect secret information from misappropriation by third parties. However, problems with secrecy in drug regulation have historically raised public concern in several countries, including Great Britain, New Zealand, Germany, Sweden and the USA (Ollila and Hamminki, 1996, p. 168).

Historically, some health authorities relied on the first application data for the evaluation of second-entrant applications for similar products. Some companies brought legal action against the authorities arguing that reliance on the knowledge derived from one file to evaluate another one (e.g., a generic equivalent) caused them commercial injury.

In a number of court cases relating to *Cimetidine* decided in the United Kingdom, Australia and New Zealand, first entrants originating registration data invoked the ordinary law of confidential information to prevent regulatory authorities from relying on the originator's file when assessing an application for the approval of an equivalent drug by a generic competitor. Courts were, however, reluctant to apply such law (Cook, 2000, p. 5).

As a result of industry lobbying, some developed countries established *sui generis* protections for test data submitted for the approval of pharmaceuticals (and agrochemicals). Under different modalities, they adopted the concept of *exclusive* use of the test data by the originator company. The U.S. adopted a regulatory data protection regime for pesticides,<sup>4</sup> and in 1984 regulatory exclusivity provisions for medicines. The U.S. health registration regulations provide for five years of exclusivity for new chemical entities, and three years for data filed in support of authorizations based on new clinical research relating to chemical entities which had already been approved for therapeutic use.<sup>5</sup>

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<sup>4</sup> This regime limits exclusivity by allowing third parties to use originator's test data if compensation is paid. In case of disagreement, the amount is determined through arbitration. See in Annex I a summary of the relevant legislation.

<sup>5</sup> In October 1997, the U.S. Senate held hearings on "Health Registration Data Exclusivity, Biomedical Research, and Restrictions on the Introduction of Generic Drugs" (Subcommittee on Labor, Health and Human Services and Education and Related Agencies, Committee on Appropriations). These hearings considered a proposal for a voluntary five-year extension of the U.S. data exclusivity period, coupled with a 6 percent R&D commitment from the company electing to take the extension. The U.S. Congress did not adopt this proposal.

In the European Union (EU), the Member States have provided exclusivity protection for the data filed in support of marketing authorizations for pharmaceuticals since 1987. One of the original objectives of this regime was to compensate for the lack of patent protection for pharmaceuticals in some Member States (Portugal, Spain), but it was maintained after those countries introduced such protection (Watal, 2001, p. 201). During the exclusivity period, health authorities cannot rely on an originator's test to approve other applications without the originator's consent.<sup>6</sup> The minimum period

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<sup>6</sup> Article 8 of Directive 65/65, as amended by Directive 87/21/EEC, establishes that "without prejudice to the law relating to the protection of industrial and commercial property:

- (a) The applicant shall not be required to provide the results of pharmaceutical and toxicological tests or the results of clinical trials if he can demonstrate:
- i. either that the proprietary medicinal product is essentially similar to a product authorized in the country concerned by the application and that the person responsible for the marketing of the original proprietary medicinal product has consented to the pharmacological, toxicological or clinical references contained in the file on the original proprietary medicinal product being used for the purpose of examining the application in question;
  - ii. or by detailed references to published scientific literature presented in accordance with the second paragraph of Article 1 of Directive 75/318/EEC that the constituent or constituents of the proprietary medicinal product have a well established medicinal use, with recognized efficacy and an acceptable level of safety;
  - iii. or that the proprietary medicinal product is essentially similar to a product which has been authorized within the Community, in accordance with Community provisions in force, for not less than six years and is marketed in the Member State for which the application is made; this period shall be extended to 10 years in the case of high-technology medicinal products within the meaning of Part A in the Annex to Directive 87/22/EEC or of a medicinal product within the meaning of Part B in the Annex to that Directive for which the procedure laid down in Article 2 thereof has been followed; furthermore, a Member State may also extend this period to 10 years by a single Decision covering all the products marketed on its territory where it considers this necessary in the interest of public health. Member states are at liberty not to apply the abovementioned six-year period beyond the data of expiry of a patent protecting the original product. However, where the proprietary medicinal product is intended for a different therapeutic use from that of the other proprietary medicinal prod-

of such protection is six years, but 10 years is obligatory for “high technology products” (most biotechnology products), and also for new chemical entity authorizations granted by the European Medicines Evaluation Agency (EMA). EMA may also grant 10 years exclusive protection for test data related to medicines administered by means of “new delivery systems which ... constitute a significant innovation”, and “medicinal products containing a new substance or an entirely new indication which...is of significant therapeutic interest” (Cook, 2000, p.18).

Most Member States (Belgium, France, Germany, Italy, the United Kingdom, the Netherlands and Sweden) have applied the 10-year period to *all* medicinal products (Dodds Smith, 2000, p. 113). Moreover, the “data exclusivity that this affords can, if a marketing authorization is obtained only late in the life of a patent, extend beyond patent expiry. The only qualification to this is an option available to those few Member States which have not availed themselves of the 10-year period for all medicinal products, and which can also elect for such data exclusivity ‘not to extend beyond patent expiry’” (Cook, 2000, p.18).

Article 1711 of the North American Free Trade Agreement (NAFTA) of 1992 also establishes an exclusivity standard, requiring signatory countries to provide a minimum five years exclusivity period counted from the date of marketing approval. This model was followed in 1993 by the Andean Group countries under Decision 344 (“Common Regime on Industrial Property”).

At the time of conclusion of the TRIPS Agreement, few countries had adopted the exclusivity approach developed in the

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- ucts marketed or is to be administered by different routes or in different doses, the results of appropriate pharmacological and toxicological tests and/or of appropriate clinical trials must be provided.
- (b) In the case of new proprietary medicinal products containing known constituents not hitherto used in combination for therapeutic purposes, the results of pharmacological and toxicological tests and of clinical trials relating to that combination must be provided, but it shall not be necessary to provide references relating to each individual constituent”.



United States and Europe. At the time, most countries in the world did not provide for exclusivity and most allowed the national health authorities to *rely* on test data submitted by the first applicant to approve subsequent applications on “similar” products.<sup>7</sup> In some countries (e.g., Argentina, Singapore, Taiwan, and the territory of Hong Kong) it was sufficient to prove that a similar product had been approved or commercialized in a foreign country.

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<sup>7</sup> Though the time of the adoption of the Agreement is to be taken into account, according to general principles of international law, for the interpretation of its obligations, it should be noted that even today, after the expiration of all except the transitional period for LDCs, only a minority of the WTO Members apparently confer data exclusivity (see, e.g. the February 2000 Pharma submission to the USTR on Section 301, at [www.pharma.org](http://www.pharma.org)). New Zealand introduced an exclusivity period in 1994, as part of implementing legislation of the TRIPS Agreement, and Australia did it in 1998 as a result of U.S. action under “Special 301” of U.S. Trade Act. The Andean Group countries, instead, revised Decision 344 in 2000 and eliminated the exclusivity period. A special exclusivity granted under the “Safety Monitoring Program” in Thailand was also abolished in January 2001.



### III. CONDITIONS OF PROTECTION UNDER TRIPS

The TRIPS Agreement establishes a minimum international standard for the protection of marketing approval data. WTO Member countries need to determine what is actually needed to fulfil their obligations under the Agreement. Understanding the obligations imposed by Article 39.3 requires a close reading of the text, an assessment of each of its components, as well as a review of the negotiating history and national practice. The remainder of this paper turns to these tasks.

#### A. Protection of test data under the TRIPS Agreement

The inclusion of test data as a category of intellectual property in TRIPS does not mean countries must provide exclusivity protections for such data.

According to Article 1.2 of the TRIPS Agreement, the protection of test data is a category of “intellectual property” like patents, copyrights and trademarks. The structure of Article 39 suggests that the regime for test data has been conceived by the negotiating parties as a *particular* case in the framework of the protection of “undisclosed” information. In this sense, the protection conferred cannot be properly deemed a *sui generis* system.

The categorization of test data as a subject matter of “intellectual property” does not mean that Article 39.3 puts their protection on the same footing as other intellectual property rights. In particular, it cannot be inferred that such protection requires *exclusive* rights. Though in most instances intellectual property rights confer a *ius excluendi*, this is far from being an absolute rule. It is well accepted, for example, that trade secrets protection in the framework of unfair

competition does not give rise to a right to exclude. Nor does the protection of geographical indications under the TRIPS Agreement entail the granting of such faculty.<sup>8</sup> Likewise, there are many situations in which copyright protection only allows the title-holder to claim remuneration, but not to prohibit unauthorized acts.

