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Unfair Competition Under the TRIPS Agreement: Protection of Data Submitted for the Registration of Pharmaceuticals
Carlos María Correa*

I. INTRODUCTION

As a condition for registration of pharmaceutical products, national authorities normally require registrants to submit data relating to quality, safety, and efficacy. 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 the new product). In such a system, other companies (often "generics" manufacturers) cannot rely on the data submitted by the first applicant for the commercialization of a similar product. The rationale for this exclusivity model is to permit the originator of data to recover the investments made for his 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 or on the registration made by a foreign authority to process and approve third parties' subsequent applications on similar products. This approach emphasizes that the registration of products should not erect barriers to

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otherwise legitimate competition. The registration system should promote price competition and access to more affordable medicines.

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 Agreement on Trade Related Aspects of Intellectual Property Rights (“TRIPS Agreement” or “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.

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. 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 World Trade Organization (“WTO”) members freedom to apply different approaches for test data protection and, in particular, the extent to which a competitive model—protection without exclusivity—is compatible with the minimum standards set forth by Article 39.3.

This paper first describes national legal practices with respect to protection of test data before the adoption of the TRIPS Agreement. It then examines the obligations established by Article 39.3 of the TRIPS Agreement and, finally, discusses the legal means that states may adopt to provide protection against commercial use of such data.

II. NATIONAL PRACTICES BEFORE TRIPS

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 US adopted a regulatory data protection regime for pesticides, and, in 1984, regulatory exclusivity provisions for medicines. It provides for five years of exclusivity for new chemical entities, and three

1. 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.
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.

The European Union has provided exclusivity protection for the data filed in support of marketing authorizations for pharmaceuticals since 1987. One of the original objectives of its regime was to compensate for the lack of patent protection for pharmaceuticals in some of the EC members (Portugal and Spain). During the exclusivity period, health authorities cannot rely on an originator’s test to approve other applications without the originator’s consent. The minimum period of such protection is six years, but ten years is obligatory for “high technology products” (most biotechnology products), and also for new chemical entity authorization granted by the European Medicines Evaluation Agency ("EMEA"). EMEA may also grant ten 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.”

Most member states (Belgium, France, Germany, Italy, the United Kingdom, the Netherlands, and Sweden) have applied the ten year period to all medicinal products. 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’.

Article 1711 of the North American Free Trade Agreement ("NAFTA") also established 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 the TRIPS Agreement was concluded, few countries had adopted the exclusivity approach developed in the United States and Europe. Most countries

2. See Jayashree Watal, *Intellectual Property Rights in the WTO and Developing Countries* 201 (Kluwer 2001) (noting that member states are also given the option of national implementation in cases of products other than biologicals, resulting in less intellectual property protection in countries such as Spain, Portugal, and Greece).
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. In some countries and territories (for example, Argentina, Singapore, Taiwan, and Hong Kong) it was sufficient to prove that a similar product had been approved or commercialized in a foreign country.

### III. TRIPS AND DATA PROTECTION

#### A. PROTECTION OF TEST DATA UNDER THE TRIPS AGREEMENT

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 negotiating parties conceived of the regime for test data 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 exclusendi*, 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 a right. Likewise, there are many situations in which copyright protection only allows the title-holder to claim a remuneration, but not to prohibit unauthorized acts.

As Article 39.3 itself indicates, test data protection is a reward for the investment in data production, rather than for the creativity or inventiveness involved. Test data are developed in accordance with standard protocols and procedures, involving a

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7. Though the time of the TRIPS Agreement's adoption 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 least-developed countries, only a minority of the WTO members apparently confer data exclusivity. New Zealand introduced an exclusivity period in 1994, as part of implementing legislation of the TRIPS Agreement, as did Australia in 1998 as a result of the US action under § 301 of the US 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.

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 permit one to draw any conclusion about the nature of the protection conferred. In particular, it does not indicate that such data should be protected through a grant of exclusive rights.

B. CONDITIONS OF PROTECTION UNDER THE TRIPS AGREEMENT

1. Data Necessary For Marketing Approval

A basic premise for the application of Article 39.3 is that a member country requires data submission as a condition for obtaining marketing approval of pharmaceuticals or agrochemical products.

