Carlos M. CORREA, University of Buenos Aires
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PROTECTING TEST DATA FOR PHARMACEUTICAL AND AGROCHEMICAL PRODUCTS UNDER FREE TRADE AGREEMENTS

This paper examines the content and importance of test data, the industry's view point on its protection, and the obligations imposed on the matter by the TRIPS Agreement and by recent free trade agreements (FTAs) subscribed with the USA.

What are test data?

The development of a *new* drug involves different stages, during which a variety of "test data" are produced in order to determine its efficacy and non-toxicity. In the preclinical stage, the new chemical entity (NCE) is tested in animals to assess its pharmacodynamic, phamacokinetic and toxicological profile. Based on these results, clinical studies in human beings are carried out in three phases.

In *Phase I* 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 member 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 underway, long-term animal toxicity studies are undertaken to determine the effects of prolonged exposure and the effects on subsequent generations.

Test data permit health authorities to assess whether to grant marketing authorization for a new chemical entity. 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 or administering it for a new therapeutic indication or group of patients (e.g. pediatric use) would require new trials and approval by the competent authority.

In the case of chemicals for agriculture (agrochemicals) efficacy and toxicity studies are also required, as well as an assessment about the impact of a product in a particular environment or with regard to a particular crop.

The results of all these studies constitute the "test data" that are protected under article 39.3 of the TRIPS Agreement as follows:

> "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 agains 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 ae protected against unfair commercial use".

Importance of test data

Test data are important for health and environmental purposes, since they permit national authorities and users to evaluate the merits and risks of new drugs and agrochemicals. They are also important for commercial purposes, as the availability of the data is a condition for obtaining marketing approval of new products, modifications or new uses of existing products[1].

The development of test data typically represents more than sixty percent of the R&D costs of new drugs (Grabowski, 2002)[2]. Given their nature (they are *scientific* data obtained on the basis of standard protocols) they are outside patent protection.

According to IFPMA (2004), "the development and bringing to market of a new drug requires the originator to conduct extensive chemical, pharmacological, toxicological and clinical research and testing, at an average cost of US $800 million, and taking 10 to 15 years to complete. The data generated by such work, while proprietary to the originator, must be submitted to the regulatory authorities of countries around the world in order to obtain approval to market the drug".[3]

On its side, Crop Life International (2004) argues that "while in the pharmaceutical sector one of every 5000 molecules investigated is approved by the FDA for marketing, in the agrochemical sector only one in approximately 140,000 studied molecules makes it from the laboratory to the field. Because of their chemical nature and the wide range of organisms potentially affected by their use, agrochemical products must pass more than 120 different safety tests. Additionally, efficacy tests must be repeated in each country, even in several regions of one country, due to differences in crops, pests, agronomical practices, climate conditions and terrains…The average development cost for a new agrochemical in the year 2000 was Euros 200 million (US$ 184 million), and the average development time is over 9 years from discovery to first commercialisation".[4]

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

[2] See, e.g, Grabowski, H (2002), Patents and new product development in the pharnaceuticak and biotechnology industries, paper presented at Duke University (mimeo). It is also important to note that while private companies generally undertake the development of new drugs, basic research and discovery is made by public institutions.

[3] IFPMA (2004), A review of existing data exclusivity legislation in selected countries (Third Revised Version, January).

[4] Crop Life International (2004), Position Paper on the protection of safety and efficacy data for existing and new crop protection chemicals, Brussels.

***Sui generis* protection of test data**

Both the figures for the cost and duration of testing activities are highly contentious[5]. Whatever costly and long they are, the research-based pharmaceutical and agrochemical industry, supported by the US and some European governments, actively seek to ensure a period of exclusive use of the data after marketing approval. During this period, national authorities would be prevented from *using* or *relying* on the data for marketing approval of generic versions of already registered products.

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 USA, Europe, Japan and other countries, the data submitted for the registration of pharmaceutical and agrochemical products, are subject to *sui generis* systems 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[6].

In other countries[7], national authorities rely on data submitted by the first applicant[8] to process and approve third parties' subsequent applications for a similar product, 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.

The issue of data protection has become especially relevant in countries that until recently did not provide patent protection for pharmaceuticals and in those under the transitional period that the TRIPS Agreement allowed until January 1, 2005. In these countries, there is a large pool of pharmaceutical products in the public domain which are subject to patent protection in other countries. Exclusive rights over data could, if provided, become a substitute for patent protection over such products.

