
Data protection: The new IP frontier — An overview of existing laws and regulations

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Abstract The paper provides an overview of laws and regulations for the protection of data submitted by pharmaceutical companies for the purposes of obtaining marketing approval for a drug in Member States of the World Trade Organization, which must comply with intellectual property provisions set in the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). Article 39.3 of the agreement requires countries to protect undisclosed test or other data against unfair commercial use but not the adoption of exclusivity periods to protect such data. In general terms, today all developed countries have implemented an array of data exclusivity provisions with specific periods of protection, whereas most developing and least developed countries have often adopted language similar to that of Article 39.3. There are exceptions to this, mainly those countries that have negotiated free trade agreements with the United States such as Chile, Morocco and Jordan, and others that have agreed to adopt periods of exclusivity under pressure from other governments and industry groups. Furthermore, trade agreements have gradually broadened the scope of the protection thus undermining generic competition and therefore consumers' access to more affordable drugs.

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INTRODUCTION

The protection of data submitted by pharmaceutical companies for the purposes of obtaining marketing approval for a drug has become one of the dominant intellectual property issues for the innovative pharmaceutical industry and today features as

one of its priorities.¹ Some argue that, with few blockbuster drugs in the pipeline, the innovative industry is trying to extend its monopolies in different ways, data exclusivity being one of them. Indeed, since the 1990s the brand name pharmaceutical industry has sought to gradually increase both the scope and the period of protection granted to pharmaceutical data, either through specific efforts to extend data exclusivity, for example in the European Union or in Canada, through the incorporation of exclusivity provisions in all recent bilateral trade agreements signed by the United States or as

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a trade-off to support the definition of a legal pathway for the approval of biosimilar drugs. Given that the standards of protection have been rapidly evolving, this paper does not seek to provide an in-depth analysis of the issue, but an overview of existing laws and regulations in member states of the World Trade Organization, which must comply with the international standards set in the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) of the Uruguay Round of the General Agreement on Trade and Tariffs (GATT).

Before going into the specific laws and regulations, a distinction must be made between data protection and data exclusivity/market exclusivity. While the first refers to the requirement to protect the data submitted by an originator company for the purposes of obtaining regulatory approval from disclosure and to prevent unfair competition, data exclusivity entails the adoption of specific periods of protection during which regulatory agencies cannot rely on that data to review or grant marketing approval to a second applicant.

The TRIPS agreement

The protection of data was the subject of much debate during the negotiations of the TRIPS Agreement where some countries proposed the adoption of periods of exclusivity. The draft text of a meeting held in Brussels on 3rd–7th December, 1990, included the following text:

Parties, when requiring, as a condition of approving the marketing of new pharmaceutical products or of a new agricultural chemical product, the submission of undisclosed test or other data, the originator of which involves a considerable effort, shall [protect such data against unfair commercial use. Unless the person submitting the information agrees, the data may not be relied upon for the approval of competing products for a reasonable time, generally no less than five years, commensurate with the efforts

involved in the origination of the data, their nature, and the expenditure involved in their preparation. In addition, Parties shall] protect such data against disclosure, except where necessary to protect the public.]².

One of the proposals circulated by the delegation of the European Communities in March 1990 had the following text:

Contracting parties, when requiring the publication or submission of test or other data, the origination of which involves a considerable effort, shall protect such efforts against unfair exploitation by competitors. The protection shall last for a reasonable time commensurate with such efforts, the nature of the data required, the expenditure involved in their preparation and shall take account of the availability of other forms of protection.³

Developing countries, however, rejected the inclusion of any reference to exclusivity periods and the following language was finally approved:

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’.

Despite the history of the negotiations, the United States and other countries have argued that the correct interpretation of the TRIPS Agreement requires member states of the WTO to grant a period of exclusivity.

General overview

This major divide between developed countries and the rest of the world is reflected

Table 1: Classification of different countries according to the basic protection granted for pharmaceutical data

Countries with no specific period of protection	Albania, Angola, Argentina, Armenia, Bangladesh, Barbados, Belize, Benin, Bolivia, Botswana, Brazil, Brunei Darussalam, Burkina Faso, Burundi, Cambodia, Cameroon, Central Africa Republic, Chad, Congo, Ivory Coast, Cuba, Democratic Republic of Congo, Djibouti, Dominica, Ecuador, Fiji, Former Yugoslav Republic of Macedonia, Gabon, The Gambia, Georgia, Ghana, Grenada, Guinea, Guinea Bissau, Guyana, Haiti, Hong Kong, India, Indonesia, Kenya, Kuwait, Kyrgyz Republic, Lesotho, Macau China, Madagascar, Malawi, Malaysia, Maldives, Mali, Mauritania, Moldova, Mongolia, Mozambique, Myanmar, Namibia, Nepal, Niger, Nigeria, Pakistan, Papua New Guinea, Paraguay, Philippines, Qatar, Rwanda, St. Lucia, Senegal, Sierra Leone, Solomon Islands, South Africa, Suriname, Swaziland, Tanzania, Thailand, Togo, Trinidad and Tobago, Tunisia, Uganda, Uruguay, Venezuela, Zambia, Zimbabwe
Countries with a period of 18 months	Jamaica*
Countries with a period of five years	Antigua and Barbuda, Australia, Bahrain, Chile, Colombia, Costa Rica, Croatia, Dominican Republic, Egypt**, El Salvador, Guatemala, Honduras, Israel, Jordan, Mauritius, Mexico, Morocco, New Zealand, Nicaragua, Oman, Panama, Peru, Saudi Arabia, Singapore, Chinese Taipei/Taiwan, United Arab Emirates, United States of America, Vietnam
Countries with a period of six years	China, Japan, South Korea***, Turkey
Countries with a period of eight years	Canada
Countries with a period of protection of ten years	Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, United Kingdom

Notes: The table was put together using various sources: (a) Information provided by Member States of the WTO to the TRIPS Council. Article 63.2 of the TRIPS Agreement requires Members to notify the laws and regulations made effective by that Member pertaining to the Agreement; (b) Collection of Laws for Electronic Access (CLEA) of the World Intellectual Property Organization; (c) Inter-American System of Foreign Trade (SICE); (d) Information provided by individual patent offices and regional organisations.

*The Patents and Design Act has not been implemented yet.

**In Egypt there is disagreement over the interpretation of the law and whether it entails a period of protection, as it will be explained in more detail later on.

***South Korea has a *de facto* six-year protection (not DE strictly speaking) and has recently negotiated an FTA with the US which will entail the adoption of a period of at least five years.

in existing laws and regulations. Indeed, in general terms today all developed countries have implemented an array of data exclusivity provisions with specific periods of protection, whereas most developing and least developed countries have not implemented exclusivity periods but have often adopted language similar to that of Article 39.3 of the TRIPS Agreement.⁴ There are exceptions to this, mainly those countries that have negotiated free trade agreements with the United States such as Chile, Morocco and Jordan, as well as others that have agreed to adopt data exclusivity provisions under pressure from other governments and industry groups.

