

**GEORGETOWN HUMAN RIGHTS ACTION/ HUMAN RIGHTS
INSTITUTE
FACT-FINDING REPORT**

Frequently Asked Questions

1. Who initiated the Georgetown project on Health and Intellectual Property in the Dominican Republic?

This investigatory report was conceptualized, researched, and written by a team of nine students and two professors from the Georgetown University Law Center, in partnership with the student group Georgetown Human Rights Action and the Law Center's Human Rights Institute. The Team spent the Fall semester of 2009 studying relevant international intellectual property agreements, Dominican and U.S. law, and international human rights law. The "fact-finding" occurred primarily during interviews conducted from January 11 through January 15, 2010 in Santo Domingo and La Romano, Dominican Republic.

2. What was the objective of the project?

The project sought to determine how the intellectual property provisions, with a special focus on the obligations included in the Dominican Republic-Central American Free Trade Agreement (DR-CAFTA), affect access to medicines in the Dominican Republic. To this end, researchers conducted extensive interviews with patients, healthcare providers, government officials, members of non-governmental organizations, lawyers, and representatives from multi-national and domestic pharmaceutical industries in Santo Domingo and La Romana, Dominican Republic, and Washington D.C.

3. How do intellectual property protections affect public health?

Intellectual property protections can raise the price of medicines. Though patents may be the most recognized form of intellectual property protection, this protection comes in a number of different shapes and sizes. Regardless of the specific type of intellectual property right, all such rights operate by excluding competition, and thereby allowing patent-holder pharmaceutical companies to charge higher prices than those that would exist on an open market.

Pharmaceutical companies argue that their high prices are justified to reimburse investment in discovery, but the actual cost of developing a new

medicine is contested and may not be as high as industry claims. In addition, each year, pharmaceutical companies spend nearly three times more in marketing campaigns than in research and development. Although high prices may create powerful incentives for creation, they also act as barriers to the right to health by placing medicines beyond the reach of many people in developing countries.

4. What is TRIPS?

TRIPS stands for the Agreement on Trade Related Aspects of Intellectual Property Rights and is a major international agreement on intellectual property rights. TRIPS was signed in 1995 and introduced minimum international property standards. Because the agreement falls under the umbrella of the World Trade Organization (WTO), its obligations are imposed on all WTO members and thus has an exceedingly far reach. The agreement, largely the result of U.S. efforts, was the first time that states were required to patent pharmaceutical products and processes. Prior to TRIPS, governments had broad flexibility to adopt the intellectual property regimes of their choosing and many states excluded pharmaceuticals from patentability. Thus, subjecting life-saving medicines to a twenty-year patent monopoly was a major shift in international intellectual property protection.

5. What are “TRIPS flexibilities”?

In an attempt to balance these new intellectual property obligations, TRIPS also recognizes the right of WTO Members to “adopt measures necessary to protect public health” and grants considerable freedom in implementing intellectual property provisions through so-called “TRIPS flexibilities.” These flexibilities legally allow states to provide for the public health of their citizens. For example, states have some flexibility in how they define what inventions meet the *criteria* to obtain a patent. Members are also allowed to determine whether or not to permit *parallel imports*, the import of a patented good that was originally sold with the permission of the right-holder in another country. Finally, members may choose to allow *compulsory licensing*, by giving a third party, such as a generic drug manufacturer, or government, the right to use a patented product or process without authorization from the patent owner subject in most cases to adequate remuneration and other conditions. These flexibilities are designed to allow states to implement intellectual property provisions that do not undermine the right to health.