Data protection has also become a strategic tool to compensate for the declining rate of industry's

[5] See, e.g. CIPR, Integrating intellectual property in development policy, London, 2002. In 1980, the duration of the clinical studies varied from about 1 to 7 years and averaged slightly less than 3 years. This period has been significantly reduced since then (Raggett, Tom, (1996), GATT and patent reform. The global strengthening of patent protection and the implications for the pharmaceutical industry, FINANCIAL TIMES Management Reports, London, p. 26).

[6] The conferred exclusivity, however, does not prevent generic firms to develop their *own* data in order to obtain marketing approval of a product (provided that it is off-patent).

[7] In a document on the status of data protection in selected countries, IFPMA identifies countries where data protection is deemed to be conferred on the basis of exclusive rights, as well as many (such as Argentina, Brazil and Israel) that have refused to grant such rights. See IFPMA (2004).

[8] In some cases, national authorities do not request the relevant test data and just rely on the approval granted in a foreign country.

success in developing new drugs[9]. As finding new chemical entities has become more difficult, despite the potential of new scientific tools (such as genomics, proteomics, combinatorial chemistry), companies tend to exploit the existing pool of products by, inter alia, developing new indications or combinations of drugs for which new clinical trials are done.

The TRIPS standard on data protection

Before the entry into force of the TRIPS Agreement, countries had full latitude to determine whether to confer or not protection on test data. The Agreement introduced the first *international* standard on the subject, as contained in its Article 39.3. But the Agreement only established broad parameters for national rules, thereby allowing WTO Member countries freedom to apply different models for such protection[10].

Article 39.3 of the TRIPS Agreement requires Members to protect test data submitted for the marketing approval of pharmaceuticals and chemical products for agriculture.

Test data must be protected if national authorities require its submission. Thus, if they rely on an approval granted in a foreign country, the obligation does not apply. In addition, Article 39.3 does not require protection be given to data that are already publicly available, but to only to undisclosed data. Further, protection is mandated only for new chemical entities. Members have considerable discretion in defining this concept, which excludes anyway second indications, new formulations or dosage forms. Finally, in order to grant protection, national regulatory authorities may request the applicant to prove that the information for which protection is sought is the result of significant investment.

Article 39.3 requires countries to protect test data against "unfair commercial use". Protection is to be conferred, hence, against dishonest commercial practices. Practices expressly required or permitted by the law (such as abbreviated or summary procedures of marketing approval) may not be deemed dishonest. Granting marketing approval to a second entrant, based on the similarity with a previously approved product, is not a proscribed "use" under Article 39.3.

Test data must be protected under the discipline of unfair competition, as established in the Paris Convention for the Protection of Industrial Property (article 10bis) and the TRIPS Agreement (article 39.1). Under such discipline *no exclusive rights are granted*, but only the right to take legal action against whom has obtained a commercial advantage by means of a dishonest practice.

Controversies about interpretation

Despite the fact that article 39.3 of the TRIPS Agreement does not provide for the granting of exclusive rights, the research-based industry and governments of some developed countries have argued that investment made for developing test data can only be ensured if a minimum period (e.g. five years for pharmaceuticals, ten years for agrochemicals) of exclusivity is granted.

[9] See FDA Innovation-Stagnation. Challenge and Opportunity on the Critical Path to New Medical Technologies, Washington D.C., 2004.

[10] See, e.g. Lucas R. Arrivillaga (2003), "An International Standard of Protection for Test Data Submitted to Authorities to Obtain Marketing Authorization for Drugs", *The Journal of World Intellectual Property*, Vol. 6 N°1, January.

This argument does not find support in article 39.3 of the TRIPS Agreement[11], since

→ the discipline of unfair competition, applicable in accordance with article 39.1 of the Agreement, does not create exclusive rights;

→ the granting of exclusivity constitutes a drastic derogation to the principle of free competition, which cannot be inferred from a text that does not provide for it;

→ the definition of what an "unfair" or "dishonest" commercial practice is depends on social perceptions in a particular country at a given time:

→ obtaining a commercial advantage, as such, is not condemnable under unfair competition rules[12];

→ the history of negotiations of article 39.3 shows that the US proposal for exclusive rights over data was rejected;

→ despite the fact that a large number of WTO members do not provide for exclusive rights over data, there has been no WTO ruling on the meaning of article 39.3.