Table 1 classifies countries according to the basic protection granted for pharmaceutical data, therefore not including exclusivity periods for new uses, new clinical information, paediatric drugs, etc.⁵ Countries are listed taking into account the periods of protection provided in their respective laws and in trade agreements, even in cases where they have not yet been implemented. For example, some EU countries have not yet transposed Directive 2004/27/EC, which established a period of protection of 8 + 2 years, while other countries have negotiated free trade agreements providing at least five years of protection but, like, Costa Rica or Panama, are still in the process of ratifying the FTAs.

DATA PROTECTION IN INDIVIDUAL COUNTRIES

Europe

The periods of protection in the European Union were harmonised following the approval of Directive 2004/27/EC, amending Directive 2001/83, which adopted an eight-year data exclusivity period with an additional two years of market exclusivity so that a generic medicinal product 'shall not be placed on the market until ten years have elapsed from the initial authorisation of the reference product'.⁶ This ten-year period can be extended to a maximum of 11 years if, 'during the first eight years of those ten years, the marketing authorisation holder obtains an authorisation for one or more new therapeutic indications which, during the scientific evaluation prior to their authorisation, are held to bring a significant clinical benefit in comparison with existing therapies'. EU Member States were bound to transpose this Directive into their domestic laws by 30th October, 2005. The Directive has been implemented in most countries although some of them must still issue additional decrees or ministerial orders to regulate the details of the provisions.⁷ That is the case of Spain, for example, where Law 29/2006 refers to subsequent regulations yet to be enacted for the implementation of some specific provisions.⁸ In addition, some new member states such as Hungary, Malta, Latvia, Cyprus, Poland and Slovenia have requested a transition period for the implementation of data exclusivity provisions.⁹

As members of the European Economic Area, Iceland and Norway must also implement a 8+2+1 period as set in Directive 2004/27/EC. With regards to other European countries, Switzerland also grants ten years which can be extended for new indications, new modes of administration, new formulations or new dosages.¹⁰

In the case of Turkey, which is currently going through a long and uncertain process of accession to the European Union, regulations

were changed in 2005 and are likely to change again if the accession process moves forward in order to comply with EU regulations. The amended Licensing Regulations for Pharmaceutical Products grant six years of data exclusivity from the first marketing authorisation date within the European Customs Union Area. Data exclusivity is limited to original products licensed in a European Customs Union country after 1st January, 2001, for which no generic manufacturers had applied for licenses in Turkey as of 1st January, 2005, and the term of exclusivity is limited to the duration of the drug patent.¹¹

The Americas

In the United States pharmaceuticals can be granted mainly four types of exclusivity.¹² A generic applicant cannot submit an abbreviated new drug application (ANDA) for a product that contains the same active moiety as in the new chemical entity for a period of five years from the date of the approval of the first approved new drug application. An additional three years can also be granted for new clinical investigations for approved drugs for which a manufacturer conducts additional clinical testing to support changes to an approved drug product, including new dosage forms, formulations, or indications, or a switch from prescription to over-the-counter (OTC) use. This market exclusivity only refers to the new indication and does not prevent the approval of a generic drug for other uses not covered by a patent or an existing exclusivity.¹³

The exclusivity periods can also be extended for six months for those manufacturers to test the effects of drugs in children. Finally, US law grants seven years of exclusivity for orphan drugs, that is, for those drugs that treat rare diseases that affect 200,000 or fewer Americans, and for which sales of the drug in the US are unlikely to cover the cost of research and development. During that time the FDA cannot approve applications for both generic and additional

innovator products that contain the same active ingredient and are labelled for the same orphan indication.

With regards to the rest of the Americas, in the early 1990s the US was the only country in the region that had adopted data exclusivity periods for the protection of test data. Since then, the US has negotiated free trade agreements with 12 countries, all of which included provisions requiring the adoption of exclusivity periods for pharmaceuticals.

The North American Free Trade Agreement (NAFTA), which entered into force in January 1994, extended data exclusivity obligations to Canada and Mexico, by requiring them to protect undisclosed test or other data submitted for obtaining marketing approval for pharmaceutical products that utilise new chemical entities for a period of not less than five years from the date approval was granted.¹⁴

As a result, in 1995 Canada adopted a period of protection of five years. In October 2006, however, the government amended the Food and Drug Regulations extending such protection to eight years for innovative drugs with a six-year no-filing period, and with another six months for paediatric studies. In addition, the new regulations addressed one of the innovative pharmaceutical industry's complaints regarding the fact that exclusivity was not granted when the Minister of Health did not examine the data contained in the innovator's submission (this had been affirmed by the Federal Court of Appeal in *Bayer Inc. v Canada (Attorney General)*, 87 C.P.R. (3d) 293). Thus, exclusivity is now granted for both direct and indirect reliance on the innovators' data. Despite its success in extending the period of protection, PhRMA has requested that in 2007 Canada be listed in the Special 301 review. Among other things, it objects to the fact that the protection is not granted to new uses and that the new regulations will not be implemented retroactively to those products that were granted a Notice of Compliance (NOC) before 17th June, 2006.¹⁵

The USTR, however, did not echo this criticism and commended Canada for issuing regulations 'correcting deficiencies in its system for protecting against unfair commercial use pharmaceutical data'.¹⁶

On 14th November, 2006, Canada's generic pharmaceutical industry filed a lawsuit in the Federal Court of Canada challenging the amendments. In a statement the Canadian Generic Pharmaceutical Association said that 'Canada's Parliament approved legislation allowing the government to make regulations necessary to comply with Canada's international trade obligations [...] But by imposing eight years of data exclusivity, the new rules vastly exceed what is necessary for Canada to comply with the North American Free Trade Agreement (NAFTA) and the Agreement on Trade Related Aspects of International Property Rights (TRIPS)'.¹⁷ Although Canada's Attorney-General brought a motion to strike the association's application for judicial review, in February 2007 a Federal Court allowed it to move forward. The government is appealing the decision.

In Mexico, Article 86 *bis* of the Industrial Property Law states that 'the information required by special laws to determine the safety and efficacy of pharmaceutical chemical and agrochemical products that utilise new chemical components shall be protected in accordance with international treaties that Mexico is a part of'.¹⁸ Mexico, however, has not yet implemented its NAFTA obligations with regards to the protection of pharmaceutical test data.

The first country in the Americas to negotiate an FTA with the US after NAFTA was Chile, followed by five Central American countries (Costa Rica, El Salvador, Guatemala, Honduras and Nicaragua — CAFTA) as well as the Dominican Republic and Panama.¹⁹ Although all of them require countries to protect data for at least five years, the scope of such protection has gradually increased throughout the years as each FTA negotiated by the US has set new standards of protection,

as it will be reviewed in more detail in the section on the FTAs.