As Article 39.3 itself indicates (see below), test data protection is a reward for the *investment* in data production, rather than for the creativity or inventiveness involved in generating the data. Test data are developed in accordance with standard protocols and procedures, involving a systematic compilation of factual information. Though the testing may refer to a novel drug, the test results themselves are merely the outcome of routine scientific practices.

Thus, the inclusion of test data in the TRIPS Agreement as a category of “intellectual property” does not determine the nature of the protection conferred. In particular, it does not indicate that such data should be protected through grant of exclusive rights.

## **B. The Article 39.3 conditions of protection**

### ***1. Data necessary for marketing approval***

A basic premise for the application of Article 39.3 is that **test data must only be protected if national authorities require their submission** for obtaining marketing approval of pharmaceuticals or agrochemical products. The first sentence of this article states:

*“Members, when requiring, as a condition of approving the marketing of...”*

Given the territoriality of the intellectual property system -- a feature that the TRIPS Agreement has not altered -- the obligation to protect test data only arises in the Member countries where national

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<sup>8</sup> See article 22.2 of the TRIPS Agreement.

regulations require the submission of such data. If a Member country opts not to require those data, Article 39.3 will be not apply.

In addition, the submission of data must be *necessary* to obtain approval. Data voluntarily submitted by an applicant, or in excess of what is required for approval, are not subject to protection under Article 39.3.

### ***2. Protected data***

The subject matter of the protection under this article is written material which details the results of scientific health and safety testing of drugs and agrochemicals, in relation to human, animal and plant health, impact on the environment and efficacy of use. The provision covers tests and other data that may be required by the authorities. These “other” data may include, for instance, manufacturing, conservation and packaging methods and conditions, but only to the extent that submission of this information is *necessary* to obtain marketing approval.

### ***3. Undisclosed data***

Article 39.3 does not require protection be given to public data submitted for marketing approval. To qualify for protection under Article 39.3, the pertinent information must be “undisclosed”. This means that information that is already public does not fall within the scope of this article. Any requirement for the submission of published or otherwise disclosed information to national regulators shall not generate any private right limiting the use of such information by the government or third parties, since the information would be in the public domain.

While a substantial part of the information on tests relating to safety and efficacy of approved drugs becomes publicly available --

because the information is published in scientific journals,<sup>9</sup> or made public by the health authority,<sup>10</sup> -- many data remain confidential such as data relating to some of the product's physical and chemical attributes and manufacturing processes.

Given that under Article 39.3 protection is only conferred on undisclosed information, it will be necessary to determine in cases of controversy which of the information accompanying an application for marketing approval is confidential and need to be protected, and which is not. The undisclosed or disclosed nature of information is an *objective* feature, and it is not dependent on the qualification given by the applicant to the information that it is submitted. Hence, any applicant's declaration that all or certain information is "confidential" or "undisclosed" should be subject to scrutiny.

#### **4. New chemical entities**

Another important condition for the application of Article 39.3 is that the data must refer to a "new chemical entity". The Agreement does not define the term "new". While the term presumably does not impose a patent standard of novelty, Member countries may choose under the Agreement to apply such a standard.

It may be also held that the test for newness under Article 39.3 refers to the date of application for approval. Thus, a chemical entity may be deemed "new" if there were no prior application for

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<sup>9</sup> In the case of the EU regulations (Directive 65/65, as amended) the possibility of obtaining market approval on the basis of published literature has been interpreted very restrictively. It only applies where a product has a well established medicinal use and the documentation submitted by the applicant covers *all* aspects of the safety and efficacy assessment (Dodds-Smith, 2000, p. 111).

<sup>10</sup> For instance, the European Medicines Evaluation Agency (EMEA) publishes summaries of clinical trials in the "European Public Assessment Report" (EPAR) However, no detailed information on toxicological/pharmaceutical tests or clinical trials is published which could be used for registration by another company. The manufacturing process is not published either.

approval of the same drug, or where the same drug was not previously known in commerce.

Article 39.3 does not clarify either whether newness should be absolute (universal) or relative (local), that is, whether “new” would mean the *first* application in the world or in the Member country where it was filed (Cook, 2000, p.6).

Occasionally, a product which is known and used in a certain field (e.g. chemical industry), may find a new application in the pharmaceutical sector. Such a new therapeutic product (generally known as “first indication”) may be deemed not to constitute a “new chemical entity”, since the chemical was already known. Alternatively, the newness may be assessed within a particular regulatory framework, and without regard to the fact that the same chemical may have been used in the context of another regulatory framework (Cook, 2000, p. 6).

All the above interpretations are equally permissible. The TRIPS Agreement deliberately avoids defining the concept of “new chemical entity”. This is one of the clear areas in which Member countries enjoy room for manoeuvre to implement the Agreement’s provisions.

Based on the ordinary meaning of the terms used, it may be also interpreted that there is no obligation to provide for protection when the test data were developed for a new *use* of a pharmaceutical product (generally called a “second indication”). In this case, it is the application or method of use of a known chemical entity that is new, but not the entity as such.

Similarly, Article 39.3 would not apply in cases where approval is sought for new indications, dosage forms, combinations, new forms of administration, crystalline forms, isomers, etc. of existing drugs, since there would be no novel chemical entity involved. The European Court of Justice indirectly addressed this issue in the

*“Squibb”* case.<sup>11</sup> The Court held that a (second) product is “essentially similar” to an earlier approved product if the second product has “the same qualitative and quantitative composition in terms of active principles”, “the same pharmaceutical form” and is bio-equivalent to the first product, “unless it is apparent in the light of scientific knowledge that it differs significantly from the original product as regards safety or efficacy”. In these cases, the original applicant does not receive new periods of so-called “marketing exclusivity” for each new indication, dosage form or dosage schedule (Jones and Nittenberg, 1998/1999, p. 152).

#### **5. Considerable effort (investment)**

The subject matter of the protection under Article 39.3 is test data which cover matters such as toxicology, clinical trials for the pharmaceuticals and field trials for agrochemicals. Because this information is not “invented” or “created”, the TRIPS Agreement does not define any substantive standard for granting protection (like inventive step or novelty). It simply mandates protection when the process of obtaining the data involved “a considerable effort”.

The text is vague about the type of effort involved (technical, economic?) and also with respect to its magnitude (when would it be deemed “considerable”?). As mentioned, the proponents of this formulation intended to protect the *investment* made in producing test data.

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<sup>11</sup> The ECJ decision was given in response to questions referred to it from the English High Court in relation to three cases. In all of them, the research-based pharmaceutical companies had made changes to certain aspects of their products and obtained marketing approval for each change. Subsequently, generic companies sought to rely not only on the original versions of the products but also on the products which had been approved more recently. The Medicines Control Agency acceded to certain of the generic companies requests, but not all of them (Jones and Nittenberg, 1998/1999, p. 152). See also Dodds-Smith, 2000, p. 112.



The extension of intellectual property beyond its boundaries so as to protect investment, and not intellectual contributions<sup>12</sup> disrupts the essence of a system conceived to reward the creators of original ideas and new inventions.<sup>13</sup> Even if it may be argued that “free riding” or “unfair use” of such data by third parties may create unfair advantages or unjust enrichment, it is not the role of the intellectual property system to solve competition problems that do not relate to the creation or use of ideas. Nonetheless, Article 39.3 exists. And it includes the considerable effort standard. Inclusion of this standard suggests national regulatory authorities may request the applicant prove that the information for which protection is sought is the result of considerable effort.

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<sup>12</sup> An investment-based system was adopted by the European Community in the form of a *sui generis* regime for the protection of data bases. Despite the efforts of WIPO, however, no agreement has been reached so far to adopt an international convention modeled on the European approach. A bill on the matter proposed in the United States has also found strong opposition, particularly from the scientific and librarian communities (Reichman and Uhler, 1999).

<sup>13</sup> According to the Trans Atlantic Consumer Dialogue (TACD), “data exclusivity provisions are part of a growing class of *sui generis* forms of protection that are designed to protect investment, rather than innovation. Because data exclusivity is not a reward for invention (which is already rewarded by patents) but rather a protection of investment, there should be greater transparency of the basis for the protection and a reasonable relationship between the investment and the protection” (available at [www.tacd.org](http://www.tacd.org)).



#### **IV. NON-DISCLOSURE OBLIGATION**

Since the TRIPS Agreement's obligations with regard to test data protection relates exclusively to undisclosed information, it seems clear that WTO Members' obligations are limited to information, effectively requested by and submitted to the government, which was at the time of submission, and later remains, "undisclosed".

The non-disclosure obligation requires that the test data be protected against "disclosure" unless:

- a) it is necessary to protect the public; or
- b) steps are taken to ensure that the data are protected against unfair commercial use.