The US government initiated a case under WTO rules complaining about Argentina's alleged failure to appropriately protect test data. The dispute was settled at the consultation stage[13] after two years of discussions. Argentina did not accept the US claim that exclusive rights should be granted for test data and maintained unchanged its law. No further action in the framework of the WTO has been taken by USA against Argentina, or any other country that does not recognize data exclusivity. However, the USTR has listed, under the Special Section 301 of the Trade Act, a large number of countries that, according to USTR, do not confer adequate (that is, exclusive) protection for test data.

Data exclusivity in FTAs

Although USA has failed to make its case for data exclusivity in WTO, it was successful in incorporating this TRIPS-plus standard in free trade agreements (FTAs) subscribed with at least one developed (Australia) and many developing countries[14]. These FTAs impose a number of obligations that dilute important flexibilities allowed by the TRIPS Agreement and increase the protection for agrochemical and, particularly, pharmaceutical products.[15]

[11] See Carlos Correa, Protection of data submitted for the registration of pharmaceuticals. Implementing the standards of the TRIPS Agreement, South Centre/WHO, Geneva, 2002.
[12] See, e.g., Kamperman Sanders, Anselm (1997), *Unfair competition Law*, Clarendon Press, Oxford.
[13] See Notification of Mutually Agreed Solution According to the Conditions Set Forth in the Agreement (IP/D/18/Add.1, IP/D/22/Add.1), available at www.wto.org.
[14] Such as Bahrain, Jordan, Panama, Singapore, Morocco, Chile, and the Dominican Republic and Central American countries (CAFTA)[14]. Trade negotiations in course include the Southern African Customs Union, Thailand and three Andean countries (Ecuador, Peru, Colombia).
[15] The FTAs oblige the Parties, *inter alia*, to extend the term of patent protection to compensate for delays in patent examination and in the marketing approval of protected products, as well as to link drug registration to the status of patent protection.

While with different formulations, all FTAs establish data exclusivity *sui generis* regimes requiring exclusive rights for *at least* five years for pharmaceuticals and ten years for agrochemicals[16].

Using data, relying on prior approval

Data exclusivity implies that if an original medicine or agrochemical is approved in a Party, no approval to a generic version thereof can be granted during five or ten years from the date of approval of the original medicine or agrochemical, respectively, in that country, whether by (a) using the data submitted by the originator company or (b) relying on such approval or the approval in another country. For instance, according to article 15.10.1 (a) of CAFTA,

> "If a Party requires, as a condition of approving the marketing of a new pharmaceutical or agricultural chemical product, the submission of undisclosed data concerning safety or efficacy, the Party shall not permit third persons, without the consent of the person who provided such information, to market a product on the basis of (1) such information or (2) the approval granted to the person who submitted such information for at least five years for pharmaceutical products and ten years for agricultural chemical products from the date of approval in the Party".

Despite the fact that, applications for registration can languish for years, and that the company that originated the data has no obligation to file for marketing approval within a limited deadline, the five years period will be counted from the date of approval in the country where the application was made[17].

Waiting period

Some FTAs contemplate a minimum waiting period within which no registration of a product on the basis of the test data used or marketing approval obtained in another country can take place without the consent of the originator of data. For instance, article 16.8 (2) of the US-Singapore FTA provides that

> "If a Party provides a means of granting approval to market a product specified in paragraph 1 on the basis of the grant of approval for marketing of the same or similar product in another country, the Party shall defer the date of any such approval to third parties not having the consent of the party providing the information in the other country for at least five years from the date of approval for a pharmaceutical product or ten years from the date of approval for an agricultural chemical product in the territory of the Party

[16] In a bilateral understanding between USA and South Korea (exchange of letters of March 12, 2002), the latter accepted six years of data exclusivity for drugs and sixteen years for agrochemicals. Guatemala adopted fifteen years data exclusivity for drugs in 2000. A turbulent legislative process subsequently led to the derogation of data exclusivity, its reinstatement for five years, and its derogation again in November 2004

[17] See, e.g., Brook Baker (2004) " The Drug Registration Battlefield: U.S. Trade Policy Erects New, Nearly Impenetrable Barriers to Lower-Cost Generic Medicines of Assured Quality", *Health GAP* , February 16, 2004.

> or in the other country, whichever is later".