In the case of Peru and Colombia, which also negotiated FTAs with the US, the issue of data exclusivity caused a rift within the Andean Community of Nations, where both countries are members together with Venezuela, Ecuador and Bolivia. Intellectual property standards in the Andean region were set in Decision 486 which requires member states to protect undisclosed information in terms very similar to those of Article 39.3 of the TRIPS Agreement, that is members are not required to adopt exclusivity periods.²⁰ In 2002, before negotiating the FTA with the US, Colombia passed Decree 2085 providing five years of data exclusivity for new chemical entities in the country, but in December 2005 the Andean Court ruled that the decree violated Andean IP norms and ordered Colombia to 'reinstate the legal order'.²¹

In April 2006 Peru, Colombia and Ecuador announced together that they would be seeking a revision of existing Andean regulations regarding data to allow for the adoption of periods of exclusivity. Soon after Venezuela notified the Andean Community of its decision to withdraw from the trade bloc partly in protest over the fact that some of its members had opted to negotiate free trade agreements with the US.

Although the negotiations of FTAs between the US and Colombia, Panama and Peru have already been concluded, on 10th May, 2007 the Democratic leadership in the US House of Representatives and the USTR announced an agreement to amend pending FTAs that would, among other things, improve provisions affecting pharmaceuticals. On 25th June, 2007 the USTR released the final text of the agreement to amend the FTA with Peru which limits the protection to undisclosed test or other data that is submitted as a condition of approving pharmaceutical products that utilise new chemical entities.²² Such protection shall be granted for a reasonable period of time which shall normally mean five years from the date

on which approval was granted. Furthermore, the existence of data exclusivity should not be an obstacle for granting a compulsory license.

The rest of the Latin American countries, such as Brazil and Argentina, have adopted laws that protect data submitted to health authorities for obtaining marketing approval against unfair commercial use but do not provide a period of exclusivity.²³ In the case of Brazil, Law 9.279 of 1996 (Intellectual Property Law) does not grant a period of exclusivity. Law 10.603 of 2002, however, established periods of protection for data related to pharmaceuticals for veterinary use, fertilisers, agrottoxins, and their components and related products.²⁴ With regards to Argentina, in 1999 the US government requested consultations in accordance with the Understanding on Rules and Procedures Governing the Settlement of Disputes (DSU) and the TRIPS Agreement on the basis that Argentina was not complying with its WTO obligations by, among other things, failing to adopt specific protection periods to protect data. After nine rounds of consultations both countries reached a mutually satisfactory solution and agreed to settle eight of the ten issues on the dispute. On the issue of the protection of test data against unfair commercial use, they, however, 'agreed to disagree'. Furthermore, 'should the Dispute Settlement Body adopt recommendations and rulings clarifying the content of the rights related to undisclosed test data submitted for marketing approval according to Article 39.3 of the TRIPS Agreement, and should Argentinean law be inconsistent with Article 39.3 as clarified by the above-mentioned recommendations and rulings, Argentina agrees to submit to the National Congress within one year an amendment to Argentinean law, as necessary, to put its legislation in conformity with its obligations under Article 39.3 as clarified in such recommendations and rulings'.²⁵ Bolivia, Ecuador, Paraguay and Venezuela do not grant exclusivity periods either.

In the Caribbean most countries do not have specific periods of protection. Barbados, for example, has adopted language which is

similar to Article 39.3 of the TRIPS Agreement as did Trinidad and Tobago.²⁶ Antigua and Barbuda, on the other hand,

Table 2: Summary of the relevant provisions

NAFTA	<ul style="list-style-type: none"> • Exclusivity is granted for pharmaceutical products that utilise new chemical entities (NCE) for not less than five years from the date the Party granted approval. • Protection is granted to undisclosed test or other data that is required to determine safety and efficacy.
US–Vietnam	<ul style="list-style-type: none"> • Exclusivity is granted for pharmaceutical products for not less than five years from the date the Party granted approval. • Protection is granted to undisclosed test or other data.
US–Jordan FTA	<ul style="list-style-type: none"> • Exclusivity is granted for pharmaceutical products that utilise new chemical entities. New chemical entities include the protection for new uses for old chemical entities for a period of three years. When reliance on evidence of approval in another country, information shall be protected for the same period of time the other country is protecting such information against unfair commercial use. • Protection is granted to undisclosed test or data, or evidence of approval in another country.
US–Singapore FTA	<ul style="list-style-type: none"> • Exclusivity is granted for pharmaceutical products for not less than five years from the date the Party granted approval. When reliance on approval in another country period of protection is of at least five years from the approval of the product in the Party of reference or in the Party whatever is later. • Protection is granted to information that is submitted as a requirement to determine safety and efficacy; Word 'undisclosed' was dropped. • Does not allow regulatory authorities to grant marketing approval for 'same or similar' product. • Shorter periods may be available if on the date of the implementation of its TRIPS Agreement, the Party had a system for protecting pharmaceutical products not involving NCE that was shorter.
US–Chile FTA	<ul style="list-style-type: none"> • Exclusivity is granted for pharmaceutical products that utilise new chemical entities for at least five years from the date the Party granted approval. • Protection is granted to undisclosed information that is required to determine safety and efficacy. • Shorter time periods may be available if on the date of its implementation of the TRIPS Agreement, a Party had a system for protecting pharmaceutical products not involving new chemical entities from unfair commercial use that was shorter.
US–CAFTA DR FTA	<ul style="list-style-type: none"> • Exclusivity is granted to new pharmaceutical products (those that do not contain a chemical entity that has been previously approved in the territory of the Party) for at least five years from the date the Party granted approval. When reliance on approval in another country the period of protection is of at least five years from the approval of the product in the Party to the person who received approval in the other territory. A country may require that such person seek approval within five years after obtaining marketing approval in the other territory. • Protection is granted to undisclosed data that is required to determine safety and efficacy. • Shorter time periods may be available if on the date of its implementation of the TRIPS Agreement, there was a system for protecting pharmaceutical products not involving new chemical entities from unfair commercial use, which conferred a shorter period of protection.
US–Australia	<ul style="list-style-type: none"> • Exclusivity is granted to new pharmaceutical products (those that do not contain a chemical entity that has been previously approved in the Party) for at least five years from the date the Party granted approval. When reliance on approval or information concerning safety or efficacy submitted to obtain marketing approval in another country the period of protection is of at least five years from the date of marketing approval by the Party or the other country, whichever is later. • Protection is granted to undisclosed test or other data that is required to determine safety and efficacy; • Additional protection of at least three years from the date of approval in the Party for (a) new clinical information (other than the information related to bioequivalency) or (b) evidence of prior approval of a product in another territory that requires such information, which is essential to the approval of a pharmaceutical product. • Does not allow regulatory authorities to grant marketing approval for 'same or similar' product. • A Party shall not alter the period of exclusivity if the patent term terminates on a date earlier so exclusivity may go beyond the term of a patent.