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 regulations require the submission of such data. If a member country opts not to require those data, Article 39.3 will 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. The actual set of data protected will vary from country to country, depending on the scope of a country's data submission requirement.

2. Protected Data

The subject matter of the protection under this Article is written material that details the results of scientific health and safety testing of drugs and agrochemicals, in relation to human, animal, and plant health, tests for environmental impact, 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, storing and packaging methods and conditions, but only to the extent that submission of this information is necessary to obtain marketing approval.

3. Undisclosed Data

To qualify for protection under Article 39.3, the pertinent information must be undisclosed. This means that information that is already public (because it has been published in scientific journals, for example) 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.

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9. This is generally the case for a large part of the information needed to obtain registration of a pharmaceutical product.
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 materials accompanying an application for marketing approval are confidential and need to be protected, and which are not. The undisclosed or disclosed nature of information is an objective feature, and it is not dependent on the label given by the applicant to the information that it is submitted. Hence, the 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 TRIPS Agreement, however, does not define the term “new.” While the term presumably does not impose a patent-like standard of novelty, member countries may choose under the Agreement to apply such a standard.

It may be the case 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 approval of the same drug, or if the same drug were not previously used in commerce.

Article 39.3 also does not clarify 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.

Occasionally a product known and used in another field may find a new application in the pharmaceutical sector. Such a new therapeutic product (generally known as “first indication”) may not be deemed 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.

All the above interpretations are equally permissible because 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 maneuver to implement the Agreement’s provisions.

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10. A large part of the clinical trials and analytical data submitted for marketing approval is generally published. In the case of the EU regulations, as amended through Directive 75/318 and interpreted by case law, the possibility of obtaining market approval on the basis of published literature is applied very restrictively, only 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. See Dodds-Smith, Data Protection at 111 (cited in note 5).


12. See id.
Based on the ordinary meaning of the terms used, the Agreement may also be interpreted to create an obligation to provide for protection when the test data were developed for a new use of a pharmaceutical product (generally called "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 itself.

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, et cetera, of existing drugs, since there would be no novel chemical entity involved. The European Court of Justice indirectly addressed this issue in Regina v The Licensing Authority Established by the Medicines Act 1968, ex parte Generics (UK) Ltd ("Squibb"). 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.

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 pharmaceutical, 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 an inventive step or novelty). It simply mandates protection when the process of obtaining the data involved "a considerable effort."

The text of Article 39.3 is vague about the type of effort (technical or economic) involved. It is also vague with respect to its magnitude, namely when the magnitude of effort would be deemed considerable. As mentioned, the proponents of this formulation intended to protect the investment made in producing test data.

The extension of intellectual property beyond its boundaries, so as to protect investment and not intellectual contributions, disrupts the essence of a system conceived to reward the creators of original ideas and new inventions. 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 an intellectual property system to solve competition problems that do not relate to the creation or use of ideas.

Nonetheless, Article 39.3 exists and includes the considerable effort standard. Inclusion of this standard suggests that national regulatory authorities may request that the applicant prove that the information for which protection is sought is the result of considerable effort.

6. Non-Disclosure Obligation

Since the TRIPS Agreement's obligations with regard to test data protection relate exclusively to undisclosed information, it seems clear that members' obligations are limited to information effectively requested by and submitted to government which was undisclosed 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 states to determine when a necessity arises, but often impose a heavy burden of proof on the member invoking.17

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.

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.

7. Acts of Unfair Commercial Use

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

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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 light of the Agreement's object and purpose.

a. Unfair

This concept must be understood, as specifically indicated in Article 39.1, in the light of Article 10bis of the Paris Convention. The concept of unfairness 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 clearly objective standard of feeling, instincts, or attitudes toward a certain conduct. Therefore, specific prescriptions involving uniform evaluation of certain acts are extremely difficult.

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 Anselm 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, but the proposal was not incorporated into the final text of the TRIPS Agreement. The US 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. 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 to maneuver they retained when signing the Agreement.