CAFTA specifically prevents both the use of test data submitted to a foreign authority as well as relying on the prior approval in a foreign country for five or ten years after the approval of pharmaceutical or agrochemical products, respectively, but allows a Party to limit the waiting period to five years. According to Article 15.10.1 (b):

> "If a Party permits, as a condition of approving the marketing of a new pharmaceutical or agricultural chemical product, third persons to submit evidence concerning the safety or efficacy of a product that was previously approved in another territory, such as evidence of prior marketing approval, the Party shall not permit third persons, without the consent of the person who previously obtained such approval in the other territory, to obtain authorization or to market a product on the basis of (1) evidence of prior marketing approval in another territory or (2) information concerning safety or efficacy that was previously submitted to obtain marketing approval in another territory for at least five years for pharmaceutical products and ten years for agricultural chemical products from the date approval was granted in the Party to the person who received authorization in the other territory. In order to receive protection under this subparagraph (b), a Party may require that the person providing the information in the other territory seek approval in the Party within 5 years after obtaining marketing approval in the other territory".

It has been questioned whether in the absence of an application by the originator during the five years term referred to in this provision, a national authority could grant marketing approval to a similar product and if so, whether this authorization would subsist after the originator obtains marketing approval in the Party. This CAFTA provision seems to give the originator company a lead time of at least five years over its competitors. Although the five years period is counted from the date of the originator's approval, it .is difficult to interpret that before that date it would be possible for national authorities to grant marketing approval to a third party without the consent of the originator company. This situation is most worrying, since it allows the originator of data to keep the market of a Party without supply of the product eligible for data protection for at least five years.

If this waiting period is fully utilized by the originator company, it may enjoy at least a full ten years (pharmaceuticals) of fifteen years (agrochemicals) period of protection during which no other party would be able to use the relevant test data or rely on a foreign marketing approval.

It is interesting to note that no waiting period was established in some FTAs. This would allow a Party to shorten the period in which the originator of data may abstain from commercializing in a Party and still preserve the exclusive use of his test data. For instance, the government of Chile (which is not subject under the US-Chile FTA to a waiting period) has prepared regulations requiring the originator of data to submit an application for approval within one year from the date of a foreign approval of the product, as a condition to enjoy data exclusivity protection in Chile. This is a commendable approach, since it limits the negative consequences for public health and agricultural production of data exclusivity protection. It seems illogical to provide the originator of test data (which lack any inventive feature) a waiting period five times longer than the priority period allowed to an inventor under the Paris Convention for the Protection of Industrial Property.

New products/chemical entities

WTO Member countries are bound to grant protection under article 39.3 of the TRIPS Agreement to pharmaceutical and agricultural chemical products that incorporate "new chemical entities", that is, molecules that were not previously incorporated into a product approved for marketing in any country. Some US FTAs (e.g. Singapore), however, oblige the Parties to apply a much broader concept of "pharmaceutical or agricultural chemical product" without specific reference to "new chemical entities". In other cases (e.g. CAFTA) the concept of "new chemical entity" is limited to entities not previously approved in the same Party. Hence, a product previously approved in a foreign country will continue to be "new" for that Party until it is registered there, even if this happens many years after its first marketing approval.

In addition, FTAs allow a Party to provide a shorter term of protection if on the date of its implementation of the TRIPS Agreement, the Party had in place a system for protecting pharmaceutical or agricultural chemical products not involving new chemical entities from unfair commercial use. Although apparently benefiting *any* Party, this exception will allow USA to keep a period of three years, as provided for in its national law, for products not involving new chemical entities, while imposing five years to other parties in FTAs.

Undisclosed data

One of the important limitations to the scope of article 39.3 is that it only applies to *undisclosed* information. However, the test data required for approval are normally published by health authorities (for instance, in the web page of the US Food and Drug Administration). Not surprisingly, a major objective of the US industry has been to extend the prohibition to directly or indirectly use test data by third parties and national authorities even if publicly available. This objective has been attained in different ways.

While the concept of "undisclosed" data is maintained in the US-Chile FTA, it has disappeared from other FTAs (e.g. Singapore and Morocco) where reference is made to the submission of "information" without qualification.

In the case of CAFTA, a tortuous legal approach has been followed. According to article 15.10.1 (d), "each Party shall not consider information accessible within the public domain as undisclosed data" *for the purposes of this paragraph only*, that is, in relation to the disclosure of data "where necessary to protect the public". But "if any undisclosed information concerning safety and efficacy submitted to a government entity, or an entity acting on behalf of the government, for purposes of obtaining marketing approval is disclosed by such entity, each Party is required to protect such information from unfair commercial use in the manner set forth in this Article". As a result, disclosed data, including information freely available to the public (is deemed, under this legal fiction, to be "undisclosed".