6. What is the Doha Declaration?

Though TRIPS guaranteed the use of certain flexibilities to protect public health, developed countries and multinational pharmaceutical companies continued to pressure developing countries to increase intellectual property rights and not to use these flexibilities. In the wake of this pressure, developing countries used the Fourth WTO Ministerial Conference in 2001 in Doha, Qatar as a platform to bring access to medicines to the forefront of the World Trade Organization. The resulting Doha Declaration affirms the sovereign right of governments to fully utilize TRIPS flexibilities, including compulsory licensing and parallel importation, to protect public health. The Declaration states that TRIPS can and should be interpreted to protect public health and promote access to affordable medicines. However, in the years since the Declaration, developing countries have been subjected to pressure in the form of bilateral trade agreements, like DR-CAFTA, that increase intellectual property rights at the expense of public health.

7. What is DR-CAFTA?

The Dominican Republic-Central American Free Trade Agreement (DR-CAFTA) is a trade agreement. Originally, the agreement encompassed the United States and the Central American countries of Costa Rica, El Salvador, Guatemala, Honduras and Nicaragua, and was called CAFTA. In 2004, the Dominican Republic joined the negotiation, and the agreement was renamed DR-CAFTA.

As a staunch advocate of strong intellectual property protections, the United States uses a variety of approaches to pressure countries to increase levels of intellectual property. The United States has pursued free trade agreements, like DR-CAFTA, to impose increased intellectual property protections. DR-CAFTA imposes intellectual property protections that require obligations beyond those required in TRIPS (these heightened obligations are known as “TRIPS-plus” provisions).

8. What are the increased intellectual property provisions in DR-CAFTA?

The Georgetown report focuses on three DR-CAFTA provisions that impose obligations beyond TRIPS: 1.) patent extensions, 2.) data exclusivity, and 3.) patent linkage.

Patent extensions increase the protected term of a patent. The extension is designed to compensate for government delays in granting a patent application or approving a drug for market. Compensation is given by extending the patent holder’s monopoly over the pharmaceutical product. However, by extending this monopoly, a patent extension further delays the entry of competition into the market and, thus, may keep prices artificially high. The patent extension provision in DR-CAFTA imposes obligations on

the Dominican Republic that exceed those contained in TRIPS. Though TRIPS requires that patent protection be given for twenty years, it makes no reference to patent extensions. DR-CAFTA, however, requires patent extensions be given for delays in granting a patent application or marketing approval. U.S. law contains patent extension provisions similar to those in DR-CAFTA, but with important limits. For example, in the United States, the total protective term of a patent given a patent extension for regulatory delay cannot exceed fourteen years from marketing approval, while this limit does not exist in Dominican law.

Data exclusivity is a form of intellectual property protection for pharmaceutical safety, efficacy and quality data. Before a pharmaceutical can be sold, data from clinical research trials must typically be submitted to a country's drug regulatory authority to show safety, efficacy and quality. Generally, when a generic manufacturer wants to enter the market, the manufacturer relies on this data to show that its drug is similarly safe and effective. Data that is protected by an exclusivity regime cannot be used or relied upon by a third party, such as a generic manufacturer, during this period of exclusivity. If generic manufacturers cannot rely on this data, they must either wait until data exclusivity expires or hold their own clinical research trials, which are often prohibitively expensive and can raise ethical questions by duplicating unnecessary testing on human beings for commercial purposes. Thus, data exclusivity prevents generic manufacturers from entering the market, providing competition, and driving down prices.

Data exclusivity provisions in DR-CAFTA are TRIPS-plus. TRIPS only requires countries to protect data from unfair commercial uses and certain types of disclosure. TRIPS leaves governments with broad discretion in implementing data protection regimes, and, consequently, allows for consideration of public health. The United States, however, has chosen to adopt a more extensive data exclusivity regime that flatly requires five years of protection for products containing new chemical entities and three years of protection for new uses or indications. The United States has attempted to promote this more extensive data exclusivity regime in other countries through free trade agreements like DR-CAFTA. Under DR-CAFTA, data submitted for regulatory approval is given at least five years of protection regardless of the purpose of its use. Further, some products that do not contain a new chemical entity are protected when they would not be under TRIPS. Thus, where generics would have an opportunity to enter the market under TRIPS (e.g. under a patent compulsory license), data exclusivity could unilaterally prohibit entry for at least five years by blocking regulatory approval.

