

U.S. FREE TRADE AGREEMENTS AND THE PUBLIC HEALTH

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I. Introduction

The United States has negotiated and continues to negotiate bilateral and regional trade agreements with a number of its trading partners. In addition to multilateral agreements, bilateral and regional agreements are the vehicles promoting the free flow of goods, services, people and capital across borders without undue barriers to such trade. Bilateral and regional trade agreements allow trading partners to reach agreement beyond what has been agreed to multilaterally to enhance trade relations and maximize trade benefits for their respective economies. Consistent with the negotiating history of the United States, these trade agreements contain important intellectual property protections. Fundamentally, including intellectual property provisions in trade agreements is as important as negotiating the reduction of tariffs, placing disciplines on agricultural subsidies, providing for favorable tax treatment, or ensuring the free-flow of cross-border services.

Many U.S. trading partners have recognized -- and this has been reflected in their trade negotiations with the United States -- that strong intellectual property protections attract foreign investment into their countries, contribute to economic development and growth, and enhance their country's access to innovative medicines and many high-technology products, which otherwise might not be made available in their markets. Such provisions are essential to the development of a wide variety of new products in the high-tech, chemical, engineering, agriculture and manufacturing sectors, which will benefit citizens of all countries. In addition, strong intellectual property protections are required to spur the development of the next generation of life-saving and life-enhancing medicines. U.S. trading partners increasingly seek the intellectual property protection provisions in order that they might produce those products and other technology capacity and capability.

That said, the right balance must be achieved between providing strong intellectual property protection so that new medicines will be developed and addressing the needs of the poorest countries to obtain essential medicines. In the multilateral context, the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), and in particular the Declaration on the TRIPS Agreement and Public Health ("Doha Declaration") and the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health ("Paragraph 6 Compromise"), provide the flexibility to ensure access to medicines to address pandemics for those countries that lack domestic manufacturing capacity. The United States has been a strong supporter of the TRIPS Agreement and both of these instruments. The inclusion of intellectual property provisions in bilateral and regional trade agreements is not inconsistent with the TRIPS Agreement, and such provisions have not been found to undermine the Doha Declaration or the Paragraph 6 Compromise.

II. The Negotiation of So-Called TRIPS-Plus Provisions

The intellectual property provisions included in FTAs and regional agreements negotiated by the United States and its trading partners have been referred to as “TRIPS-plus,” because, it is alleged by some, they impose obligations that extend beyond those expressly set forth in the TRIPS Agreement and thus violate TRIPS. Characterizing these provisions as TRIPS-plus is misleading, however, because these provisions are, in fact, fully compliant with the framework established by TRIPS. While it is true that these provisions often are more specific and provide greater intellectual property protection than that provided by the TRIPS Agreement, that does not mean they violate the TRIPS Agreement. As discussed in greater detail in Section III, national governments are within their sovereign rights to exceed the TRIPS obligations with enhanced protections.

But before analyzing the legality of TRIPS-plus provisions under the TRIPS Agreement, it is essential to understand the negotiating context for these provisions. It is untrue, as well as overly-simplistic and naïve, to conclude that the U.S. Government is “strong-arming” its trading partners to accept TRIPS-plus provisions at the behest of the pharmaceutical industry or any other industry.

When two sovereigns are at the negotiating table, they each have their own set of priorities and they are aware of what their economies can accommodate. They are willing to agree to trade-offs if necessary because the overall agreement is in their interest. This is the very essence of the process by which rules-based trade and open markets among nations is achieved. Ultimately, no sovereign signs a trade agreement unless the overall agreement is in the country’s interest. Thus, it is misleading to conclude that countries agree to strong intellectual property protections in FTAs that are against their interests. It is also important to note that many countries have been very aggressive in seeking FTAs with the United States. If countries believed that an FTA with the United States was not in their best interests, they would not pursue such agreements.

Countries engage in discussions regarding trade treaties with any number of priorities in mind. Each negotiation has its own dynamic and the participants seek important provisions for their nation, fully aware that a balanced agreement must benefit all or the final execution of the agreement is unlikely. Thus, no party ever achieves each and every special priority its negotiators might advance.