Table 2: Continued

US–Morocco FTA	<ul style="list-style-type: none"> • Exclusivity is granted to new pharmaceutical products (those that do not contain a chemical entity that has been previously approved in the Party) for at least five years from the date the Party granted approval. • Protection is granted to safety and efficacy data or evidence of prior approval of the product in another territory that requires such information. • Additional protection of at least three years from the date of approval in the Party for (a) new clinical information that is essential to the approval of a pharmaceutical product (other than the information related to bioequivalency) or (b) evidence of prior approval of a product in another territory that requires such information. • A Party shall not alter the period of exclusivity if the patent term terminates on a date earlier so exclusivity may go beyond the term of a patent.
US–Bahrain FTA	<ul style="list-style-type: none"> • Exclusivity is granted to new pharmaceutical products (those that do not contain a chemical entity that has been previously approved in the Party for use in a pharmaceutical product) for at least five years from the date the Party granted approval. When reliance on approval in another country the period of protection is of at least five years from the approval of the product in the Party. • Protection is granted to information concerning safety and efficacy the submission of which is required or permitted. Term ‘undisclosed’ was dropped. • Additional protection of at least three years for new clinical information (other than information related to bioequivalency). When reliance on approval for the new clinical information in another country the period of protection is of at least three years from the approval of the product in the Party (ie not in the first country). • Does not allow regulatory authorities to grant marketing approval for ‘same or similar’ product. • A Party shall not alter the period of exclusivity if the patent term terminates on a date earlier so exclusivity may go beyond the term of a patent.
US–Oman FTA	<ul style="list-style-type: none"> • Exclusivity is granted to new pharmaceutical products (those that do not contain a chemical entity that has been previously approved in the Party for use in a pharmaceutical product) for at least five years from the date the Party granted approval. When reliance on approval in another country the period of protection is of at least five years from the approval of the product in the Party. • Protection is granted to information concerning safety and efficacy the submission of which is required or permitted. Term ‘undisclosed’ was dropped. • Additional protection of at least three years for new clinical information (other than information related to bioequivalency). When reliance on approval for the new clinical information in another country the period of protection is of at least three years from the approval of the product in the Party (ie not in the first country). • Does not allow regulatory authorities to grant marketing approval for ‘same or similar’ product. • A Party shall not alter the period of exclusivity if the patent term terminates on a date earlier so exclusivity may go beyond the term of a patent.
US–Peru FTA	<ul style="list-style-type: none"> • Exclusivity is granted to pharmaceutical products that utilise a new chemical entity for a reasonable period of time which shall normally mean five years from the date on which the Party granted approval to the person that produced the data for approval to market its product, taking account of the nature of the data and person’s efforts and expenditures in producing them. • Protection is granted to undisclosed test or other data necessary to determine safety and effectiveness. • Where there is reliance on approval granted by the other Party, and the Party grants approval within six months of the filing for marketing approval, the reasonable period of exclusive use of the data shall begin with the date of the first marketing approval relied on. • The protection may not be enforced to protect public health according to the Doha Declaration on the TRIPS Agreement and Public Health, TRIPS waivers or amendments. • A Party shall not alter the period of exclusivity if the patent term terminates on a date earlier so exclusivity may go beyond the term of a patent.
US–Colombia FTA	<ul style="list-style-type: none"> • Exclusivity is granted to pharmaceutical products that utilise a new chemical entity for a reasonable period of time which shall normally mean five years from the date on which the Party granted approval to the person that produced the data for approval to market its product, taking account of the nature of the data and person’s efforts and expenditures in producing them. • Protection is granted to undisclosed test or other data necessary to determine safety and effectiveness. • Where there is reliance on approval granted by the other Party, and the Party grants approval within six months of the filing for marketing approval, the reasonable period of exclusive use of the data shall begin with the date of the first marketing approval relied on. • The protection may not be enforced to protect public health according to the Doha Declaration on the TRIPS Agreement and Public Health, TRIPS waivers or amendments. • A Party shall not alter the period of exclusivity if the patent term terminates on a date earlier so exclusivity may go beyond the term of a patent.

Table 2: Continued

US–Panama FTA	<ul style="list-style-type: none"> • Exclusivity is granted to pharmaceutical products that utilise a new chemical entity for a reasonable period of time which shall normally mean five years from the date on which the Party granted approval to the person that produced the data for approval to market its product, taking account of the nature of the data and person's efforts and expenditures in producing them. • Protection is granted to undisclosed test or other data necessary to determine safety and effectiveness. • Where there is reliance on approval granted by the other Party, and the Party grants approval within six months of the filing for marketing approval, the reasonable period of exclusive use of the data shall begin with the date of the first marketing approval relied on. • The protection may not be enforced to protect public health according to the Doha Declaration on the TRIPS Agreement and Public Health, TRIPS waivers or amendments. • A Party shall not alter the period of exclusivity if the patent term terminates on a date earlier so exclusivity may go beyond the term of a patent.
US–South Korea FTA	<ul style="list-style-type: none"> • Exclusivity is granted to new pharmaceutical products (those that do not contain a chemical entity that has been previously approved in the Party for use in a pharmaceutical product) for at least five years from the date of marketing approval in the Party. When reliance on approval in another country the period of protection is of at least five years from the approval of the product in the Party. • Protection is granted to information concerning safety and efficacy the submission of which is required or permitted. Term 'undisclosed' was dropped. • Additional protection of at least three years for new clinical information that is essential to the approval of the pharmaceutical product containing the previously approved chemical entity (other than information related to bioequivalency). When reliance on approval for the new clinical information in another country the period of protection is of at least three years from the approval of the product in the Party (ie not in the first country). • Does not allow regulatory authorities to grant marketing approval for 'same or similar' products. • A Party may not alter the period of exclusivity if the patent term terminates on a date earlier.

precludes reliance on the data submitted in support of an application for product approval 'for a reasonable period of time after the submission of those tests or data and the period of time shall be determined by the Court, taking account of the nature of the data and the person's efforts and expenditure in producing them, and shall normally not be less than five years'.²⁷

Africa

With regards to Africa, the vast majority of countries have not adopted periods of exclusivity for the protection of data. The Bangui Agreement, for example, which defines patent rights in the 16 member states of the African Intellectual Property Organization (OAPI) provides for the protection of confidential data in terms that are very similar to Article 39.3 of the TRIPS Agreement.²⁸

Morocco, however, signed a free trade agreement with the US in 2004 accepting the adoption of a period of at least five years for

new pharmaceutical products from the registration in the Party and three for new clinical information (see more details in Table 2). In 2003 the US also started negotiations with the countries of the Southern African Customs Union (Botswana, Lesotho, Namibia, South Africa and Swaziland), none of which has adopted a period of exclusivity for the protection of data, but the negotiations stalled due to core differences and in 2006 the USTR announced that for the time being they had agreed 'to establish a framework through which the Parties will remain vigorously engaged in growing and deepening our bilateral relationship'.