The application of the first exception is subject to a "necessity test". In determining necessity, GATT/WTO rules and jurisprudence generally provide deference to Member countries to determine when a necessity arises, but impose an often heavy burden of proof on the Member invoking it (Trebilcock and Howse, 1999, p. 140; Correa, 2000).

The second exception would permit a Member to disclose any information, if its unfair commercial use can be prevented. The key questions are what constitutes unfair use and how that protection can be guaranteed. This issue is discussed below.

Article 39.3 aims at preserving the confidentiality of the information submitted for marketing approval without any time limit. There is no indication in the provision about the duration of the obligation, certainly a weak point in the text. In principle, the confidentiality obligation continues until the information becomes known. It may also be possible, however, for a Member to establish a maximum period of confidentiality.

In any case, as mentioned above, because of the public health implications of the release into the market of a new drug, a substantial part of, but not all, the results of safety and efficacy tests and other data become available to the public. Some public health specialists have strongly opposed the possibility of keeping confidential pharmaceutical data, such as information obtained during pre-clinical tests. It has been argued that

*“The earliest point in the career of the drug when one obtains a glimpse as to which its adverse effects might be is, without doubt, the phase of pharmacological and toxicological studies in animals. Very properly, the community requires of the pharmaceutical industry that the work performed at this stage be conscientiously carried out and painstakingly reported when the drug is submitted to Drug Control Authorities... Very improperly, the community then goes on to tolerate a situation whereby these reports, having been used for this purpose, are then commonly deposited in confidential archives where they are inaccessible to the medical world at large... It follows that when the first clinical evidence of a particular and unexpected side effect reaches us there is often no simple and direct means of comparing it with what has been reported in dogs, rabbits and mice. If these data were public property, it might be simpler to identify at an early stage those adverse reaction reports from the clinics which, because they run parallel to animal findings, deserve particular attention....” (Dukes, 1977).*

Public health concerns were only marginally present in the negotiation of the TRIPS Agreement.<sup>14</sup> The non-disclosure obligation was established on the basis of commercial considerations, without a proper weighing of public health interests in the openness of drug information (see Box 2).

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<sup>14</sup> See, e.g., Article 8.1.

**BOX 2**

**THE BENEFITS OF OPENNESS OF DRUG INFORMATION<sup>15</sup>**

**The importance of access to information**

Full availability of information is essential if all parties involved in health care are to participate effectively. Openness facilitates adequate feedback, proper setting of priorities and development of trust. A culture of openness protects conscientious individuals working in organizations of all kinds.

Knowledge relating to all drugs evolves constantly, as do standards and expectations relating to them, their producers and health care providers. However thorough the investigations made before a drug is licensed and marketed, much more will be learned about its efficacy, proper use and risks once it is marketed and used on a much larger scale.

Almost no new element of knowledge emerges suddenly; as a rule it begins with impressions and hypotheses. Where these arise – for example, in reports of possible serious side effects in the journals -- all existing relevant information will need to be mobilized to verify or discount this evidence so that the trust can be established as quickly as possible. Much of the information needed for that purpose, including data on both animal and human experience, is unpublished and lies only within the files of agencies. By using it, the truth can be established much more quickly than if one is reliant purely on published evidence.

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<sup>15</sup> Extracts from the Statement of the “International Working Group on transparency and accountability in drug regulation “(Uppsala, 11-14 September, 1996).

**Box 2 (continued)**

**Consequences of excessive secrecy in drug regulation**

If a substantial part of the information existing on drugs remains hidden within regulatory agencies, and sometimes fragmented between them, the development of knowledge will be impeded. This is particularly dangerous where suspicion arises of a hitherto unknown risk.

Malpractice can be hidden from view; legal discovery in the course of litigation has for example revealed cases of falsification or suppression of unfavorable data by certain companies, or submission of inconsistent files on the same drug to different agencies. Secrecy facilitates the circulation and use of sub-standard drugs.

Where a drug is subject to negative findings, the failure of a drug agency to explain its conclusions or provide background data, can leave the way clear for the sometimes very different and emphatic account given from the manufacturer. In a climate of secrecy and mistrust, the public is unlikely to believe even accurate and meticulously prepared official statements – assuming that they cannot be taken at face value and that some relevant information has probably been withheld.

The incomplete availability and irregular release of information promotes a climate in which suspicion is generated and in which sensational and poorly founded stories on drugs break in the popular press, their reliability cannot be checked and unnecessary panic can be caused.

Secrecy has consequences which can be wasteful and even inhumane; scientific work, e.g., in humans or animals which has already been performed by one company but hidden within regulatory files, may be repeated unnecessarily.

If drug utilization data are not available irrational drug use may continue unrecognized and unchecked.

If research is sponsored by companies, unfavourable or unclear results may be withheld or the research itself may be stopped.

## V. PROSCRIBED ACTS OF UNFAIR COMMERCIAL USE

### A. The TRIPS Agreement text

One of the crucial interpretative issues in Article 39.3 is whether the reliance by a national authority on data submitted by one company (the “originator”) to evaluate a subsequent application by another company (a “follower”), constitutes an “unfair commercial use” of the information.

The expression “*unfair commercial use*” is not defined in Article 39. Pursuant to Article 31 (1) of the Vienna Convention, its interpretation should be based on the ordinary meaning of the terms of the treaty in their context and in the light of the agreement’s object and purpose.

#### 1. “Unfair”

The ordinary meaning of “unfair” is “*not equitable or honest or impartial or according to rules*”<sup>16</sup>. In the case of Article 39.3, this concept must be understood in the light of Article 10*bis* of the Paris Convention.

The concept of “unfair” is relative to the values of a particular society at a given point in time. It varies among Members, and this variation is in fact one of the premises on which the discipline of unfair competition is grounded. There is no absolute, universal rule to determine when certain practices should be deemed “unfair”:

*“Morality, which is the source of the law of unfair competition, is a simple notion in theory only. In fact it reflects customs and habits anchored in the spirit of a particular community. There is no*

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<sup>16</sup> *The Concise Oxford Dictionary*, Seventh Edition, Oxford University Press, Oxford, 1989.

*clearly objective standard of feeling, instincts, or attitudes toward a certain conduct. Therefore, specific prescriptions involving uniform evaluation of certain acts are extremely difficult.*

*The pressures existing in the various countries for the suppression of acts of unfair competition differ greatly. Generally, the development of law of unfair competition depends on active and intense competition in the marketplace by competing enterprises. It is the pressure of conflicting interests which leads to the establishment of clear rules of law. This pressure is not uniform in all countries and indeed it is evolving continuously” (Ladas, 1975, p. 1685-1686).*

Ladas concludes his treatise’s discussion of the issue by indicating that:

*We look for a standard by which we may judge the act complained of. This is an objective standard: the honest practices in the course of trade in the particular community and at the particular time” (Ladas, 1975, p. 1689).*

Given this diversity, it is likely that different countries will judge certain situations differently, depending on their values and competitive advantages. Some countries may consider it an “unfair practice” for a “follower” company to commercially benefit from the data produced by the originator, via a marketing approval system based on “similarity”; or hold that such commercial benefit gives rise to claims of “unjust enrichment” leading to a compensation for the use of the data. In others, it may be regarded as the legitimate exploitation of an externality created during legitimate competition in the market. As noted by Kamperman Sanders,

*“Where exploitation of another’s achievements becomes inequitable, unfair competition law acts provides a remedy. This means that the mere fact that another’s achievement is being exploited does not call for any impediment on the basis of unfair competition provisions. On the contrary, appropriating and building on others’*



*achievements is the cornerstone of cultural and economic development. The axiom of freedom to copy epitomizes the principles of the free market system”.*

Certainly, specific regulations could be adopted at the international level in order to harmonize the treatment of these cases. The United States made such a proposal in the TRIPS negotiations,<sup>17</sup> but it was not incorporated into the final text of the TRIPS Agreement. The U.S. proposal would have obliged countries to prevent any use of test data, without the consent of the right holder or on payment of “the reasonable value of the use”, if that use led to the “commercial or competitive benefit of the government or of any person”. This provision would have obliged countries to prevent *any* practice that would create such benefit. The final proposal, by contrast, used the term “unfair commercial practices”. The rejection of the US proposal indicates that the negotiating parties deliberately opted under Article 39.3 to mandate regulation of certain *types* of practices (those that are commercially *unfair*) and not to prevent any practice based on its possible *effects* on benefits allocation.

In other words, Article 39.3 only applies when a competitor obtains a benefit or advantage from the use of the originator’s testing data *as the result of unfair commercial practices*. It is the qualification of the practice that counts, not the mere existence of an advantage or benefit. Such qualification is left to Members’ discretion; it is part of the room for manoeuvre that they retained when signing the Agreement.