Current backdoor efforts to bring to bear public pressure and ridicule on U.S. trading partners for entering into arms-length agreements with the United States negotiated in good faith undermine the global trading system and insult the sovereigns involved in the negotiations.

Contrary to what some may believe, when the United States sits down at the negotiating table with a sovereign trading partner, it does not hold all of the bargaining

power. While the U.S. may be negotiating from a strong position, trade negotiations are complex by definition. Once official negotiations have begun, there is a great deal of pressure politically on the U.S. Administration to reach an agreement, and the negotiators sitting across the table are well aware of this. Every agreement involves compromises on both sides, and the U.S. has often made compromises that were not entirely well received by all of its own industries. Only once both sovereign parties determine that the compromises made, and the agreement overall benefit their interests are negotiations concluded and trade agreements signed.

Finally, it is essential to recognize that the protection of intellectual property goes far beyond the interests of the pharmaceutical industry. All economic sectors are affected by intellectual property protections – from high-tech and communications, to manufacturing and engineering to agriculture and media and entertainment. As discussed in greater detail in Section V., U.S. trading partners also recognize the benefits of intellectual property protection to their own development and growth.

III. Intellectual Property Provisions in Bilateral and Regional Agreements are in Compliance With the TRIPS Agreement

Beginning in 1979 with the Tokyo Round of multilateral trade negotiations, trading partners have recognized that tariffs imposed on goods are but one barrier to the free flow of trade. Multilateral trade agreements have evolved from simply addressing tariffs on imported goods and trade restrictions at the borders to addressing the full spectrum of trade barriers, such as inadequate intellectual property protection, unreasonable restrictions on investments, barriers to trade in services, and unfair subsidies and restrictions on the movement of agricultural products, as well as providing for enhanced dispute settlement mechanisms.

The recognition that adequate and effective protection for intellectual property rights is an integral part of trade among nations culminated in the negotiation of the TRIPS Agreement during the Uruguay Round. Allegations that recently negotiated provisions in bilateral and regional agreements by the United States and its trading partners are in violation of the TRIPS Agreement represent a fundamental misunderstanding of that Agreement.

The TRIPS Agreement was clearly designed to provide a floor, and not a ceiling, for the protection of intellectual property rights. The parties agreed to certain minimum standards that must be implemented in the national laws of all WTO Members, albeit at varying times depending on the Member's level of development.¹ Specifically, Article 1 of the Agreement, entitled "Nature and Scope of Obligations," provides that:

¹ Countries joining the WTO were provided various dates in which to come into compliance with the terms of the TRIPS Agreement (1995, 2000, 2005, and more recently 2016). These staggered implementation schedules, along with specific unique exceptions for pharmaceutical products, were particularly exceptional, and were designed to give countries time to plan for full compliance. There is

“Members shall give effect to the provisions of this Agreement. Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement. Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.”

Thus, the TRIPS Agreement itself anticipated that individual Members could implement stronger protections. While all WTO Members were not able to reach consensus on more specific patent protections in the context of the TRIPS Agreement, nothing precludes individual countries from deciding in bilateral negotiations with the United States that enhanced patent protections will benefit their countries.

Some TRIPS-plus provisions contained in FTAs negotiated by the United States in recent years have come under attack as allegedly violating the TRIPS agreement. These include provisions on data exclusivity, market linkage, extensions of patent terms, secondary use patents, and restrictions on parallel trade. As detailed below, these provisions are fully compliant with the TRIPS requirements.

Data exclusivity

Many U.S. FTAs contain “data protection” or “data exclusivity” provisions. Data exclusivity is an independent intellectual property right, not to be confused with the protection of patents. Data exclusivity refers to the protection of clinical trial and other test data which drug companies are required to generate and provide to national drug approval agencies in order to achieve marketing approval for a particular drug in a particular country. This right guarantees that data generated by the right holder may not be referred to or used by another person or company to gain marketing approval for the same drug for a specific period of time. Unlike a patent right, data exclusivity does not prevent another company from generating this data and receiving marketing approval based on its own data.