Beyond patent expiry

Some FTAs (e.g. Singapore) establish that the period of data exclusivity will continue in force after the expiry of a patent that covers the product in question. Although this situation may be

rare, there are cases in which data exclusivity may survive patent protection[18].

Early working, compulsory licenses and the Doha Declaration

It is unclear whether data exclusivity would prevent a third party from initiating the procedures for the marketing approval of a generic product *before* the expiry of the exclusivity period. In order to allow for this possibility, the resolution by the European Parliament of December 17, 2003 on centralized drug registration distinguishes between "data exclusivity" (8 years) and "marketing exclusivity" (2 years).[19] Bolar-type activities can be undertaken during this latter period.

Data exclusivity, while in force, may represent an effective barrier for the approval and commercialization of generic versions of pharmaceutical and agrochemical products, even in cases where a compulsory license is granted. During the exclusivity period, in effect, a Party would not be able to approve applications by third parties (including from a compulsory licensee[20]) who do not have the consent of the originator of test data for using them or relying on a prior marketing approval. This barrier may, in principle, also impede the application of the "solution" found by the Council for TRIPS and adopted by the WTO General Council on August 30th, 2003, for the problems raised by paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (hereinafter "the Doha Declaration").[21]

Aware of the political implications of this and other TRIPS-plus standards contained in FTAs, the USA has agreed to state in "side letters" or "understandings" –without referring, however, to the Doha Declaration[22]- that such standards do not affect the Parties' ability to protect public health. For instance, the US and Morocco exchanged letters in June 2004 indicating that:

> "The obligations of Chapter Fifteen of the Agreement do not affect the ability of either Party to take necessary measures to protect public health by promoting access to medicines for all, in particular concerning cases such as HIV/AIDS, tuberculosis, malaria, and other epidemics as well as circumstances of extreme urgency or national emergency. In recognition of the commitment to access to medicines that are supplied in accordance with the Decision of the General Council of 30 August 2003 on the Implementation of Paragraph Six of the Doha Declaration on the TRIPS Agreement and public health (WT/L/540) and the WTO General Council Chairman's statement accompanying the

[18] See Pugatch, Meir P. (2004), Intellectual property and pharmaceutical data exclusivity in the context of innovation and market access, paper presented at the ICTSD Dialogue on Ensuring Policy Options for Affordable Access to Essential Medicines, Bellagio, 12-16 October.

[19] An additional one year of exclusivity is allowed for new indications of existing products.

[20] In the United States a compulsory license may extend to the relevant test data in order to permitting the effective execution of the license. For example, in the case of the acquisition of shares of Rugby-Darby Group Companies by Dow Chemical Co., the Federal Trade Commission required Dow to license to potential entrants into the dicyclomine market, formulations, patents, trade secrets, technology, know-how, specifications, processes, quality control data, the Drug Master File, and all information relating to the United States Food and Drug Administration approvals.

[21] See Correa, Carlos (2002), Implications of the Doha Declaration on the TRIPS Agreement and public health, WHO, Geneva.

[22] The Doha Declaration is mentioned in the Preamble of the Intellectual Property Chapter of the US-Chile FTA.

> Decision (JOB(03)/177, WT/GC/M/82) (collectively the "TRIPS/health solution"), Chapter Fifteen does not prevent the effective utilization of the TRIPS/health solution. With respect to the aforementioned matters, if an amendment of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights enters into force with respect to the Parties and a Party's application of a measure in conformity with that amendment violates Chapter Fifteen of the Free Trade Agreement, our Governments shall immediately consult in order to adapt Chapter Fifteen as appropriate in the light of the amendment".

A similar statement is contained in an "Understanding regarding certain public health measures" made between the signatories of CAFTA on August 5, 2004 and in an exchange of letters with Bahrain. In addition, in a letter by the General Counsel of the United States Trade Representative (USTR) to a Member of the US Congress on the US-Morocco FTA it was stated that:

> "...if circumstances ever arise in which a drug is produced under a compulsory license, and it is necessary to approve that drug to protect public health or effectively utilize the TRIPS/health solution, the data protection provision in the FTA would not stand in the way".[23].