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. Each approach is valid under Article 39.3. Article 39.3 mandates protection against unfair commercial practices, but permits member countries to determine which practices will be deemed commercially unfair. Differences among countries are likely to exist, consistent with Article 10bis of the Paris Convention.

b. 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 would be a substantial difference between the underlying principle in Article 39.1, which refers to relationships between competitors, and Article 39.3, which would include governmental acts. The EU argument, however, disregards the fact that Article 39 develops, and does not add to, Article 10bis of the Paris Convention. Article 39 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. This concept underlies the World Intellectual Property Organization “Model Provisions on Protection Against Unfair Competition,” which, in relation to data protection, suggests the adoption by national laws of provisions on “any act or practice, in the course of industrial or commercial activities.”


Finally, for Article 39.3 to apply, there must be use of the information submitted by the originator. Depending on the applicable legal system, national health authorities can follow different approaches for the approval of a second-entry marketing application. The authority may:

(a) require the second entrant to produce its own testing 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; 
(c) use the originator's data in order to examine second-entry applications technically. In this case, the authority directly relies on the originator's data; or
(d) approve a second application without examining and relying upon the originator's data.

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). Bio-equivalence studies are generally required for this purpose.

In accordance with a strict interpretation of Article 39.3, none of these situations would fall under the concept of unfair commercial use. In case "d" there is no use at all, since the authority does not possess (or use) the testing data, it merely relies on public information and/or on the existence of a foreign marketing approval.

Further, in cases "b," "c," and "d," the competitor does not use the data. The second entrant does not need to have access to the data in any form, since he is not obliged to submit them for product approval.

IV. HEALTH AUTHORITY RELIANCE ON TEST DATA

The nature and extent of data protection rights were examined in *Ruckelsbaus v Monsanto Co* (a US case) and *Bayer, Inc v Canada (Attorney General)* (a Canadian case).

The *Ruckelsbaus* 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. The basic argument of the plaintiff was that the possibility given to a competitor by US law of using the data submitted for the registration of a product without compensation nullified the data originator's "reasonable investment-backed expectation." However, the US Supreme Court described the extensive practice of relying on data submitted by the first applicant in the United States and rejected Monsanto's complaint. The Court 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. In the absence of a specific provision granting an exclusivity period as currently provided by US law, relying on data to approve subsequent applications would not be considered an illegitimate misappropriation of trade secrets.

The General Court of Appeal of Canada decided a second and more significant case in Bayer. Despite the fact that NAFTA provides for a minimum term of exclusivity, the Court found the approval of a subsequent application on the basis of a prior registration to be legitimate. 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. The issue was decided under Canadian law and NAFTA Article 1711. The Court concluded that the Canadian law and NAFTA are responsive to the requirement that innovators of pharmaceutical products disclose confidential information to the government. 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-year protection from 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.

A contrary interpretation holds that even indirect reliance on data constitutes a form of use. Under this interpretation, the competent authority must be proscribed from using the data to support review of second entrant applications for marketing approval for a set amount of time unless authorized by the originator.25

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 reexamination of the data). In the US complaint against Australia,

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for instance, the US 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.”

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.

However, if despite the express provision of exclusivity as contained in NAFTA,
the mere reliance on a prior registration without use of the data does not allow one to
claim exclusivity (as decided in the Bayer case), a fortiori the same conclusion must be
reached when the exclusivity is not specifically established, as in the case of Article
39.3.

In sum, whatever the intention of some of the negotiating parties may have been,
the expression “unfair commercial use,” reasonably interpreted, does not sustain a
reading that Article 39.3 requires the provision of exclusivity or of a compensation.

In fact, an unfair commercial use may be determined to exist in situations in
which a competitor obtains, through fraud, breach of confidence, or other dishonest
practices, the results of testing data and then uses them to submit an application for
marketing approval to 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 in their cost.”

V. MEANS OF PROTECTION AGAINST UNFAIR COMMERCIAL USE

A key issue for the application of Article 39.3 is to determine what is the nature
and extent of the obligation to protect “against unfair commercial use.” 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 the Agreement stipulates that “[i]n
the course of ensuring effective protection against unfair competition as provided in
Article 10bis of the Paris Convention (1967), members shall protect . . . 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 behavior. 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, and 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.