Virtually every OECD country provides data protection, some for longer periods of time than the five years required under U.S. law and in the FTAs negotiated by the United States. For example, the EU protects such data for 6 to 10 years. The importance of data exclusivity has also been recognized by countries in various stages of development, such as Panama (10 years), Colombia (5 years), Brazil (5 years), China (6 years) and Egypt (5 years).

Data exclusivity protections provide important and necessary incentives for research and innovation. The process of developing and testing a new pharmaceutical product requires a huge commitment of resources. In the case of medicines, both discovery and development does take well over 10 years and cost hundreds of millions

concern now that these extensions and the possibility of additional ones have made some countries stall on their effort to meet their compliance obligations.

of dollars. The data generated by drug companies through such clinical trials to show that a new chemical entity meets the quality, safety and efficacy standards to warrant marketing approval is thus very valuable and is the property of the companies. Normally, such data would not be disclosed to any outside parties. Since government regulators need this data to grant approval, they agree in return not to disclose the information or allow it to be used by an unauthorized party. Along with adequate patent protection, data exclusivity protection ensures that companies have sufficient incentives to invest significant resources not only into developing a new drug, but also into carrying out all necessary clinical trials. Developing countries which do not protect drug registration data and allow competitors to rely freely on data provided by an innovator immediately thus remove the economic incentive for an innovator to launch a particular drug in their market.

Art. 39(3) of the TRIPS Agreement provides protection for data submitted to regulatory agencies for marketing approval and provides no minimum or maximum duration for data exclusivity. The data exclusivity provisions negotiated by the United States in FTAs and bilateral agreements are based on U.S. law – five years of protection from the date of marketing approval – and are consistent with Art. 39(3) of the TRIPS Agreement. Under U.S. law, after five years a generic manufacturer is free to rely on the originator's test data to seek approval of the generic version of the innovative medicine if the original patent on chemical (medicine) has expired. As stated above, data protection periods are even longer in Europe and some other countries at various levels of economic development. The five-year term established through FTAs thus reflects broad international practice and does not run counter to any provisions in the TRIPS agreement.

Critics of the data protection provisions in FTAs contend that the inclusion of these provisions is a novel way to circumvent the Paragraph 6 Compromise. In fact, the United States has been negotiating data exclusivity provisions in its FTAs and bilateral agreements long before the Paragraph 6 Compromise was reached, and such provisions are part of the domestic law of many countries. Countries such as Morocco, which have concluded FTAs with the United States, have affirmed that the data exclusivity provisions contained in the FTAs do not affect their ability to protect public health. The data protection provisions contained in bilateral and regional FTAs thus benefit developing countries by providing incentives to innovators to launch and register their products there after receiving the necessary approvals, and in many cases, these protections reflect already existing international practice. At the same time, countries retain their ability to protect public health under the Paragraph 6 Compromise. (For further information about data exclusivity provisions, please see Attachment A.)

Market linkage

Some U.S. FTAs provide that national drug regulatory authorities shall not grant marketing approval for a patented drug to a third party without consent or acquiescence by the patent owner (e.g. U.S.-Chile FTA, Art 17.10.2(c)). These provisions ensure that government-marketing approval agencies will not grant approval to patent-violating products. Such provisions do not violate Art. 28(1) of the TRIPS Agreement which

clearly gives patent holders a right to prevent the unauthorized sale of their products. Countries are free to agree to prevent the unauthorized sale of patented products through government regulations.

Extension of patent terms

The TRIPS Agreement provides for a minimum length of 20 years for any patent. At the same time, Art. 1.1 of the TRIPS agreement recognizes every party's right to implement more extensive protections in their laws. FTAs which allow for an extended patent term in cases where an unreasonable delay occurs in granting the patent (e.g. Art. 15.9 CAFTA) are thus compliant with the TRIPS Agreement. In the CAFTA Agreement for example, an unreasonable delay is defined as a delay in the issuance of a patent of more than five years from the date of the filing of the application, or three years after a request for examination of the application was made. Making up for such unreasonable delays does not provide the patent holder with a longer de-facto life of the patent, the extension is mere compensation for the lost time during which the innovator could not benefit from its invention. As a matter of policy, this is a fair balance which ensures that the incentive for innovators as originally intended is preserved. Even if this leads to a slightly more extensive protection of patents, that is consistent with Art. 1.1 of the TRIPS Agreement.