The extent to which a "side letter" or "understanding" may determine the interpretation and application of the intellectual property provisions in FTAs is uncertain. Such instruments may be deemed a "subsequent agreement between the parties regarding the interpretation of the treaty or the applications of its provisions" that should "be taken into account together with the context" (article 31.3 (a) of the Vienna Convention on the Law of the Treaties)[24]. Its possible use as an interpretive tool is likely to be limited. The USTR General Counsel's opinion, moreover, may be ignored by title holders who seek to enforce their rights against potential compulsory licensees.[25]

Ethical implications

The important financial resources and long time required to undertake test data create a market barrier that is too high or insurmountable to generic companies, particularly small and medium companies in developing countries.

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23 See the letter from USTR General Counsel John K. Veroneau to Congressman Levin dated July 19, 2004, available at Inside US Trade.

24 The referred to letter by the USTR General Counsel indicates in this regard: "As stated in the side letter, the letter constitutes a formal agreement between the Parties. It is, thus, a significant part of the interpretive context for this agreement and not merely rhetorical. According to Article 31 of the Vienna Convention on the Law of Treaties, which reflects customary rules of treaty interpretation in international law, the terms of a treaty must be interpreted 'in their context,' and that 'context' includes 'any agreement relating to the treaty which was made between all the parties in connection with the conclusion of the treaty" (*ibidem)*.

25 The Industry Functional Advisory Committee on Intellectual Property Rights for Trade Policy Matters (IFAC-3), which has acted as an advisory body of USTR in FTA negotiations, recalled in relation to the US-Morocco FTA "(i) that the WTO Trade Ministers agreed, in Paragraph 4 of the Doha Declaration on the TRIPS Agreement and Public Health of November 14, 2001, "that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health" and (ii) that the Doha Declaration did not amend TRIPS Article 8, which provides that measures taken to protect public health should be "consistent with the provisions of this Agreement" (Industry Functional Advisory Committee on Intellectual Property Rights for Trade Policy Matters (IFAC-3), The U.S.-Morocco Free Trade Agreement (FTA) The Intellectual Property Provisions Report of the IFAC-3, April 6, 2004).

The duplication of preclinical and/or clinical trials in order to develop anew the test data necessary for the approval of a drug also raises ethical concerns, and generates an additional obstacle for generic competition. Such tests may cause unnecessary animal suffering or death, and put human beings at risk when placebo (no treatment) is used for purposes of comparison. The Declaration of Helsinki of the World Medical Association on " Ethical Principles for Medical Research Involving Human Subjects"[26], which is relied upon on ethical maters by health authorities and the medical profession in many countries, states that

> "The benefits, risks, burdens and effectiveness of a new method should be tested against those of the best current prophylactic, diagnostic, and therapeutic methods. This does not exclude the use of placebo, or no treatment, in studies where no proven prophylactic, diagnostic or therapeutic method exists (paragraph 29).[27]

When tests data for an approved drug already exist, repeating tests with placebo or otherwise creating risks for patients is clearly unethical and would be unacceptable under many health regulations.

Mitigating the impact of data exclusivity

If a data exclusivity regime were adopted in a developing country –despite its disadvantages for generic competition and public health- some measures may be adopted by mitigate its negative implications. They may include a narrow definition of new chemical entity, short periods of

[26] Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964, and amended by the 29th WMA General Assembly, Tokyo, Japan, October 1975, 35th WMA General Assembly, Venice, Italy, October 1983
41st WMA General Assembly, Hong Kong, September 1989, 48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996, and the 52nd WMA General Assembly, Edinburgh, Scotland, October 2000.

[27] A "Note of clarification" on this paragraph added by the WMA General Assembly in Washington 2002 states the following:

"The WMA hereby reaffirms its position that extreme care must be taken in making use of a placebo-controlled trial and that in general this methodology should only be used in the absence of existing proven therapy. However, a placebo-controlled trial may be ethically acceptable, even if proven therapy is available, under the following circumstances:

- Where for compelling and scientifically sound methodological reasons its use is necessary to determine the efficacy or safety of a prophylactic, diagnostic or therapeutic method; or

- Where a prophylactic, diagnostic or therapeutic method is being investigated for a minor condition and the patients who receive placebo will not be subject to any additional risk of serious or irreversible harm.

protection (there is no rule imposing the 5-10 years term, as well as the following[28]:

Early working

If a product were subject to data exclusivity but off-patent, a generic company could produce or import samples in order to undertake the studies required for marketing approval. However, it would be important to clarify that a generic company could initiate the procedures in order to start commercialization immediately after the expiry of the data exclusivity period. If the product were on-patent, the possibility of undertaking the required studies will depend on the existence of a Bolar exception.