There are many instances in which the production of goods, notably intangibles, in a competitive environment generate externalities that benefit competitors. In describing the nature of competition, Ladas has noted that:

*“it is an undeniable fact of modern business life that successful manufacturers or traders have to cope with the danger of having the goodwill of their business, their connection with the purchasing*

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<sup>17</sup> See below the history of the negotiation of article 39.3.

*public, interfered with by competitors...In a competitive economy is it to be expected that each manufacturer or trader necessarily seeks to maintain and improve his market position by obtaining the benefit of a public demand, even though this demand be created by other manufacturers or traders...*

*“...where does lawful competition end and unlawful competition begin? The fact that a competitor may derive a profit from his act of competition or cause monetary loss to another is not, in itself, unlawful. The dictum “no one should reap where he has not sown” requires delicate application. Progress would be paralyzed and monopoly would become general if we should attempt to prevent persons from using the work or experience of others. We must encourage people in the same trade or industry to compete for the custom of the public on the most favorable terms. The issue is whether the means employed in such competition are fair and lawful. An act may lack tact or taste but not be dishonest” (Ladas, 1975, pp. 1676, 1677 and 1689).*

Many countries do not treat commercialization of a “similar” product approved by reference to a previous registration, or by reliance on data submitted by the originator company, as an unfair commercial practice, but some do. Under Article 39.3, each approach is valid. Article 39.3 mandates protection against “unfair commercial practices”, but permits Member countries to determine which practices will be deemed commercially unfair. As mentioned, differences among countries are likely to exist, consistent with Article 10*bis* of the Paris Convention.

## **2. “Commercial”**

Article 39.3 only covers “commercial” uses. This requirement clearly excludes use by the government, notably by the national health authority to assess the efficacy and toxicity of a pharmaceutical or agrochemical product.

In the view of the European Union, however, there is a substantial difference between the underlying principle in Article 39.1, which refers to relationships between competitors and Article 39.3, which includes governmental acts:

*“The main question of interpretation is what is meant by “unfair commercial use”. Clearly, this concept is different from the concept of “unfair competition”, as used in Article 39.1 with a reference to Article 10bis of the Paris Convention on the protection of Industrial Property, and which relates to behaviour among competitors. Protection of registration data is a government function. Article 39.3 does not indicate whether the notion of “unfair commercial use” refers to unfair commercial use by generic manufacturers to those who have submitted the data (usually research-based pharmaceutical industry) or to use by regulatory authorities of these data to the benefit of competitors. Protecting data against “unfair commercial use” is also different from protecting them from disclosure, since the latter is a separate and distinct obligation under Article 39.3” (EU, 2001, p.3).*

The EU argument, however, disregards that Article 39 *develops* and does not add to Article 10bis of the Paris Convention. It only incorporates *examples of the general principle contained in paragraph (2) of Article 10bis*.

In addition, though the use by the governments will *indirectly* have commercial consequences (the entry of a competitor in the market), it does not represent a *commercial* activity as such, but a legitimate State practice. In order to be “commercial”, the use of the information should be made by an entity which is actually in commerce. As also noted by Ladas,

*“The general clause of Article 10bis, in establishing as its foundation “honest usages,” looks to the relations between competitors and to the interests of customers, and these provide an objective test which reflects an evolving pattern of competition in most of the present world...By definition, competition in commerce refers to the efforts of two or more persons, acting independently, to secure the*

*custom of third parties, with the results that one may increase the sale of his goods and reduce the sale of the goods of the other”* (Ladas. 1975, p. 1688).

The same concept underlies the WIPO “Model Provisions on Protection Against Unfair Competition” which, in relation to data protection, suggests the adoption by national laws of the following provision:

***“Use or Disclosure of Secret Information Submitted for Procedure of Approval of Marketing: Any act or practice, in the course of industrial or commercial activities, shall be considered an act of unfair competition if it consists or results in an unfair commercial use of secret test or other data, the origination of which have been submitted to a competent authority for the purposes of obtaining approval of the marketing of pharmaceutical or agricultural chemical products which utilize new chemical entities”*** (emphasis added) (WIPO, 1996).

### 3. “Use”

Finally, for Article 39.3 to apply, there must be “use” of the information submitted by the originator.<sup>18</sup>

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<sup>18</sup> In one of the texts under consideration by the negotiating parties in July 1990, the broader concept of “exploitation” was proposed (but not finally adopted). The text read:

*“3Aa. Parties, when requiring the publication or submission of undisclosed information consisting of test [or other] data, the origination of which involves a considerable effort, shall protect such data against unfair exploitation by competitors. The protection shall last for a reasonable time commensurate with the efforts involved in the origination of the data, the nature of the data, and the expenditure involved in their preparation, and shall take no account of the availability of other forms of protection”.*

#### **4. Analysing “Unfair Commercial Use”**

Thus, given the flexibility inherent in Article 39.3, and depending on the applicable legal system, national laws can follow different approaches for the approval of a second-entry marketing application. They may:

- a) require the second-entrant to produce its own testing and other data or to obtain an authorization of use from the “originator” of the data;
- b) allow the second-entrant to rely on the “originator’s” data against payment of a compensation to the “originator” (when the “originator” has not given his consent for the use of the data);<sup>19</sup>
- c) examine and rely upon the data submitted by the “originator” to evaluate the second-entrant application;
- d) approve a second entry marketing application without examining or otherwise relying upon confidential information submitted by the originator.

In all cases, the authorities will normally require that the second-entrant prove that his product is similar or “essentially similar” to the already registered product (in terms of its physical and chemical characteristics and attributes).<sup>20</sup> Different types of bioequivalence studies are generally required for this purpose.<sup>21</sup>

In cases a) and b) the data receive specific protection, either on the basis of exclusivity or compensation. In case c) the second-entrant does not *use* the data; it is the authority who examines and

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<sup>19</sup> This compulsory licence approach is the one applicable, under certain circumstances, in accordance with the U.S. FIFRA. See Annex I.

<sup>20</sup> See, e.g., article 4.8 (a)(ii) of the EC Directive 65/65/EEC.

<sup>21</sup> In some countries, bio-availability studies are also required for the approval of generic versions of existing products.

relies on the data in its possession. In case d), finally, there is no “use” at all, since the authority does not use the testing and other data (which it may not even possess); it merely relies on public information and/or on the existence of a prior (domestic or foreign) marketing approval.

Neither in cases c) or d) is there a “commercial use” of the data. A contrary interpretation holds that even indirect reliance on data by a national authority constitutes a form of commercial use. Under this interpretation, the competent authority must be proscribed from “using” the data to support, clear or otherwise review second entrant applications for marketing approval for a set amount of time unless authorized by the “originator” (WHO, 2000, p. 39)

According to this interpretation, national authority reliance on the data submitted by the originator in order to assess a subsequent application constitutes “unfair commercial use”, even when neither the authority nor the competitor actually “use” the data without the originator’s authorization (for instance, when approval is given without any re-examination of the data). In the U.S. complaint against Australia, for instance, the USA argued that relying on the innovator’s data allowed free-riding by generic drug companies on

*“the innovator company’s investment in developing the test data and thus puts the innovator company at a competitive disadvantage...The U.S. claims that Article 39 para.(3) means that generic companies are not allowed to derive commercial benefit from the innovator’s test data”* (Priapantja, 2000, p.6).

Under this view, the fact that a competitor obtains a commercial benefit or advantage constitutes an “unfair commercial use” of the data, notwithstanding that actual use may not occur and that the practice as such may not be “dishonest” or contrary to a country’s prevailing values of morality or fairness in commercial activities.

This latter interpretation, however, clearly goes beyond what the provision mandates. It does introduce an obligation not negotiated during the Uruguay Round that, in practice, would limit legiti-

mate competition and thereby erect barriers to the access to medicines.

### **B. National case law**

Available national case law supports the view that granting marketing approval to a second entrant, based on the second product's similarity to a previously approved first product, is not a proscribed "use" under Article 39.3.

The nature and extent of data exclusivity rights were examined in two important decisions by the U.S. Supreme Court (*Ruckelshaus v. Monsanto Co.*, 467 US 986, 104 S.Ct.2862, June 26, 1984) and the Canadian Federal Court of Appeal (*Bayer Inc. v. The General Attorney of Canada, the Minister of Health, Apotex Inc. and Novopharm Ltd.*, May 19, 1999). The second decision, in particular, examined the extent to which a national health authority can *rely on* the originator's data, *even when an exclusivity period applies*.