Secondary use patents

Secondary use patents provide protection for products which offer incremental innovation and improvements over a previously patented product. By definition, these improved products must still be new inventions and comply with all requirements for a new patent. In the area of pharmaceuticals, incremental innovations often consist of new and improved methods of administering a drug. One example is the development of a combination pill where patients previously needed to take multiple pills to achieve a particular medical result. The TRIPS Agreement protects all forms of innovation in Art. 27(1). The Agreement clearly does not distinguish between "breakthrough" and "incremental" innovation. Both forms of innovation lead to significant public benefits. It is also important to recognize that incremental innovations both in the pharmaceutical field as well as other areas in turn often enable future breakthrough findings, and that generic competition for the original product is allowed once the patent term for that original product expires. A generic firm is still able to make and sell the original product after the patent expires but not the new delivery product under the secondary patent. Secondary patents for incremental innovations are thus protected within the TRIPS Agreement.

Restrictions on parallel trade

The TRIPS Agreement, and the Doha Declaration give each Member the option to establish its own regime for national or international patent exhaustion without challenge. The principle of patent exhaustion refers to the ability of a patent holder to control the first sale of a product in a country where that product is patented. Under a regime of national exhaustion, as implemented in the United States, the holder of a U.S.

patent for a particular product is the only person authorized to make the first sale of that product in the United States. By definition, this prevents the importation of a patented product from a third country into the United States without the permission of the U.S. patent holder. Only such a regime of national exhaustion ensures that a patent holder is in fact able to use the patent for a product in individual markets and recoup R&D expenses. If third parties were allowed to freely import for example products which are patented in the United States from other countries, the U.S. patent would be undermined and rendered worthless to the patent holder.

Under the TRIPS agreement, WTO Members are free to establish regimes of national exhaustion, as the United States has done. U.S. FTAs which restrict parallel importation are merely an expression of the national exhaustion principle. The inclusion of such provisions in FTAs reflects an agreement among sovereign parties that parallel importation of products without the consent of patent holders into their market shall not be allowed. Under the premise that all TRIPS Members may freely decide to establish a national exhaustion regime, such restrictions of parallel importation are compliant with the TRIPS Agreement.

IV. The Intellectual Property Provisions in FTAs Do Not Undermine the Doha Declaration and the Paragraph 6 Compromise

While the primary purpose of the TRIPS Agreement was to promote the effective and adequate protection of intellectual property rights, the Agreement recognizes that there may be certain circumstances where greater flexibility is required, such as in the case of public health emergencies. To the extent that there were questions about the parameters of the flexibilities embodied in TRIPS, WTO Members clarified those ambiguities in the Doha Declaration and the Paragraph 6 Compromise, along with the General Council Chairperson's Statement.

In the context of these clarifications, WTO Members also reiterated their support for the intellectual property protections of the Agreement, acknowledging the public benefits both from access to existing medicines and the development of new medicines. For example, the Doha Declaration states that the Members recognize the flexibilities of the Agreement, "while maintaining our commitments in the TRIPS Agreement," and "while reiterating our commitment to the TRIPS Agreement."

The United States is not attempting to undermine the Doha Declaration and the Paragraph 6 Compromise by including strong intellectual property provisions in FTAs with its trading partners. In fact, the United States has been negotiating intellectual property protections in its bilateral and regional trade agreements for years, even prior to the time when the TRIPS Agreement came into force. For example, NAFTA, which the United States began negotiating in 1989, contains strong intellectual property protections, including five years of data exclusivity protection.