Under the discipline of unfair competition, protection is not based on the existence of property rights. Hence, the provision of protection under such a discipline does not give rise to claims of property rights, with respect to 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, such as trademarks or patents.

During the TRIPS negotiations the US 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 from European and developing countries essentially because of divergences about the legal concept of property as applied to trade secrets.

The TRIPS Agreement clearly does not treat undisclosed information as property. The fact that it deems undisclosed information to be a category of intellectual property does not imply the existence of a property right.

Because the TRIPS Agreement embraces an unfair competition approach to undisclosed information, a logical consequence 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


29. For the different approaches in continental and common law with regard to trade secrets, see generally Allison Coleman, The Legal Protection of Trade Secrets (Sweet & Maxwell 1992).

30. 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 of the TRIPS Agreement should be interpreted.
exclusive rights system leads to the need for competitors to duplicate tests (often involving suffering of animals) to reach results that are already known.

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. It has been used to confirm the interpretation reached by the application of the principles of Article 31.1 of the Vienna Convention.  

The negotiating parties considered requiring test data exclusivity but rejected this approach. Bracketed text under consideration at the Brussels Ministerial Meeting in December 1990 would have required not less than five years of data exclusivity. That text also explicitly included a prohibition against reliance on data submitted by the originator. But this concept disappeared from the final text. It is also suggestive in this sense that the most active proponents of such an approach are currently proposing to review the TRIPS Agreement to include an exclusivity period.

The Article 39.3 obligation may be implemented through less onerous means, such as laws to deny the use of information acquired through dishonest practices (for example, espionage or breach of confidence) in an independent submission for marketing approval.

Implementing legislation may also require the subsequent user to pay compensation, without providing for exclusive rights. The US Federal Insecticide, Fungicide, and Rodenticide Act ("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


32. The EU has pointed out that "[a]ccording to one commentator, the US negotiators 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.'" European Union, Questions on TRIPS and Data Exclusivity at 20 (cited in note 20).

compulsory license 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 license for registration data to all potential competitors.34

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.35 The obligation that it imposes may be satisfied by other means, not specified in the Agreement. As stated by the UN Conference on Trade and Development (“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.”36

In sum, Article 39.3 clearly requires some form of protection for test data. Its main purpose is not to prevent the use of such data by governments, but such use by competitors. The wording, context, and purpose of the article do 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 history of the negotiation of the TRIPS Agreement.37

VI. Conclusion

The use by health authorities and competitors of test data that 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 US and EU, have established data protection


35. See also Watal, Intellectual Property Rights at 199 (cited in note 2) (concluding 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.”).

36. UNCTAD, The TRIPS Agreement and Developing Countries 48 (UN 1997); see also Watal, Intellectual Property Rights at 204 (cited in note 2) (noting that exclusive marketing terms are used elsewhere in TRIPS, and for that reason it is improper to believe that treaty provisions without such terms incorporate any further obligations on authorities to keep test data secret or to prohibit others from accessing the test data).

37. The suggested interpretation has also been held by the Africa Group of the WTO. See TRIPS and Public Health, para 39, WTO Doc No IP/C/W/296 (June 29, 2001): 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 10bis 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.
regulations based on the exclusive use of such data by the originator company. In other countries, however, off-patent generic products can be approved on the basis of similarity by relying on the data available to health authorities or on a prior registration in third world countries.

The TRIPS Agreement has obliged WTO member countries to treat test data as a component of intellectual property. Yet, the TRIPS Agreement has deferred to members in the determination of the legal means to be used to make protection of intellectual property effective. Hence, members may opt for protection against unfair commercial use which allows for the approval of similar products without the use of, or reliance upon, the previously submitted data. Members may, but are not obliged to, opt 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 to increase access to medicines which are outside of patent protection. From a public health perspective, the introduction of TRIPS-plus standards does not seem to be the best approach for developing countries.

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 beneficial 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.