The *Ruckelshaus v. Monsanto Co.* case relates to the protection of data submitted for the registration of an agrochemical product. Though a subsequent applicant was obliged to compensate for the use of Monsanto's original data, Monsanto argued that such use undermined its reasonable "investment backed expectations" and was unconstitutional. A basic argument of the plaintiff was that the possibility given to a competitor of using the data against payment of a compensation nullified its "reasonable investment-backed expectation". However, the Supreme Court described the extensive practice of relying on data submitted by the first applicant in the United States, and rejected Monsanto's complaint (see Box 3).

**Box 3**

**Relying on data: the U.S. Supreme Court decision  
in *Ruckelshaus v. Monsanto Co.***

The Supreme Court considered that Monsanto could not have had a reasonable, investment-backed expectation that the Environmental Protection Agency (EPA) would keep the data confidential beyond the limits prescribed in the amended statute itself. Monsanto was on notice of the manner in which EPA was authorized to use and disclose any data turned over to it by an applicant for registration.

Excerpts from the Court's decision:

- “In addition, Monsanto was aware that information relating to formulae of products could be revealed by EPA to “any Federal agency consulted and [could] be revealed at a public hearing or in findings of fact” issued by EPA “when necessary to carry out” EPA’s duties under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) § 10(B)<sup>22</sup>. The statute also gave Monsanto notice that much of the health, safety, and efficacy data provided by it could be disclosed according to the data-consideration and data-disclosure provisions in the statute. Monsanto chose to submit the requisite data in order to receive a registration, it can hardly argue that its reasonable investment-backed expectations are disturbed when EPA acts to use or disclose the data in a manner that was authorized by law at the time of the submission.”
- “Because the market for Monsanto’s pesticide products is an international one, Monsanto could decide to forego registration in the United States and sell a pesticide only in foreign markets. Presumably, it will do so in those situations where it deems the data to be protected from disclosure more valuable than the right to sell in the United States.”

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<sup>22</sup> See a summary of FIFRA in Annex I.



**Box 3 (continued)**

- “*A fortiori*, the Trade Secrets Act cannot be construed as any sort of assurance against internal agency use of submitted data during consideration of the application of a subsequent applicant for registration. Indeed, there is some evidence that the practice of using data submitted by one company during consideration of the application of a subsequent applicant was widespread and well known. Thus, with respect to any data that Monsanto submitted to EPA prior to the effective date of the 1972 amendments to FIFRA, we hold that Monsanto could not have had a “reasonable investment-backed expectation” that EPA would maintain those data in strictest confidence and would use them exclusively for the purpose of considering the Monsanto application in connection with which the data were submitted.”
- “When Monsanto provided data to EPA during this period, it was with the understanding, embodied in the FIFRA, that EPA was free to use any of submitted data that were not trade secrets in considering the application of another, provided that EPA required the subsequent applicant to pay “reasonable compensation” to the original submitter. § 3(c)(1)(D), 86 Stat. 979. But the statute also gave Monsanto explicit assurance that EPA was prohibited in connection with the application of another, to use any data submitted by an applicant if both the applicant and EPA determined the data to constitute trade secrets.”

The U.S. Supreme Court in this case recognized that the authority could use the data submitted by the originator to assess second-entrant applications. According to the law applicable at the time of the complaint, Monsanto was entitled to compensation, but not to exclusive use of the data. The solution has probably not substantially changed in the United States despite the adoption of the Second Restatement of Unfair Competition Law (1997). In the absence of a

specific provision granting an exclusivity period as currently provided for medicines by U.S. law, relying on data to approve subsequent applications would not be considered an illegitimate misappropriation of trade secrets.<sup>23</sup>

The General Court Appeal of Canada decided a second and more significant case on issues related to data exclusivity. Despite the fact that NAFTA provisions, as mentioned before, provide for a minimum term of exclusivity, the Court found legitimate the approval of a subsequent application on the basis of a prior registration. The court argued that the health authority neither requested undisclosed information a second time nor examined it; the authority just checked whether the original and subsequent products were indeed the same (see Box 4). The issue was decided under Canadian law and NAFTA Article 1711 on "Trade Secrets", which establishes the following:

"5. 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 data involves considerable effort, the Party shall protect against disclosure of the data of persons making such submission, where the origination of such data involve considerable efforts, 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.

6. Each Party shall provide that for data subject to paragraph 5 that are submitted to the Party after the date of entry into force of this Agreement, no person other than the person that submitted them may, without the latter's permission, rely on such data in support of an application for the product approval during a reasonable period of time after their submission. For this purpose,

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<sup>23</sup> Personal communication by Prof. J. Reichman (Duke University), October 2001.

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.

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

**Box 4**

**Canadian Federal Court of Appeal: the Bayer case**

The Federal Court of Appeal held, *inter alia*, the following:

“When a generic manufacturer files an Abbreviated New Drug Submission (ANDS), the safety and effectiveness of the generic product may be demonstrated by showing that the product is the pharmaceutical and bioequivalent of the innovator's product. If the generic manufacturer is able to do so solely by comparing its product with the innovator's product which is being publicly marketed, the Minister will not have to examine or rely upon confidential information filed as part of the innovator's New Drug Submission (NDS). In such case, the minimum five year market protection referred to in the regulation will not apply.

**Box 4 (continued)**

“On the other hand, if in order to be satisfied of the safety and effectiveness of the generic product, the Minister examines and relies upon information filed by the innovator in its NDS, the minimum five years market protection for the innovator will apply. This is because the safety and effectiveness of the generic product will only be established by reference to confidential information provided to the Minister by the innovator. It is only this use of that confidential information by the Minister on behalf of the generic manufacturer that gives rise to the minimum five years protection from competition for the innovator.

“The appellant says that whenever an ANDS is filed by a generic manufacturer comparing the generic product with the innovator’s product, the Minister must implicitly be examining and relying upon the confidential information filed by the innovator in its NDS. We do not read subsection C.08.004.1(1) in this way. To do so would be to interpret it as invariably providing a minimum five years of market protection to an innovator when an ANDS is filed by a generic manufacturer. Rather, the regulation contemplates that the Minister may or may not examine and rely upon confidential information filed by the innovator. The appellant’s argument reads out of the regulation the option given to the Minister as to whether or not to examine and rely on the confidential information filed by the innovator.

“The NAFTA provisions are intended to protect trade secrets. If the generic manufacturer exercises the option of having the Minister examine the confidential information filed by the innovator in support of its application for a Notice of Compliance, it is, in effect, relying on that information within the meaning of section 6 of Article 1711. It is apparent that if confidential data is not relied upon, the trade secrets provisions of the NAFTA are not applicable. Specifically, if a generic manufacturer is able to establish the safety and effectiveness of its product on the basis of bioequivalence or bioavailability studies without the Minister having to examine and rely upon confidential data filed by the innovator, there is no reason or justification for the minimum five years protection from competition. This interpretation of subsection C.08.004.01(1) is consonant with section 5 and 6 of Article 1711 of the NAFTA.

**Box 4 (concluded)**

“If a generic manufacturer compares its product to an innovator’s product solely on the basis of public information, providing the innovator with protection from competition for a minimum of five years is tantamount to granting it the protection a patent would provide. Put another way, even if the Minister did not examine and rely on the innovator’s confidential information, the innovator would be entitled to the minimum of five years protection from competition. The words of subsection C.08.004.1(1) cannot be construed to yield such a result.”

The Court, in sum, concluded that, under Canadian law and NAFTA, if the health authority actually uses the data submitted by the originator on behalf of the generic manufacturer in order to assess the latter’s application, the minimum five years protection from the competition for the innovator applies. But if the authority does not examine and rely on that confidential or trade secret information on behalf of the generic manufacturer, there is no use of data and the exclusivity provision is not applicable.

If despite the express provision of exclusivity, the mere reliance on a prior registration without use of the data does not allow to claim exclusivity, *a fortiori* the same conclusion should be reached when the exclusivity is not specifically established, as in the case of Article 39.3.

In sum, whatever the desire of some of the TRIPS negotiating parties might have been, the expression “unfair commercial use”, reasonable interpreted, does not sustain a reading that Article 39.3 requires the provision of exclusivity, or of a compensation. It has left wide room for manoeuvre for Member countries to determine:

- a) when such a use exists, and
- b) the means of protection (see next section).

An “unfair commercial use” may be determined to exist, for instance, in situations in which a competitor obtains through fraud, breach of confidence or other “dishonest” practices, the results of testing data and *uses* them to submit an application for marketing approval in its own benefit. It would also apply in cases where the government provides access to undisclosed testing data in order to provide an advantage to a firm which did not produce them or share their cost.<sup>24</sup>

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<sup>24</sup> This would represent a violation of the non-disclosure obligation as well as an “unfair commercial use”.