The United States supported and is committed to the Doha Declaration, the Paragraph 6 Compromise and their contribution to the access of medicines in health

crises. That said, the existence of the Doha Declaration does not preclude the United States from continuing its long tradition of negotiating important intellectual property provisions in its bilateral and regional trade agreements. To the extent that a U.S. trading partner harbors any doubt as to whether certain FTA provisions affect the use of the Paragraph 6 mechanism in public health emergencies, specific provisions can be included in the FTA confirming the intentions of the parties to give effect to the Paragraph 6 Compromise.

For example, the U.S.-Morocco FTA states that nothing in the intellectual property chapter of the agreement shall “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.” The FTA also states that it will not prevent the effective utilization of the Paragraph 6 Compromise allowing developing countries that lack pharmaceutical manufacturing capacity to import drugs under compulsory license. Such provisions reflect the desire of the parties not to undermine the Doha Declaration and the Paragraph 6 Compromise.

Article 31, the Doha Declaration and the Paragraph 6 Compromise are fundamentally “exceptions” to the intellectual property protections embodied in the TRIPS Agreement. These are important exceptions that recognize the dire need some developing and many least-developed nations face in ensuring access to medicines to treat public health crises, such as HIV/AIDS, malaria, and tuberculosis. But these exceptions cannot swallow the rule: Strong intellectual property protections remain essential to foster innovation and creativity.

V. The Importance of Strong Intellectual Property Protection to Economic Development and Public Health

Strong intellectual property protections are critical both to the economic development and public health of U.S. trading partners. During the Uruguay Round negotiations, there was a strong sense among many developing nations that the intellectual property protections provided by the TRIPS Agreement mainly benefited developed nations where companies conduct most research and innovation, in particular in the pharmaceutical area. Since the conclusion of the Uruguay Round in 1994, many important U.S. trading partners such as India, Mexico, Chile, Morocco, Jordan, Singapore and Bahrain have come to recognize the advantages of strong intellectual property protections for their own benefit, and this has been evident in their negotiations with the United States. Mexico’s acceptance of strong intellectual property protections in NAFTA, India’s implementation of patent protection for medicines in 2005, and the conclusion of Free Trade Agreements between the U.S. and Chile, Morocco, Jordan, Bahrain, and Singapore reflect this evolving commitment to creating strong patent regimes in those nations.

Intellectual property protections benefit virtually all industries and sectors, from high-tech and biotech to manufacturing and agriculture. Such protections should not

divide countries based on their levels of development as they encourage and reward innovation by domestic firms and promote increased foreign direct investment and technology transfers. Many U.S. trading partners have come to recognize that intellectual property protections strengthen the incentives for more research and innovation to take place within their borders and not just in the U.S., Europe and Japan. Such incentives lead to development through economic growth, increased innovation and more highly-skilled jobs.

Beyond broader economic benefits derived from better patent protections many recent examples specifically illustrate the public health advantages reaped by nations that have strengthened their patent regimes. Such protection can also help ensure that patients both in developed and in developing nations have better and faster access to new, innovative medicines.

Jordan, which entered into a free trade agreement with the U.S. in 2000, implemented strong intellectual property provisions and saw a dramatic increase in foreign investment from major pharmaceutical companies. Many firms opened offices in Jordan or expanded their commercial and research activities in Jordan. Jordanian exports of pharmaceuticals increased by 33% between 1999 and 2001. At the same time, prices for new, patent-protected medicines did not exceed pre-patent prices, and the generic industry benefited from an increase in foreign investment that generated work for these companies.² Since 2000, there have been 32 new innovative drug launches in Jordan, greatly increasing Jordanians' access to medicines.³ Beyond these innovations, the foreign direct investment seen in Jordan from the pharmaceutical sector – a high-tech, knowledge-based industry – has had the important secondary impact of improving the science base and clinical science, building capacity, and helping with scientist and physician retention.