In Egypt, on the other hand, in 2002 the government passed Law 82 (Law on the Protection of Intellectual Property Rights), Part III of which is devoted to the protection of undisclosed information. Article 56 states that '[p]rotection conferred by the provisions of this law shall extend to undisclosed information that involved a considerable effort, submitted on request to the competent

authorities for marketing of pharmaceutical or agrochemical products which utilise new chemical components necessary for the tests undertaken to allow such marketing. The competent authorities who receive such information shall protect it against disclosure and unfair commercial use from the date of its submission to the competent authorities until it is no longer confidential, or for a period not exceeding five years, whichever comes first...'

The innovative pharmaceutical industry has interpreted the law as granting data exclusivity and has complained about the specifics, for example, that the data should be protected from the date it is approved and not from its submission. In January 2005 PhRMA sent a letter to the Office of the USTR opposing the launching of negotiations of a FTA between both countries following the Ministry of Health's approval of generic drugs, which the association claimed was in violation of its laws and its WTO obligations under Article 39.3 of the TRIPS Agreement.

The Egyptian government, however, has a different interpretation of both Law 82 and its obligations under the TRIPS Agreement. In April 2005 Magdy Rady, a cabinet spokesman and a former adviser to the Minister of Health was quoted as saying that 'We don't have this concept of data exclusivity in Egypt... We have trade secret protection only if the three conditions stipulated in the law exist upon the registration of the drug in Egypt'.²⁹ According to Rady, there are two ways through which medicines can be registered in Egypt. The first, and most common route, is to use benchmark approvals, which means that if a drug is registered and approved in countries such as the US, certain members of the EU or Japan — and it can be verified that the drug is registered and has been tested by their regulatory agencies — the registration of the drug is accepted. Only in cases where a drug is not already approved in a benchmark country does the Ministry of Health apply the second method of registration, drug testing and data gathering.

In this case, the Ministry requests that the drug company submit previously undisclosed data on a drug's formula, efficacy and trials for it to review. As explained by Rady, it is only in this case that data is considered exclusive, 'but this scenario has never actually taken place in Egypt'.³⁰

Middle East

As regards to the Middle East, in 2005 Israel adopted legislation amending the Pharmacists Ordinance to increase protection for confidential test data submitted to the Ministry of Health in connection with an application seeking regulatory approval for medicines that contain a 'new chemical entity'. Under the new legislation, confidential data submitted to a regulatory authority cannot be relied on for the approval of a generic drug without the originator's permission for a period of five and a half years from the date that such drug was first approved for use in a 'recognised country', or five years from the date of registration in Israel, whichever comes first.³¹

Jordan, on the other hand, was one of the first countries to negotiate a free trade agreement with the US that included the adoption of a period of exclusivity for new chemical entities. The language, however, puts Jordan in a vulnerable position with regards to its implementation as it states that 'Jordan shall at a minimum protect such information against unfair commercial use for the same period of time the other country is protecting such information against unfair commercial use', that is, Jordan must at least implement standards of protection similar to those that exist in the US Article 8 of the Trade Secrets and Unfair Competition Law of 2000 (Law 15 of 2000) states that the secret formulae or any data obtained through considerable efforts that is submitted for obtaining the marketing approval of pharmaceuticals containing new chemical entities shall be protected for five years as of the date the first applicant obtained marketing approval. Jordan has, however, been under enormous pressure from

the US government with regards to the implementation of footnote 10 of the agreement which specifies that ‘It is understood that protection for “new chemical entities” shall also include protection for new uses for old chemical entities for a period of three years’, since both countries have been at odds with regards to the definition of what constitutes a new use. In June 2006 the Jordanian government determined that the term ‘new uses’ refers to new therapeutic indications, thus excluding new dosage forms, new combinations, etc.

Other countries, such as Qatar and Kuwait do not grant periods of protection. Bahrain and Oman have negotiated free trade agreements with the United States, both of which include provisions requiring them to implement data exclusivity periods and the law in Saudi Arabia grants a minimum of five years of exclusivity.

Australia and New Zealand

With regards to Australia and New Zealand, both countries provide five years of data exclusivity. Section 23 of New Zealand’s Medicines Act of 1981 protects confidential supporting information relating to the application for an innovative medicine (active ingredient of the medicine to which the application relates) for a period of no more than five years. In Australia, the Therapeutic Goods Act of 1989 provided a five-year period for therapeutic goods consisting of or containing a new active component even before the negotiation of the FTA with the US (see Table 2 for details of the provisions of the FTA).³²

Asia

In Asia, some countries such as Indonesia, the Philippines, Thailand, Pakistan, Sri Lanka and Malaysia do not grant periods of exclusivity for the protection of data. Malaysia is, however, currently negotiating a free trade agreement with the United States which has proposed the adoption of exclusivity periods. Others, like Vietnam and Singapore, have

already concluded agreements with the US and as a result have implemented five-year data provisions in their laws (see details in Table 2).³³

South Korea does not have data exclusivity provisions but the Pharmaceutical Safety and Efficacy Review Regulation provides *de facto* protection through a drug reexamination procedure which has been described as follows:³⁴

- The protection applies to all new pharmaceutical chemical products for which undisclosed information must be submitted as a condition for obtaining marketing approval.
- That is, a subsequent applicant cannot rely on pharmaceutical test data submitted by others for a period of six years, counted from the date of marketing approval of the new drug, unless the subsequent applicant has obtained permission of the original applicant or original developer.
- During the six-year period, a subsequent applicant must submit a full dossier for marketing approval. The data submitted by the subsequent applicant must meet the same criteria for approval as applied against the data of the original applicant. After the six-year period, the subsequent applicant is only required to submit the bioequivalence test data.

On 1st April, 2007 South Korea concluded the negotiation of a free trade agreement with the US which will require that the government implement a period of at least five years of exclusivity for new pharmaceutical products.³⁵

With regards to China, the government has described existing provisions in the following terms: ‘According to Article 35 of the Implementation Provisions of the Drug Administration Law of the People’s Republic of China, the government shall provide protection to the undisclosed test and other data, which was gathered and submitted by the manufacturer or distributor as required in

support of applications for marketing approval of pharmaceutical products which utilised new chemical entities, against unfair commercial use. Within 6 years from the date on which a manufacturer or distributor was granted marketing approval of a pharmaceutical product [that] utilised new chemical entities, if any second applicant applies for market authorisation using the said undisclosed data without the permission of the prior applicant, the competent authority for drug administration shall not grant the market authorisation, except for that the second applicant submits his own data. The competent authority for drug administration shall not disclose the said data, except where (a) the disclosure of such data was necessary to protect the public, or (b) steps were taken to ensure that the data are protected against unfair commercial use'.³⁶

PhRMA has, however, raised concerns with regards to the 'inadequate enforcement of intellectual property rights with respect to clinical data protection' and the existing loopholes in the law and claims that 'the current law is ambiguous as to how data exclusivity (DE) is implemented. For example, certain key concepts such as "new chemical ingredient" and "unfair commercial use" are undefined'.³⁷

Another key country that must be looked at is India. The law currently does not grant a period of exclusivity for the protection of pharmaceutical data but the government is under pressure from the innovator pharmaceutical industry and other governments to change existing provisions.