## VI. MEANS OF PROTECTION AGAINST UNFAIR COMMERCIAL USE

A key issue for the application of Article 39.3 is to determine the nature and extent of the obligation to protect “against unfair commercial use”. As noted, the interpretation of this rule has created considerable controversy.

The TRIPS Agreement mandates the protection of “undisclosed information” in the framework of the discipline of “unfair competition”. Article 39.1 of Agreement stipulates that

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

Article 10bis of the Paris Convention requires protection against “unfair competition”, defined as

*“any act of competition contrary to honest commercial practices in industrial or commercial matters”.*

The discipline of unfair competition protects fairness in commercial activities. As mentioned, there are no universal moral values or a unique concept of what is “honest” in commercial behaviour. The definition of what constitutes “fair” or “honest” practices varies among countries. They may include competitor’s misrepresentation, fraud threats, defamation, disparagement, enticement of employees, betrayal of confidential information commercial bribery, among others. In many but not all jurisdictions, the misappropriation of trade secrets is regulated under unfair competition law, as is the case with the TRIPS Agreement.

The present status of international competition law in the Paris Convention is outlined in Box 5.

**Box 5**  
**International protection against unfair competition under the Paris Convention**

- Pursuant to Art.10 *bis* (1), the contracting states are obliged to ensure citizens of other contracting states “effective protection against unfair competition”.
- In Art.10 *bis* (2) (general clause), unfair competition is defined as any act of competition which is “contrary to honest practices in industrial or commercial matters”.
- Three cases are named in Art.10 *bis* (3) which “in particular shall be prohibited”, namely creating the risk of confusion, discrediting competitors through false allegations and making misleading indications or allegations about one’s own goods. This list is not enumerative, so that other competitive acts can also be covered by the general clause.
- Pursuant to Art.10 *bis* (1) of the Paris Convention, appropriate legal remedies must be made available to the citizens of other contracting states, in order to ensure the effective repression of acts contravening Art.10 *bis*; these must also include the power of federations and associations to take legal action (Art.10 *ter* (2)).

*Source:* Henning-Bodewig, 1999, p. 173.

Under the discipline of unfair competition, protection is not based on the existence of “property” rights. Hence, the provision of protection under such discipline does not give rise to claims of property rights, including in respect of trade secrets and data submitted for marketing approval. There is only “possession” of this information.



The TRIPS Agreement itself, in Article 39.3 refers to undisclosed information “under the control” of a person, in clear contrast to the concept used in the sections relating to other categories of intellectual property rights.<sup>25</sup> A comparison between patents and trade secrets protection illustrates this important difference (see Box 6):

**Box 6**  
**Patents vs. undisclosed information**

- A patent confers property rights.
- A patent owner obtains the exclusive use of his/her rights. This means he/she is the only one who can use the invention, commercialize the product, etc. A patent owner can prevent any other person from using that invention. Even if a third party has developed the same product in an independent manner, without knowing or relying on the technology of the patent owner, the former is not allowed to use it, since the exclusive rights conferred are absolute.
- In the case of undisclosed information, under most legal systems, there is only “possession” of certain information.
- The value of undisclosed information does not lie in the inventive step or novelty -- even a list of clients can be protected, though obviously this is not an invention -- but in the fact that the undisclosed information has commercial value and in the fact that it is secret.
- Unlike patents, which in general last for 20 years from the filing date, in the case of undisclosed information there is no defined time limit. Undisclosed information is protected as long as it is kept undisclosed. The duration of the protection, therefore, depends on the *factual* situation, not on any legal provision.

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<sup>25</sup> See, e.g., articles 16.1 and 28.1 which refer to the “owner” of a trademark and of a patent, respectively.

Though during the TRIPS negotiations the United States suggested the consideration of undisclosed information as “property” -- in accordance with the concepts developed in its own legal system -- that approach did not find support, particularly from European and developing countries.<sup>26</sup>

The TRIPS Agreement clearly does not treat undisclosed information as “property”.<sup>27</sup> The fact that TRIPS deems “undisclosed information” to be a “category” of intellectual property does not imply, as mentioned before, the existence of a property right.<sup>28</sup>

Because the TRIPS agreement embraces an unfair competition approach to undisclosed information, a logic consequence of the Agreement is that Article 39 does not obligate countries to confer *exclusive* rights.

Exclusive rights are merely one “TRIPS-plus” option to deal with issues covered by Article 39.3. There are heavy costs and ethical concerns associated with such an approach, however. In the absence of mechanisms that permit the use of the data, an exclusive rights system leads to the need for competitors to duplicate tests (often involving suffering of animals) in order to reach results that are already known.

The Article 39.3 obligation may be implemented through less onerous means, such as through the legal faculty to impede the use of information acquired through dishonest practices (e.g. espionage,

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<sup>26</sup> On the different approaches in continental and common law with regard to trade secrets, see Coleman, 1992; Font Segura, 1999.

<sup>27</sup> According to Engelberg, U.S. law does not recognize “any property rights in the data submitted to support an application for approval of a new drug... The non-patent, market exclusivity provisions of the Drug Competition Act of 1984 were created as an arbitrary means of providing investment incentive for the development of drug products that had little or no patent protection and not as a purposeful determination to create a new form of intellectual property based on undisclosed data”.

<sup>28</sup> It is generally accepted, particularly under European law, that unfair competition is one of the disciplines of industrial property, and it is in this sense that article 1.2 should be interpreted.

breach of confidence), as background for an independent submission for marketing approval.

Implementing legislation may also require the subsequent user to pay compensation, without providing for exclusive rights. The U.S. FIFRA, for instance, recognizes the possibility of using the originator's test data for the approval of a subsequent application, without the originator's consent but with payment of compensation. The law thus establishes a form of compulsory licensing for such data. The United States required such a compulsory licence -- without payment of compensation -- in approving Dow Chemical's acquisition of Rugby-Darby Group Companies. Approval of the merger was contingent on the issuance of a licence for registration data to all potential competitors (see Box 7).

**Box 7**

**Compulsory licensing in the U.S. involving test data**

***Acquisition of shares of Rugby-Darby Group Companies by Dow Chemical Co.***

The Federal Trade Commission required Dow to license to potential entrants, intangible dicyclomine assets, including all formulations, patents, trade secrets, technology, know-how, specifications, designs, drawings, processes, quality control data, research materials, technical information, management information systems, software, *the Drug Master File, and all information relating to the United States Food and Drug Administration Approvals* that are not part of the acquired company's physical facilities or other tangible assets.

Source: [www.cptech.org](http://www.cptech.org)

In sum, Article 39.3 -- interpreted according to the ordinary meaning of the words used, in their context (notably Article 39.1)

and taking into account the object and purpose of the Agreement as expressed in Articles 7 and 8 -- does not require the granting of exclusive rights.<sup>29</sup> The obligation that it imposes may be satisfied by other means, not specified in the Agreement. As stated by UNCTAD in relation to data covered by Article 39.3,

*“authorities are not prevented...from using knowledge of such data, for instance, to assess subsequent applications by third parties for the registration of similar products”* (UNCTAD, 1996, p.48).

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<sup>29</sup> See also Watal (2001) who concludes that “in the end in the TRIPS text there is no clear obligation not to rely on the test data for the second or subsequent applicants nor a fixed duration of market exclusivity, failing which the first registrant is assured reasonable compensation. This is a clear contrast to the corresponding provisions in NAFTA” (p. 199).

## VII. THE EXCLUSIVITY APPROACH

The pharmaceutical industry, the United States and the European Union disagree with the contention that Article 39.3 does not require the granting of exclusive rights. According to the industry, the only way to effectively protect test data against unfair commercial use is to provide an exclusivity period for the use of the data:

*“To have a meaningful purpose this provision (Article 39.3) must be interpreted to require the protection of data against use by the competitors. Even if there is some concern about government use of such data in a commercial manner, it is minuscule in comparison to the problem of competitors’ use of the data. Consequently, in light of the maxim of statutory construction that a provision will be interpreted so that no part will be inoperative or superfluous, void or insignificant, Article 39 para.(3) must be interpreted to provide protection against the use of data by competitors for some period of time” (Priapantja, 2000, p. 4).*

The Office of the U.S. Trade Representative (USTR) has interpreted Article 39.3 of the TRIPS Agreement 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 authorised by the original submitter of the data. Any other definition of this term would be inconsistent with logic and the negotiating history of the provision”.*<sup>30</sup>

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<sup>30</sup> Office of the General Counsel, U.S. Trade Representative, “The protection of Undisclosed Test Data in Accordance with TRIPS Article 39.3”, unattributed paper for submission in bilateral discussions with Australia (May 1995).