Implementing its obligations under the TRIPS Agreement, India passed legislation to enact pharmaceutical patent protection beginning in 2005. Dr. Ragnath A. Mashelkar, Director General of the Council of Scientific and Industrial Research, president of the Indian National Science Academy, and vice-chairman of CIPIH, noted recently: “in anticipation of the new challenges that will follow in the wake of [TRIPS implementation], Indian drug and pharmaceutical industries have increased their R&D spending by 400% in the past 4 years, and they are now looking to hire hundreds of Ph.D.’s.”⁴ This development of course will alleviate and possibly reverse the dramatic brain drain of young scientists leaving India for more promising positions in the United States that has been seen in recent years, thus creating further economic growth and prosperity in India. With research costs only about a seventh of those in the United States, the improved patent regime has already attracted foreign pharmaceutical firms looking for a cost advantage in India.⁵

² Undersecretary of State for Economic, Business and Agricultural Affairs Alan P. Larson, in a speech to the Confederation of Indian Industry in Mumbai, India, November 8, 2003, available at www.usinfo.state.gov.

³ www.ustr.gov.

⁴ Ragnath A. Mashelkar, India's R&D: “Reaching for the Top,” *Science*, Vol. 307, pp. 1417, 4th March 2005.

⁵ “Are Days of Cheap ARVs Over?”, *AllAfrica*, 6 January 2005.

Chile signed a free trade agreement with the United States which came into effect in January 2004. As early as September 2003, multinational pharmaceutical companies were already increasing their investments in Chile, as two Dutch research-based companies relocated their regional headquarters to Chile in anticipation of strengthened patent laws.⁶ Morocco, another trading partner which entered into a free trade agreement with the United States in June 2004, expressed in a letter sent to a U.S. Congressman that “the Government of Morocco is strongly committed to and has agreed to the highest-standard intellectual property rights provisions in the free trade agreement. The Government of Morocco believes that effective intellectual property rights protection will play a vital role in the continued economic development of our country.”

Mexico strengthened pharmaceutical patent protection in 1991 in anticipation of entering into the NAFTA Agreement. As a result, investments in research and development and pharmaceutical facilities increased markedly. All of these examples show that U.S. trading partners have entered into free trade agreements containing strong intellectual property protections for the benefit of their own economies, as well as the benefit of their people who gain better and faster access to innovative medicines by creating a secure investment climate for pharmaceutical research.

Another important point which is often overlooked in the debate about patent protections and access to essential medicines is that an estimated 95% of all essential medicines as defined by the WHO worldwide are not patented.⁷ A recent study showed that patenting of medicines listed on the WHO Essential Medicines List in Sub-Saharan African countries is extremely rare, with only about 1.4% of these drugs actually under patent. The study concluded that “patents do not cause essential drugs to be inaccessible in ‘many’ developing countries, because they do not exist 98.6% of the time.”⁸ Even in India, where patent legislation was recently implemented, the Indian Minister for Commerce and Industry noted in December 2004 that the new patent law would have a very minimal impact on the access to medicines as 97% of the products on the Indian market are unpatented.⁹ Others have noted that 95% of drugs sold in India are molecules which existed prior to 1995 and thus are not captured by the new patent law.¹⁰ Patent protections in U.S. trade agreements thus affect only a small percentage of world-wide medicines.

In sum, the critical role that innovation plays in protecting public health is illustrated by the huge developments made in the treatment of HIV/AIDS through

⁶ Akzo Nobel Chooses Chile to Establish Regional HQ, World Markets Analysis, September 26, 2003; Dutch Drug Maker Organon Establishes Regional Headquarters in Chile, World Markets Analysis, November 13, 2003.

⁷ WIPO, Emerging Issues in IP: Patents & access to drugs and health care, “Striking a Balance: Patents and Access to Drugs and Health Care.” http://www.wipo.org/about-ip/en/studies/publications/health_care.htm.

⁸ Attaran, A., How Do Patent and Economic Policies Affect Access to Essential Medicines in Developing Countries, Health Affairs, Vol. 23 (3), 2004.

⁹ “No spiraling of drug prices says Kamal Nath”. The Hindu, Business Line, Vol. 11 no. 359. December 28, 2004.