In 2004 the government constituted an Inter-Ministerial Committee to act as a Consultative Group and recommend appropriate measures to be adopted in the context of the implementation of data protection provisions under Article 39.3 of TRIPS. The report, which was finally submitted on 31st May, 2007, proposes that, after a transition period, a system is put in place for pharmaceuticals granting five years

of protection for NCE. Furthermore, it recommends that:

- Protection should apply to only undisclosed proprietary data and not to data already published or publicly available.
- In the case of data protection for patented drugs, the period of protection should in no case go beyond the 20-year period of patent protection in India.
- The period of protection may be counted from the date of the first marketing approval anywhere in the world and the Originator must apply for marketing approval in India within 24 months of that date.
- Marketing approval of a new drug should cease to be valid if the product is not marketed within six months from the date it was granted and if it is not marketed for 12 consecutive months at any time thereafter.
- India should follow a system that will allow generic filing to be done during the Data Protection period as under Section 107 of Patent Act, 1970 (Bolar Provision).
- Provisions should be introduced in the relevant laws so that if a compulsory license has been issued there would be an automatic waiver of data protection.
- Government should have the right to waive off all or any provision pertaining to data protection in case of a public health emergency.
- The provisions relating to data protection should not restrain manufacture for export to countries, which either do not have provision for data protection or where the term of protection has expired.

The government must now decide whether to follow these recommendations.

In Japan, the Pharmaceutical Affairs Law provides a reexamination system to reconfirm the safety and efficacy of a drug. The reexamination periods vary depending on the type of drug:

- orphan drugs and drugs confirmed at the time of approval to require a

- comprehensive evaluation using pharmacoepidemiological methods based on indices of the overall therapeutic effect, including life-prolonging effects, improvements in quality of life, effectiveness in preventing complications, etc with long-term use: ten years;
- drugs containing new active ingredients, new combination drugs, and drugs with new administration routes: six years;
 - drugs with efficacy and effects different from those of previously approved drugs and drugs with uses and dosages clearly different from those of previously approved drugs: four years;
 - drugs identical to other new drugs still within their reexamination period: remainder of the reexamination period of the new drug.

Free trade agreements: New standards for the protection of data

Trade agreements have been gradually setting new standards for the protection of IPR. In the report on the agreement concluded with Oman, the Industry Trade Advisory Committee on Intellectual Property Rights (ITAC-15) of the US government described the importance of these negotiations in the following terms:³⁸

The FTA process has become the principal process through which the IPR-based industries are able to ensure that the standards of protection and enforcement keep pace with new developments. ITAC-15 welcomes the successful negotiation of the OFTA (Oman FTA). While ITAC-15 recognizes that the negotiation of FTAs with individual countries and regions is labor-intensive, especially when compared with the negotiation of a multilateral agreement among the 148 Members of the WTO, FTA negotiations provide the most effective approach currently available to the United States for improving global intellectual property protection. The negotiation of an

individual FTA provides the opportunity to deal with specific intellectual property concerns that US industry may have in the particular negotiating partner. Our goal in the negotiation of an FTA is to set a new baseline for all future FTAs, including a possible FTAA. This baseline is continually reflected in the model FTA agreements, which are constantly changing based on what we learn through negotiating each of the FTAs.

ITAC-15 recognizes that, to a large extent, the negotiation of FTAs has become the primary focus of the US trade agenda and supports the use of all policy tools to gain worldwide improvement in intellectual property protection. ITAC-15 urges US negotiators to ensure that FTAs remain part of a coordinated, multi-dimensional program that not only includes multilateral and regional initiatives but also focuses on substandard intellectual property protection and enforcement in countries that are not parties to FTA negotiations.

Besides the adoption and ensuing efforts to gradually extend data exclusivity periods there is a worrying trend towards broadening the scope of such protection. This is specially reflected in those agreements negotiated by the United States which have gradually increased the standards of protection through the incorporation of provisions regarding the following:³⁹

a. Period of protection

The FTAs negotiated by the US include a period of protection of 'at least 5 years' for new chemical entities or for new pharmaceutical products thus setting the floor for future extensions. Furthermore, as described above, that period could be much longer since the five years start running from the registration in the country, so if a company delays the registration in country B after the first registration in country A, generic competition and consumers' access to that drug in B is delayed. As explained in a letter sent by

12 US representatives to the USTR, 'current US law provides data exclusivity, but places strict caps on the periods available. In contrast, the recent FTAs require data exclusivity periods but do not require caps. As a result, developing countries may face pressure to adopt longer exclusivity periods, presenting a scenario where the wait for generics could be even longer in a developing country than in the United States. Even if a developing country institutes limits equal to those in the United States, the wait for generics could still be longer if a company launching a new medicine in the United States does not seek approval in the developing country until later'.⁴⁰

The implementing legislation passed in some countries has sought to set limits. In Chile for example, the protection is not granted if the pharmaceutical product has not been marketed in the national territory within 12 months, counted from the sanitary registration or authorisation in Chile or if it has had a registration or sanitary authorisation abroad for more than 12 months.⁴¹ In addition, some of the FTAs provide 'at least 3 years' of protection for new clinical information.

In addition, most of the FTAs state that the term of protection shall not be altered in the event that the patent protection terminates on a date earlier than the end of the period of exclusivity.

b. Scope of protection

The FTAs have also gradually broadened the scope of protection:

- *New pharmaceutical products*: In some of the agreements the protection is granted to products that do not contain a chemical entity that has been previously approved in the territory of the Party so, as it happened in Colombia after Decree 2085 was issued, the protection may be granted to chemical entities that are old elsewhere in the world but which have not been registered in the country.

- *Same or similar products*: Some FTAs prevent authorities from granting marketing approval for same or similar products, so that the exclusivity protection that is granted to one drug may bar the approval of a whole therapeutic class of drugs or the approval of biosimilar drugs.
- *Protection of undisclosed information*: Some of the agreements have dropped the word 'undisclosed' thus extending the protection to information that may be in the public domain.
- *Protection of information that is 'required or permitted'*: Some agreements also protect information that is not necessarily required to determine the safety and efficacy of a drug, but which the authorities permit a company to submit during the marketing approval process, thus broadening the scope of protection.