The United States maintained this position, for instance, in its complaint (initiated in April 1996), under Special 301 Section of U.S. Trade Act, against Australia.<sup>31</sup> Australia did not grant exclusivity, and generic companies only had to demonstrate bio-equivalence in order to obtain marketing approval of a similar product. In addition, Australian authorities granted certificates of free sale which permitted generic companies to export to other countries where marketing approval was automatically granted on the basis of the Australian certificates.

The U.S. argued that the Australian regime violated Article 39.3. The U.S. pressure forced an amendment to the Australian law. Under the Therapeutic Goods Legislation Amendment Act 1998 (No.34, 1998) test data in Australia now have five years of “*exclusivity*”. During this time, another company wishing to register a generic copy of an originator’s product will be required to seek the agreement of the originator company to use its data, or to develop its own data package (Priapantja, 2000, p. 6).

The exclusivity approach was also incorporated, as a result of U.S. demands, in the USA-Jordan Agreement on the Establishment of a Free Trade Area (Washington D.C., 24 October, 2000), according to which “in situations where there is reliance on evidence of approval in another country, Jordan shall at a minimum protect such information against unfair commercial use for the same period of time the other country is protecting such information against unfair commercial use” (Article 22, fn. 11)<sup>32</sup>.

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<sup>31</sup> This case was not brought to a panel resolution under the WTO’s Dispute Settlement Understanding (DSU) rules. The U.S. instead threatened to impose unilateral trade sanctions on Australia, even though TRIPS had already entered into force in both countries. The U.S. also applied economic sanctions to Argentina in 1997, arguing Argentina maintained insufficient protection of confidential information. More recently, the U.S. has started consultations under the DSU on, *inter alia*, Argentina’s compliance with Article 39.3.

<sup>32</sup> In addition, this Agreement establishes a TRIPS-plus standard in relation to the concept of “new chemical entities”: it is understood that such concept “shall also include protection for new uses for old chemical entities for a period of three years” (article 22, fn. 10). The U.S. has also criticized the amendment of the Thai “Safety Monitoring Programme” (SMP) established in 1993 as a

The EU argues, similarly, that Article 39.3 established an exclusivity obligation. All that is left to Member countries, according to the EU, is the determination of the *duration* thereof.<sup>33</sup>

*“the only way to guarantee that no “unfair commercial use” within the meaning of Article 39.3 shall be made is to provide that regulatory authorities should not rely on these data for a reasonable period of time, the determination of what is a reasonable period of time being left to the discretion of the Members.*

*In theory, Article 39.3 appears to give Members the discretion to provide for different means of data protection, although it is very difficult to imagine other ways than non-reliance over a certain period of time, except for a (temporary) refusal to grant any second market approval to similar products (even if the second applicant submits its own data), as is the case in at least one WTO Member and maybe for an obligation to pay as a compensation for reliance on proprietary data without having to obtain consent from the first applicant. The question remains whether such payment would indeed be sufficient to guarantee that any “unfair commercial use” of test data takes place. For instance, it would be essential that such payment reflects the investments made by the original applicant -- which may not always be easy to establish.*

*In theory, any country maintaining an effective system to implement obligations under 39.3 even if different from non-reliance*

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result of USTR demands aimed at ensuring a two years minimum exclusivity period for drugs patented abroad between 1986 and September 1991. In January 2001 the SMP was amended and generics companies were allowed to conduct bioequivalence studies at any time regardless of whether or not the original products are under the SMP. If the original products are under the SMP, however, those generic products must also be under the SMP. According to the Thai authorities, the SMP had led to unaffordable high prices for new drugs. In the USTR view, this reform would mean the relinquishment of the benefits affording data protection in accordance with the U.S.-Thai 1993 Bilateral Agreement, and would create – at least until a “satisfactorily TRIPS-consistent Trade Secrets Law is enacted and implemented in Thailand -- an unacceptable gap in data protection coverage (Kwa, 2001, p. 49-50).

<sup>33</sup> See also Lobato García-Miján, 2000.

*over time, would not be in breach of its TRIPS obligations, but we are not aware of many alternatives and it is clear that what the TRIPS-negotiations had in mind was data exclusivity over a certain period of time. On the other hand, as it does not set any time limit, Article 39.3 would not prevent a country from providing for data exclusivity for an unlimited period of time” (EU, 2001, p. 4-5).*

The EU position suffers from several shortcomings, however. First, had the negotiating parties agreed to embrace the concept of exclusivity, they simply could have done so explicitly. The TRIPS Agreement’s obligations in relation to copyrights, trademarks, industrial designs, patents and integrated circuits (via incorporation of the Washington Treaty), all explicitly provide for exclusivity.

The EU admits that there was substantial disagreement during negotiations:

*“It must be admitted that the following of Article 39.3 does not, from a prima facie reading, appear to impose data exclusivity during a certain period of time. This lack of clarity is the obvious result of a difficult negotiation process where divergences of views arose between developing and industrialized countries as to the necessity of EC/U.S. like type of data protection as well as among industrialized countries on the length of the data exclusivity period” (EU, 2001, p. 3).*

The disagreement among the parties was, however, more substantial than that argued by the EU, and there was no international established practice on which to rely. The negotiating history of Article 39.3 reveals that the parties considered at length, but did not adopt, text which clearly required exclusivity for test data.

Second, if the negotiating parties only left the Members the freedom to determine the *duration* of the exclusivity period, on what basis could a panel or the Appellate Body establish an “adequate” duration? The basic rule of Article 3.2 of the WTO’s Dispute Settle-



ment Understanding prohibits dispute settlement bodies from adding to or subtracting from WTO agreement rights.<sup>34</sup> The EU itself admits that there was disagreement among the developed countries even about the duration of such period:

*“Would this be 5 years (as in the case inter alia in US), 4 years or 3 years? This remains an open question”.*

As noted by Watal,

*“It can be argued that if the intention had been to have such exclusive marketing rights, this term, which is used in Article 70.9 of TRIPS, would have been used here too. Further, given the differences in the TRIPS and NAFTA texts of this provision, it is clear that the scope and purpose in TRIPS is intended to be more limited as otherwise the text would have been as specific. No additional obligations, which are not present in the text, can be imported through interpretation. Therefore, a reasonable interpretation would be that the obligation on the authorities would be to keep the test data secret and to prohibit others from accessing this test data for unfair commercial use, such as sale to rival firms” (Watal, 2001, p. 204).*

In sum, Article 39.3 clearly requires some form of protection for test data. Its main purpose is not to prevent the commercial use of such data by governments, but the use by competitors. The wording, context and purpose of the article does not support an interpretation that the required protection can be implemented only on the basis of an *exclusivity* protection. This interpretation is confirmed by the his-

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<sup>34</sup> Article 3.2: “Recommendations and rulings by the Dispute Settlement Body cannot add to or diminish the rights and obligations provided in the covered agreements”.

tory of the negotiation of the TRIPS Agreement, as reviewed below.<sup>35</sup>

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<sup>35</sup> The suggested interpretation has also been held by the Africa Group, Barbados, Bolivia, Brazil, Dominican Republic, Ecuador, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand and Venezuela in a recent submission to the Council of TRIPS on "TRIPS and Public Health": "Protection of Test Data: Article 39.3 of the TRIPS Agreement leaves considerable room for Member countries to implement the obligation to protect test data against unfair competition practices. The Agreement provides that "undisclosed information" is regulated under the discipline of unfair competition, as contained in article 10 *bis* of the Paris Convention. With this provision, the Agreement clearly avoids the treatment of undisclosed information as a "property" and does not require granting "exclusive" rights to the owner of the data" (para. 39) (IP/C/W/296, 19 June, 2001).

## VIII. THE HISTORY OF THE TRIPS NEGOTIATIONS

The history of the TRIPS Agreement negotiations also provides important evidence for interpreting Article 39.3. Such history has been accepted in recent WTO jurisprudence as an interpretative source under Article 31 (2) of the Vienna Convention on the Law of the treaties. It has been used to *confirm* the interpretation reached by the application of the principles of Article 31 (1) of the Convention.<sup>36</sup>

An early precedent of Article 39.3 can be found in the “Statement of Views of the European, Japanese and United States Business Communities”,<sup>37</sup> which also influenced the drafting of other articles of the TRIPS Agreement. In their submission, the business communities advocated for the protection of test data as follows:

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

This proposal clearly specified the obligation to establish a data exclusivity period. The same approach was reflected in the U.S. proposal:

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<sup>36</sup> See, e.g. the panel report in *United States-Section 110(5) of the Copyright U.S. Copyright Act*, WT/DS160/R, 15 June 2000, para. 6.50; *United States-Section 211 Omnibus Appropriations Act of 1998*, WT/DS176/R, 6 August, 2001, para.8.378.