¹⁰ “Are Days of Cheap ARVs Over?”, All Africa, January 6, 2005.

medication. It would be particularly ironic to eliminate the intellectual property protection that led to such innovation in the name of public health. The real challenge is to provide access to these medicines to populations in the poorest countries without eviscerating the intellectual property protections that are so critical to innovation.

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Attachment A

REALITIES BEHIND DATA EXCLUSIVITY AND DEVELOPING COUNTRIES

What is data exclusivity?

Before approving a pharmaceutical product for introduction into a national market, regulatory authorities require that the company producing that product supply evidence demonstrating that the product meets national standards of quality, safety and efficacy. Producing this data can cost hundreds of millions of dollars and take many years to produce. This data is thus very valuable and is the property of the company generating this data. Normally, such valuable, proprietary data would not be disclosed to any outside party. However, as government regulators must see this data in order to approve a product for marketing, companies are required to disclose this data to the regulators for review. In return, the regulatory authorities agree to not disclose this information or to allow it to be used by unauthorized parties for unfair commercial advantage. Such protection against disclosure or unfair use is called “data exclusivity”.

The obligation of WTO Member States to institute and enforce data exclusivity is mandated in TRIPS Art. 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.

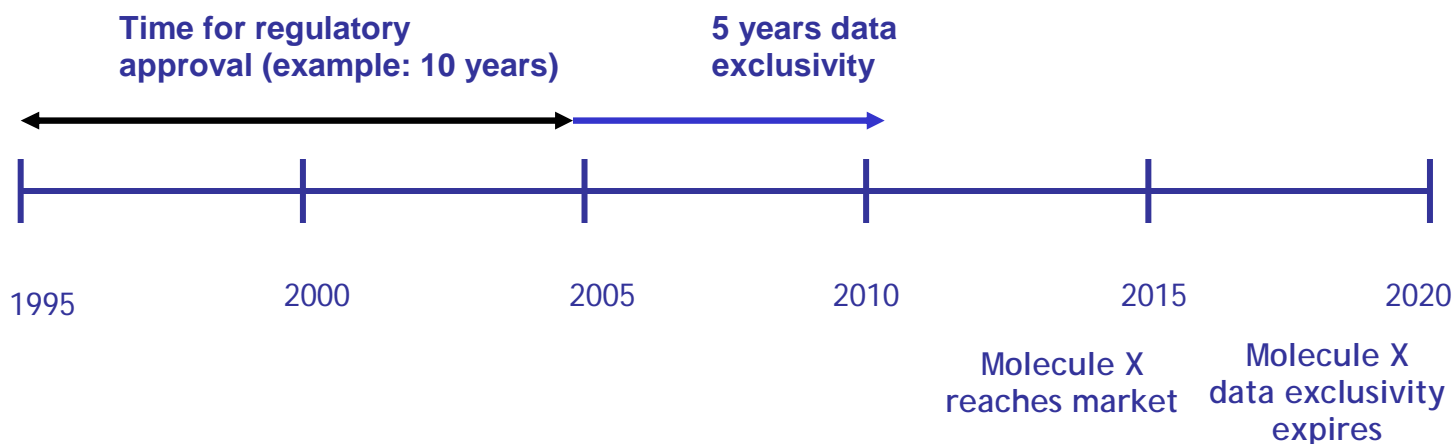
Two aspects of TRIPS 39(3) should be emphasized: governments should protect against disclosure of confidential information *and* they should protect such disclosure against “unfair commercial use”. In the pharmaceutical field, such protection means that companies wishing to copy a pharmaceutical product should not be allowed to rely upon this confidential data for getting their copy product approved. Given that the data required by drug authorities for registration of medicines in major markets is quite substantial and takes many years to produce on average, allowing copiers to simply say that their product is just the same as the original product and thus the data showing that the original product meets standards of safety, efficacy and quality would also apply to their product would give these copiers a substantial commercial advantage over the originator, as they would not need to incur large expenses and expend years of effort to get their copy products registered.

How long is data exclusivity valid?