Exceptions

Like in the case of patents, exceptions may be provided for cases of emergency or public health, or when duplicating the test data would be unethical. Exceptions may also be provided for essential medicines.[29]

Compulsory licenses/government use

A data exclusivity regime should not be, but can be an obstacle for the execution of a compulsory license or government use. Since a compulsory license or government use only permits the use of the patent, it may be necessary to waive the rights conferred under data exclusivity in order to obtain marketing approval of the relevant product.

Waiting period

Data exclusivity protection may be invoked by the originator company even if it had not submitted an application or obtained marketing approval in a particular country. The originator company can, in fact, delay the application for marketing approval of its product and still prevent others from obtaining approval for commercialization. This possibility may be limited by establishing a waiting period, after the expiry of which data exclusivity could not be claimed. This period may be of six months or one year (as established for the Paris Convention in relation to the priority right).

Expiry of patent protection

In the case of products that were on patent at the time data exclusivity protection was acquired, protection may be deemed to terminate with the expiry of the patent. This option was provided for by the European *sui generis* regime on test data.

Conclusions

[28] Many of the measures proposed below are contained in the draft legislation under consideration in Chile for implementation of the obligations imposed by the US-Chile FTA.

[29] Since data exclusivity is not imposed by the TRIPS Agreement, there would be no limitation for a WTO Member to confine data exclusivity to drugs (and agrochemicals) that are not deemed essential for public health or food security, respectively, or to other categories they may wish to define.

Although the establishment of exclusive protection for test data is not required under the TRIPS Agreement, it has been provided for in developed countries and in a growing number of FTAs. Such exclusivity operates in some cases like a substitute for patent protection, thereby detracting from the public domain products that should be freely available. The implications of this *sui generis* protection for public health and agricultural production are significant, particularly as data exclusivity may run for long periods and block generic competition, even under compulsory licenses.

Developing countries have sound reasons to resist pressures to increase protection for test data beyond the TRIPS standard. Many of them, however, have made concessions in this field in recent FTAs with the USA.

If, despite its implications for public health and agricultural production, data exclusivity is adopted, its negative impact may be mitigated, *inter alia*, by a narrow definition of new chemical entities, the provision of exceptions in cases of emergency, the availability of compulsory licenses, and the stipulation of short periods of protection. Alternatively, other models for data protection may be considered, such as the establishment of liability rules that permit to recover the investment made without creating a quasi-monopolistic situation[30].

[30] Robert Weismann (Essential Action., rob@essential.org) has elaborated a proposal of this type whereunder payment would be based on a cost-sharing approach.

Annex

Test data protection in TRIPS and selected FTAs

Agreement		
TRIPS	Article 39.3	"Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use."
Chile	Article 17.10 (1)	"If a Party requires the submission of undisclosed information concerning the safety and efficacy of a pharmaceutical or agricultural chemical product which utilizes a new chemical entity, which product has not been previously approved, to grant a marketing approval or sanitary permit for such product, the Party shall not permit third parties not having the consent of the person providing the information to market a product based on this new chemical entity, on the basis of the approval granted to the party submitting such information. A Party shall maintain this prohibition for a period of at least five years from the date of approval for a pharmaceutical product and ten years from the date of approval for an agricultural chemical product. Each Party shall protect such information against disclosure except where necessary to protect the public."
Morocco	Article 15.10	1. If a Party requires, as a condition of approving the marketing of a new pharmaceutical or agricultural chemical product, the submission of: (a) safety and efficacy data, or (b) evidence of prior approval of the product in another territory that requires such information, the Party shall not permit third persons not having the consent of the person providing the information to market a product on the basis of the approval granted to the person submitting that information for at least five years for pharmaceutical products and ten years for agricultural chemical products from the date of approval in the Party's territory. For purposes of this paragraph, a new product is one that contains a new chemical entity that has not been previously