<sup>37</sup> See Annex III of Beier and Schricker, 1989.

*“Contracting parties which require that trade secrets be submitted to carry out governmental functions, shall not use the trade secrets for the commercial or competitive benefit of the government or of any person other than the right-holder except with the right holder’s consent, on payment of the reasonable value of the use, or if a reasonable period of exclusive use is given to the right-holder”.<sup>38</sup>*

It is interesting to note that this proposal referred to the “commercial or competitive benefit” obtained by a third party, rather than to “unfair commercial use” as is the Agreement’s text. The proposal is based on the effects of the use (the creation of a benefit), while Article 39.3 is based on an ethical qualification of the use as “unfair”. The U.S. proposal turned on whether a commercial or competitive benefit (independently of the qualification of the use that generated it) was obtained; under Article 39.3, the key issue is whether there is unfairness in the use (as provided by Article 10bis of the Paris Convention) and not whether a third party obtains a benefit.

The negotiating parties considered requiring test data exclusivity, but rejected this approach. Bracketed text under consideration at the Brussels Ministerial Meeting (December 1990) would have required not less than five years of data exclusivity. The draft read as follows:

*“Parties, when requiring as a condition of approving the marketing of new pharmaceutical products or of a new agricultural chemical product, the submission of undisclosed test or other data, the originator of which involves a considerable effort, shall [protect such data against unfair commercial use.*

*Unless the person submitting the information agrees, the data may not be relied upon for the approval of competing products for a reasonable time, generally no less than five years, commensurate with the efforts involved in the origination of the data, their nature, and the expenditure involved in their preparation. In addition, Parties*

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<sup>38</sup> See MTN.GNG/NG11/W/70, reproduced in Correa and Yusuf, 1998..

*shall] protect such data against disclosure, except where necessary to protect the public]”.*<sup>39</sup>

Notably, this text also explicitly included a prohibition on *reliance* on the data submitted by the originator. But this concept disappeared from the final text. The negotiating history of Article 39.3, in sum, does not support the thesis that it was intended to provide exclusive rights.<sup>40</sup> On the contrary, it shows that such concept was rejected. It is also suggestive in this sense that the most active proponents of such approach are currently proposing to *review* the TRIPS Agreement in order to include an exclusivity period<sup>41</sup>.

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<sup>39</sup> See Gervais, 1998, pp. 182-183.

<sup>40</sup> The EU has pointed out that “according to one commentator, the U.S. negotiations finally decided to drop the more explicit language of above drafts because they did not view such wording as essential because, in any event, “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” (EU, 2001, p. 4).

<sup>41</sup> In its position paper on the WTO Millennium Round, the International Federation of Pharmaceutical Manufacturers’ Association (IFPMA) has called, *inter alia*, for the adoption of a 10-year data exclusivity period (see “What is at stake in Seattle”, in [www.pharma.org](http://www.pharma.org)). See also IPI (2000), where it is noted that Article 39.3 “requires WTO Members to protect health registration data from disclosure or unfair commercial use, but its exact boundaries of “unfair commercial use” are not entirely clear (p. 26).



## IX. CONCLUSIONS

The use by health authorities and competitors of test data which must be submitted to obtain marketing approval of pharmaceutical (and agrochemical) products has been subject to specific regulations in several jurisdictions. Some developed countries, notably the U.S. and EU, have established data protection regulations based on the exclusive use of such data by the originator company. In other countries, however, off-patent generic products can be approved by relying on the data available to health authorities or by reference to a prior registration either domestic or in third countries. In all cases, the physical and chemical similarity (or essential similarity) with the registered product must be demonstrated.

The TRIPS Agreement has obliged WTO Member countries to treat test data as a component of “intellectual property”. However, the rationale for test data protection is the investment made in data production, rather than their creative or inventive content.

Article 39.3 of the TRIPS Agreement requires data protection against disclosure and “unfair commercial use”. Article 39.3 develops Article *10bis* of the Paris Convention; that is, it requires the protection of data against dishonest commercial practices.

The non-disclosure obligation admits exceptions where necessary to protect the public, and in other cases where measures are adopted to ensure that the information is not used in an unfair commercial manner. Considerable room has been left to Members for defining the grounds for the application of these exceptions.

In implementing the obligation to protect against unfair commercial use, the Member States can determine, in accordance with their own values and practices, the standards demarcating dishonest commercial practices. Further, the TRIPS Agreement has

deferred to Members the determination of the legal means to be used in order to make such protection effective. Hence, Members may opt for means of protection against unfair commercial use which allow for the approval of “similar” products without the use of the data or relying on them. Members may also opt, but are not obliged to, grant “TRIPS-plus” protection on the basis of data exclusivity, as some countries currently do.

In making such choices, policymakers will have to weigh the protection of the interests of originator companies against the importance of creating a competitive environment in order to increase access to medicines that are outside patent protection. From a public health perspective, the introduction of TRIPS-plus standards does not seem the best approach for developing countries.

In sum, developing countries should carefully consider the scope of regulations on approval of pharmaceutical products. Such regulations should be enacted with a pro-competitive intent, in a manner that maximizes legitimate competition and access to drugs, while respecting the legitimate interests of the originators of data in accordance with the standards of protection established by the TRIPS Agreement.



## **ANNEX I**









### **EXCLUSIVE USE OF DATA AND COMPENSATION UNDER THE U.S. FEDERAL INSECTICIDE, FUNGICIDE AND RODENTICIDE ACT (FIFRA)**

1. Under the “exclusive use” provision, some data are temporarily protected from use by a data submitter’s competitors. FIFRA § 3(c) (1) (D) (i). Registrants are granted a ten-year period of exclusive use for data on new active ingredients first registered after September 30, 1978. FIFRA § 3(c) (1) (D) (i). During that period, no other applicant may use the data to support an application for registration. To be eligible for exclusive use, data must pertain to a “new” complete data package. The second registrant, however, is not necessarily required to duplicate exactly the original submitter’s data package.
2. Under the “data compensation” provision, most data can be used by any company willing to pay compensation to the data submitter. FIFRA § 3(c) (1) (D) (ii). Compensation is required whenever data submitted after December 31, 1969 is considered by EPA in support of another company’s registration. § 3(c) (1) (D) (ii). The duty to pay compensation, however, ends fifteen years after the data are submitted, after which no further payment is required for use of the data. § 3(c) (1) (D) (iii). In the case of an active ingredient subject to exclusive use protection, the data are subject to compensation for five years after the ten-year period of exclusivity expires.
3. Under the “joint data development” provision, two or more registrants can agree to develop jointly, or to share the cost of, new data needed for re-registration or to respond to data call-ins. FIFRA § 3(c) (2) (B) (ii). Registrants may agree to develop jointly new data needed by EPA for re-registration. FIFRA § 3(e) (2) (B) (ii). Applicants for re-registration which are not developing re-registration data either alone or jointly must offer to share in

the cost of the data being developed by other registrants. See FIFRA §§ 4(d) (3) (B) (ii), 4(e) (1) (H) (ii). FIFRA does not establish a formula or standard for determining the amount of compensation under § 3(c) (1) (D) or the manner in which costs should be shared under § 3(c) (1) (D). Instead, the statute leaves it to the parties themselves to work out compensation or cost sharing arrangements, or to agree upon a dispute resolution procedure. Any party, however, has the right to initiate binding arbitration proceedings in order to resolve a data compensation or cost sharing dispute. FIFRA § 3(d) (1) (D) (ii), 3(c) (2) (B) (iii).


4. Under FIFRA's binding arbitration provisions, data compensation or cost sharing disputes can be resolved by a neutral arbitrator. FIFRA § 3(c) (1) (D) (ii), 3(c) (2) (B) (iii). In the *Thomas v. Union Carbide Agricultural Products Co.*, 473 U.S. 568 (1985). case, several pesticide manufacturers challenged the FIFRA arbitration system on the grounds that it delegated too much power to an arbitrator to determine compensation, without review of the soundness of arbitration awards by the federal courts. The Supreme Court concluded that this delegation of adjudicatory power to arbitrators, rather than the courts, does not violate the "separation of powers" required by the Constitution. 473 U.S. at 592-93. A federal district court subsequently held that the lack of a standard in FIFRA for measuring compensation is not unconstitutional. *PPG Industries v. Stauffer Chemical Co.*, 637 F. Supp. 85 (D.D.C.1986), *appeal dismissed*, No. 86-5502 (D.C. Cir.Nov.4, 1987).

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