The TRIPS Agreement does not give any maximum or minimum duration of exclusivity. In practice, however, countries implementing data exclusivity legislation, including the USA and many developing countries, give a minimum of five years of exclusivity. Many countries give more than five years, including emerging markets such as China (which has a six year period of exclusivity). In the European Union, exclusivity can last for ten years.

Does data exclusivity block access to generic copies in developing countries after the patent expires?

In practice, data exclusivity does not extend beyond the expiry of the patent on the product in question in developing countries. (Some estimates say that in 90% of drugs studied, the data exclusivity expired before the patent expired.) In the pharmaceutical sector, patents are applied for early in the product life. This means that, before the product comes to market, up to 12 years of the patent life may have expired. The data protection is given at the time of market approval, however. To take a theoretical example, if Product X was patented in 1995 and came to market in 2005, its data exclusivity would expire in 2010 (assuming a five year period of exclusivity), but its patent would expire later, in 2015. (please see figure below for a illustration of this process.) Thus, the data exclusivity period would have no effect on protecting the invention after the patent expiry, as the exclusivity would have expired before the patent. While there may be a theoretical chance of data exclusivity in cases of a long data exclusivity of ten years and a late market entry, in practice no developing countries have such a long period of exclusivity – they generally have five years of exclusivity.



Is including data exclusivity in free trade agreements (FTAs) “TRIPS-Plus”?

No. As noted above, TRIPS mandates that governments should protect against disclosure of confidential information *and* they should protect such disclosure against “unfair commercial use”. While some critics have called five years of data exclusivity to be “TRIPS Plus”, it must be noted that TRIPS does not give a maximum duration for such exclusivity. The practice among countries is to give at least five years of exclusivity; the number of developing countries instituting such exclusivity increases every year.

Furthermore, countries which have concluded FTAs have affirmed that data exclusivity provisions of these FTAs do not affect their ability to protect public health. As the Government of Morocco stated in its letter to US Representative Levin on 19 July 2005 regarding a recently-concluded FTA with the USA:

The Government of Morocco considered carefully the data exclusivity provisions in the agreement. We do not believe that they present any risk to our ability to meet the health needs of our citizens.

But can data exclusivity lead to “evergreening”?

“Evergreening” is a concept which is often poorly defined. Some critics of intellectual property rights have claimed that intellectual property protection on products can be extended for much longer than the length of the original patent or other intellectual property protection and call such extension of IP protection as “evergreening”. Such critics have asserted that data exclusivity can be used for extending intellectual property protection unfairly. However, this is not the case in reality. Data can be developed and submitted to regulatory authorities for obtaining marketing authorization for new uses of a product. As noted above, WTO Member States are required to protect that data against disclosure or unfair commercial use for a period of time (five years or more, depending on the jurisdiction) after marketing approval for that new use has been granted. However, the exclusivity of the **original** data used to bring the product to market would remain unaffected by the new data exclusivity – the exclusivity period for the original data would expire at the originally-determined date. After that date, copiers could refer to the original data to get their product approved for the original indication and bring their products to market.

Is there any advantage from data exclusivity to local inventors in developing countries?

Yes. As noted above, incremental innovation and new uses of existing products can have effective protection under data exclusivity. Experience has shown that innovators in emerging markets and developing countries focus on such incremental innovation, as the resources and technical expertise required for such innovation are within the reach of relatively small- and medium-sized

innovator companies in these markets. Data exclusivity can give protection for these innovator's inventions making innovative, new uses of products, even after the original patent has expired and copiers can make copies of the product for the original indication.

Furthermore, implementing data exclusivity can be beneficial for expanding the capacities of national regulatory authorities as well. At present, many developing countries do not receive or evaluate the complete data package due to lack of skill and experience by the national regulatory authorities. In order to improve their skills and their ability to safeguard the safety of their respective populations, such authorities should want more data to evaluate for determining approval of new drugs. In turn, they must see to it that this data is not being used for others' commercial benefits for a finite period of time of at least five years. Under an effective data exclusivity regime, companies would be more willing to submit data to authorities for review and thus give these authorities more experience in reviewing and evaluating product dossiers.