As mentioned above, however, the agreement of 10th May, 2007 between the Ways and Means Committee and the Office of the USTR would, however, significantly improve the data provisions in the FTAs pending approval: Colombia, Panama and Peru.⁴² The importance of this agreement cannot be underestimated since it may reverse the existing trend towards increasing standards of intellectual property protection. Furthermore, many are hopeful that this bipartisan agreement will be the first step towards changing the FTA template that has been used in trade negotiations led by the Office of the USTR and redressing the balance between ensuring consumers' access to affordable generic drugs and fostering pharmaceutical innovation that was absent from the FTAs.

Table 2 shows a summary of the data provisions of the FTAs as negotiated by the United States.

The Russian Federation

A separate reference must be made with regards to Russia, although it is not yet a member of the WTO. Currently the law does

not grant an exclusivity period for the protection of pharmaceutical data. as part of the bilateral negotiations with the US on Russia's accession to the WTO, however, both countries agreed on a binding blueprint for actions to be taken by Russia in the area of intellectual property rights which includes the protection of pharmaceutical test data.⁴³

Specifically:

- Russia agreed to enact legislation by 1st June, 2007, to protect undisclosed information (such as test data) submitted to obtain marketing approval of pharmaceuticals. This is still pending.
- Russia has proposed legislation that would provide a period of protection of at least six years.

CONCLUSION

Since the TRIPS Agreement was signed in 1994, the protection of data has been gradually moving towards the adoption of exclusivity periods which are not required under the terms of Article 39.3 of the agreement. More recently, bilateral and regional trade agreements have broadened the scope of protection thus further undermining generic competition and therefore consumers' access to more affordable drugs. Although the implications of the new bipartisan trade policy agreed by the US Congress and the USTR remain unclear, it is apparent that many Members of Congress believe that the standards that were being set in the free trade agreements were going too far. Only the future will tell whether other countries will follow the new template or whether they will yield to the pressure of the innovator industry and continue the ever-increasing trend towards more extensive protection for pharmaceutical data.

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Notes and references

1. In its 2007 submission to the Special 301 annual review of the Office of the United States Trade Representative (USTR) which identifies countries that deny adequate and effective protection of intellectual property rights, the Association of Pharmaceutical Research and Manufacturers of America (PhRMA) detailed its concerns regarding IP protection in 48 countries. PhRMA criticises 37 of them which, in its opinion, are failing to adequately protect pharmaceutical test data. See: Pharmaceutical Research and Manufacturers of America (PhRMA), 'Special 301 Submission 2007', February 2007.
2. Multilateral Trade Negotiations — The Uruguay Round, 'Draft Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations', MTN.TNC/W/35/Rev.1, 3rd December, 1990. Special distribution. Page 215.
3. Multilateral Trade Negotiations — The Uruguay Round, 'Draft Agreement on Trade Related Aspects of Intellectual Property Rights', Negotiating Group on Trade Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods, Restricted, MTN.GNG/NG11/W/68, 29th March, 1990. Special Distribution. Page 13.
4. Countries on the United Nations list of least developed countries were given a transitional period of 11 years to meet their obligations under the TRIPS Agreement. The Doha Declaration on the TRIPS Agreement and Public Health extended the period until 2016.
5. The WTO currently has 150 members. The table does not include St. Kitts and Nevis, St. Vincent and the Grenadines, and the EU as a regional organisation (individual members were included).
6. Directive 2004/27/EC of the European Parliament and of the Council of 31st March, 2004, amending Directive 2001/83/EC on the Community code relating to medicinal products for human use. Article 1,8.
7. Source: Beata Stepniewska, 'Key Provisions Related to Generic Medicines', Presentation made before the Drug Information Association, 19th Annual EuroMeeting, Vienna, March 2007.
8. Spain, 'Ley 29/2006, de 26 de julio, de garantías y uso racional de los medicamentos y productos sanitarios'.
9. Poland, Hungary and Latvia are in the process of implementing their EU exclusivity obligations.
10. Switzerland, 'Loi federale sur les médicaments et les dispositifs médicaux' (Loi sur les produits thérapeutiques), 15 Decembre 2000 (Etat le 27 decembre 2006). Article 12 ((RS 812.21). The Swiss Act as well as others are applicable in Liechtenstein according to the Customs Union Treaty and a special bilateral agreement relating to the application of the Swiss legislation on therapeutic goods in Liechtenstein.