		approved in the Party's territory(12). 2. If a Party requires the submission of (a) new clinical information that is essential to the approval of a pharmaceutical product (other than information related to bioequivalency), or (b) evidence of prior approval of the product in another territory that requires such new information, the Party shall not permit third persons not having the consent of the person providing the information to market a pharmaceutical product on the basis of such new information or the approval granted to the person submitting such information for at least three years from the date of approval in the Party. A Party may limit such protection to new clinical information the origination of which involves considerable effort (13). Footnote 12: As of the date of signature of this Agreement, neither Party permits third persons not having the consent of the person providing such information to market a product on the basis of such information submitted in another territory or evidence of prior approval of the product in another territory. In addition, when a product is subject to a system of marketing approval pursuant to this paragraph and is also subject to a patent in the territory of a Party, that Party may not alter the term of protection that it provides in accordance with this paragraph in the event that the patent protection terminates before the end of the term of protection specified in Article 10.1. Footnote 13: As of the date of signature of this Agreement, neither Party permits third persons not having the consent of the person providing such new information to market a product on the basis of such information submitted in another territory or evidence of prior approval of the product in another territory. In addition, when a product is subject to a system of marketing approval pursuant to this paragraph and is also subject to a patent in the territory of a Party, that Party may not alter the term of protection that it provides in accordance with this paragraph in the event that the patent protection terminates before the end of the term of protection specified in Article 10.2.
Singapore	Article 16.8 (1), (2), and (3)	"(1.) If a Party requires the submission of information concerning the safety and efficacy of a pharmaceutical or agricultural chemical product prior to permitting the

		marketing of such product, the Party shall not permit third parties not having the consent of the party providing the information to market the same or a similar product on the basis of the marketing approval granted to the party submitting such information for a period of at least five years from the date of approval for a pharmaceutical product and ten years from the date of approval for an agricultural chemical product. (2.) If a Party provides a means of granting approval to market a product specified in paragraph 1 on the basis of the grant of approval for marketing of the same or similar product in another country, the Party shall defer the date of any such approval to third parties not having the consent of the party providing the information in the other country for at least five years from the date of approval for a pharmaceutical product or ten years from the date of approval for an agricultural chemical product in the territory of the Party or in the other country, whichever is later. (3.) Where a product is subject to a system of marketing approval pursuant to paragraph 1 or 2 and is also subject to a patent in the territory of that Party, the Party shall not alter the term of the protection that is provides pursuant to paragraph 1 or 2 in the event that the patent protection terminates on a date earlier than the end of the term of such protection."
CAFTA	Article 15.10 (1) and (3)	Article 15.10 1. (a) If a Party requires, as a condition of approving the marketing of a new pharmaceutical or agricultural chemical product, the submission of undisclosed data concerning safety or efficacy, the Party shall not permit third persons, without the consent of the person who provided such information, to market a product on the basis of (1) such information or (2) the approval granted to the person who submitted such information for at least five years for pharmaceutical products and ten years for agricultural chemical products from the date of approval in the Party.14 (b) If a Party permits, as a condition of approving the marketing of a new pharmaceutical or agricultural chemical product, third persons to submit evidence concerning the safety or efficacy of a product that was previously approved in another territory, such as evidence of prior marketing approval, the Party shall not permit third persons,

		without the consent of the person who previously obtained such approval in the other territory, to obtain authorization or to market a product on the basis of (1) evidence of prior marketing approval in another territory or (2) information concerning safety or efficacy that was previously submitted to obtain marketing approval in another territory for at least five years for pharmaceutical products and ten years for agricultural chemical products from the date approval was granted in the Party to the person who received authorization in the other territory. In order to receive protection under this subparagraph (b), a Party may require that the person providing the information in the other territory seek approval in the Party within 5 years after obtaining marketing approval in the other territory. (c) For purposes of this Article, a new product is one that does not contain a chemical entity that has been previously approved in the Party. (d) For the purposes of this paragraph, each Party shall protect such undisclosed information against disclosure except where necessary to protect the public, and each Party shall not consider information accessible within the public domain as undisclosed data. Notwithstanding the foregoing, if any undisclosed information concerning safety and efficacy submitted to a government entity, or an entity acting on behalf of the government, for purposes of obtaining marketing approval is disclosed by such entity, each Party is required to protect such information from unfair commercial use in the manner set forth in this Article. Footnote 14: "Where a Party, on the date of its implementation of the TRIPS Agreement, had in place a system for protecting pharmaceutical or agricultural

		chemical products not involving new chemical entities from unfair commercial use which conferred a period of protection shorter than that specified in paragraph 1, that Party may retain such system notwithstanding the obligations of paragraph 1".