11. The European Commission has stated that ‘The provisions on data exclusivity, although a significant improvement compared to the previous regime which did not envisage data exclusivity, still cause concerns as on a number of aspects they fall short of full compliance by Turkey with its commitments under the WTO rules and the EC-Turkey Customs Union Agreement. These include essentially the issue of the so-called pending generic applications tabled with the Turkish Ministry of Health until 31 December 2004 and the conditional data exclusivity afforded to original products approved in the Customs Union Area between 1 January 2001 and 31 December 2004.[...] The Commission continues to monitor developments and has urged Turkey to fully comply with the relevant EC acquis on the matter. The matter was again discussed on 30 June 2006 at an expert’s meeting held in Brussels between Commission services and representatives of the Turkish Ministry of Health and the Turkish Delegation to the EU in Brussels’ (Source:http://ec.europa.eu/trade/issues/respectrules/tbr/cases/tur_pha.htm).
12. U.S. Code, Title 21, Chapter 9, Subchapter V, Part A, § 355(c) (3) (E). New Drugs. U.S. Code Title 21. Chapter 9. Subchapter V. Part A § 355a. Pediatric studies of drugs. U.S. Code-Title 21-Chapter 9-Subchapter V-Part B-Sec. § 360bb. Designation of drugs for rare diseases or conditions.
13. See: Elizabeth, H. D. (1999). FDA’s role in making exclusivity determinations. *Food and Drug Law Journal* **54**; Valerie, J. (2004). Drug marketing exclusivity under United States and European union law’. *Food Drug Law J.*, **59**.
14. NAFTA, Article 1711, paragraphs 5, 6 & 7.
15. PhRMA, ‘Special 301 Submission 2007’, February 2007, pages 221–223. The Special 301 Report of 2007 released at the end of April retained Canada in the Watch List and stated the following: ‘The United States commends Canada for issuing regulations correcting deficiencies in its system for protecting against unfair commercial use pharmaceutical data generated to obtain marketing approval’. The report can be found at http://www.ustr.gov/assets/Document_Library/Reports_Publications/2007/2007_Special_301_Review/asset_upload_file230_11122.pdf.
16. Office of the USTR, ‘2007 Special 301 Report’, Page 30.
17. Canadian Generic Pharmaceutical Association (CDMA), ‘Generic Drug Makers Launch Legal Challenge to New Federal Data Exclusivity Rules’, 14th November, 2006 (http://www.canadiangenerics.ca/en/news/nov_14_06.shtml).
18. Similar language was included in a decree issued by the Health Secretariat on 19th September, 2003: ‘Decreto por el que se reforma el Reglamento de Insumos para la Salud y el Reglamento de la Ley de Propiedad Industrial’, *Diario Oficial, Viernes 19 de septiembre de 2003*, pages 106–107.
19. The approval of the FTA in Costa Rica is still pending (a national referendum will be held on the FTA in October 2007). The Peruvian Congress has approved the FTA but the approval by the US Congress is still pending. The agreements with Panama, Colombia and South Korea still have to be approved by their respective congresses as well as by the US.
20. Andean Community of Nations (CAN), Decision 486, Article 266.
21. Ruling of the Andean Court, 15th December, 2005. See also Resolution 817 of the General Secretariat of the Andean Community, 14th April, 2004.
22. For the complete text see:http://www.ustr.gov/assets/Trade_Agreements/Bilateral/Peru_TPA/Final_Texts/asset_upload_file692_9546.pdf.
23. For Argentina, see Law 24.766 of December 1996 (Ley de Confidencialidad sobre información y productos que estén legítimamente bajo control de una persona y se divulgue indebidamente de manera contraria a los usos comerciales honestos).
24. Brazil’s Law 10.603 of 2002 provides ten years of exclusivity for products that utilise new chemical or biological entities from the date of approval or from the first registration in any country, or whichever it first, guaranteeing a minimum of one year of protection; five years if the entities are not new, also with a minimum of one year, and if new data is required after the approval, such data is protected for the remaining period or one year from the submission of the new data, whichever is later.
25. World Trade Organization, ‘Argentina- Patent Protection for Pharmaceuticals and Test Data Protection for Agricultural Chemicals (WT/DS171); Argentina-Certain Measures on the Protection of Patents and Test Data’ (WT/DS196); Notification of Mutually Agreed Solution According to the Conditions Set Forth in the Agreement. WT/DS196/4 IP/D/18/Add.1 IP/D/22/Add.1 20th June, 2002 (02-3427).
26. Barbados, ‘Protection against Unfair Competition Act 1998-20’, Article 4; Trinidad and Tobago, ‘Protection Against Unfair Competition Act 1996’ (No. 27 of 1996, as amended by Act No. 18 of 2000), Article 9.
27. Antigua and Barbuda, ‘Protection Against Unfair Competition Act 2001’, Article 8.
28. These 16 member states are Benin, Burkina Faso, Cameroon, Central Africa, Congo, Ivory Coast, Equatorial Guinea, Gabon, Guinea, Guinea Bissau, Mali, Mauritania, Niger, Senegal, Chad and Togo. See Agreement Revising the Bangui Agreement of 2nd March, 1977, on the Creation of an African Intellectual Property Organization (Bangui (Central African Republic), 24th February, 1999), Annex VIII, Article 6.4.
29. Under Article 55 of Law 82, undisclosed information shall be protected when it meets the following criteria: (1) Information which is confidential, in the sense that it is not, as a body or

- in the precise configuration or assembly of its components, generally known or common among those skilled in the art within the scope of which the information falls; (2) Information that has commercial value because it is confidential; (3) Information that depends on the effective measures taken by the person lawfully in control of it, to keep it confidential.
30. Réhab, E. -B. (2005). Jagged little pills. *Zawya, Business Monthly*, April.
 31. World Trade Organization, 'Trade Policy Review Body — Trade Policy Review — Report by the Secretariat. Israel. Revision', WT/TPR/S/157/Rev.1, 24th March, 2006. The recognised countries (as defined in the Pharmacists Regulations) are Australia, Canada, the EU member States, Iceland, Japan, New Zealand, Norway, Switzerland and the United States.
 32. Australia, 'Therapeutic Goods Act 1989, Act No. 21 of 1990 as amended', Section 25A. Although Australia accepted at least three years for new clinical investigations, a footnote recognises that Australia's existing data protection system meets its obligations under this provision. A 'new active component' under Section 25A.3 'is a substance that is, or one of the substances that together are, primarily responsible for the biological or other effect identifying the goods as therapeutic goods'.
 33. Vietnam, 'Law on Intellectual Property', November 2005; and 'Decision No. 30/2006/QĐ-BYT-Ministry of Health; Singapore: Medicines Act (Amended June 2003)'.
 34. United States-South Korea, Korea Exchange of Letters on Data Protection, 2002 (http://tcc.export.gov/Trade_Agreements/All_Trade_Agreements/exp_005678.asp).
 35. US-South Korea Free Trade Agreement, Chapter 18, Article 18.9.
 36. World Trade Organization, Council for Trade-Related Aspects of Intellectual Property Rights, 'Review of Legislation, China', WTO, P/Q/CHN/1, IP/Q2/CHN/1, IP/Q3/CHN/1, IP/Q4/CHN/1, 10th December, 2002.
 37. PhRMA, 'Special 301 Submission 2007', pages 52–54.
 38. 'The U.S. Oman Free Trade Agreement (FTAA). The Intellectual Property Provisions', Report of the Industry Trade Advisory Committee on Intellectual Property Rights (ITAC-15), 15th November, 2005. Pages 5–6.
 39. Most other trade agreements include IP sections that are very broad. There are some exceptions, for example the one signed between Chile and the European Free Trade Association (EFTA). Annex XII, Article 4.2 of the agreement requires parties to protect the information submitted for a product with a new chemical entity for at least five years. Annex XIII of the EFTA with the Republic of Korea of 2005 states that data must be protected for an 'adequate number of years from the date of approval' which shall be determined by the laws and regulations of the parties. The EFTA signed with Egypt in January has language similar to Article 56 of Egypt's Law 82 (Annex V), but those negotiated with Mexico (2000-Annex XXI), Croatia (2001-Annex VII) and Jordan (2001-Annex VI) only require countries to provide 'adequate and effective protection of undisclosed information'.
 40. Letter to Ambassador Susan Schwab, United States Representative, signed by Representatives Henry A. Waxman, Tom Allen, Jim McDermott, Lloyd Doggett, Janice D. Schakowsky, Pete Stark, Diana DeGette, Chris Van Hollen, Barbara Lee, Earl Blumentauer, Barbara Lee, John Lewis and Rahm Emanuel. 12th March, 2007.
 41. Chile, 'Texto de la ley de propiedad industrial (Ley 19.996 que "Modifica la Ley N° 19.039 sobre Propiedad Industrial")', Article 91. A similar limit of six months was adopted in Israel. Also, the implementing laws of the Dominican Republic, Honduras, Guatemala and El Salvador included a five-year limit while in Nicaragua the law states that the authorities may require that it be registered within five years of the first registration in the other territory (Nicaragua, Ministerio de Salud, 'Resolución Ministerial 115-2006', 22nd March, 2006).
 42. Source: http://www.ustr.gov/assets/Trade_Agreements/Bilateral/Peru_TPA/Final_Texts/asset_upload_file692_9546.pdf.
 43. Office of the USTR, Results of Bilateral Negotiations on Russia's Accession to the World Trade Organization (WTO), Action on Critical IPR Issues, 19th November, 2006.