Patent linkage refers to a system where drug regulatory bodies are linked with patent enforcement. If the drug is patented, the drug regulatory agency

generally cannot approve the drug for purchase and must inform the patent owner that someone else, a generic usually, has tried to obtain approval to sell the drug. Most linkage systems require the drug regulatory authority to determine whether a patent exists for a drug before granting marketing approval to sell that drug. Though patent linkage mechanisms can be designed in different ways, designing a linkage system that does not unduly impair a generic manufacturer's ability to place drugs on the market can be difficult for developing countries.

Unlike DR-CAFTA, TRIPS does not require a country's drug regulatory body to be linked with patent enforcement. DR-CAFTA imposes an increased burden on the Dominican drug regulatory authority by requiring it to 1.) refrain from granting marketing approval of a patented drug during the term of the drug's patent, and 2.) notify the patent owner of a generic manufacturer's request for marketing approval. By requiring these two actions by the drug regulatory authority, the linkage system required by DR-CAFTA places the burden of patent enforcement on the Dominican government to protect the patent rather than on the patent owner.

Though the United States adopted a patent linkage system, U.S. law contains significant safeguards that can be used to protect public health. For example, U.S. law requires patent owners to identify and list patents in a publicly available register called the Orange Book and to affirmatively enforce their patent after being informed of a generic manufacturer's attempt to gain marketing approval by starting a litigation within 45 days. Further, the U.S. law provides a mechanism for and even incentivizes generic manufacturers to challenge the validity of patents by rewarding a generic manufacturer that successfully challenges a patent with 180 days to exclusively sell their generic product.

9. How will DR-CAFTA affect health in the Dominican Republic?

TRIPS-plus provisions such as those found in DR-CAFTA can profoundly impact access to medicines. The experience of other developing countries is illustrative. Jordan, for example, experienced a twenty percent increase in the price of pharmaceuticals five years after its free trade agreement with the United States. Prices in Jordan were two to ten times more for some new medicines than those in Egypt, a market which was not subject to heightened intellectual property provisions imposed by U.S. free trade agreements. In Guatemala, DR-CAFTA decreased competition by forcing some generics off of the national market and delaying the entry of new generics into the market even when those generic medicines were available in the United States.

A recent study by Fundación Plenitude, ICTSD and the Pan-American Health Organization on the impacts of DR-CAFTA in the Dominican Republic indicates that the Dominican Republic is also likely to experience an increase in pharmaceutical prices because of DR-CAFTA. The price of pharmaceuticals in the Dominican Republic is expected to increase by nine to fifteen percent by 2027.. Eighty percent of this price increase is attributed to the effects of data exclusivity. With increasing prices under DR-CAFTA, the Dominican government may face significant difficulty in providing its citizens with the medications they need. Such an increase in price could be deadly for Dominican patients who are affected in many different ways.

A nurse in the Dominican Republic that we interviewed explained that patients currently cannot afford to take “anything that is non-generic” on a daily basis. Even though HIV/AIDS medicines are largely free for patients in the Dominican Republic, HIV/AIDS advocates noted that doctors delay some HIV/AIDS testing because “if *a doctor+ doesn’t prescribe drugs, he saves the government money.” Despite the fact that the Dominican Republic receives mostly free HIV/AIDS medicines through international donors, more advanced patients require more expensive treatment which may not have been accounted for in the Dominican health budget or grant from international donors. TRIPS-plus provisions in DR-CAFTA could therefore, critically limit the Dominican Republic’s ability to uphold the right to health for its citizens.

10. What is the New U.S. Trade Policy?

The United States has begun to recognize that heightened intellectual property provisions have negative consequences for developing countries and undermine the public health protections affirmed in the Doha Declaration. In recognition of these negative consequences, the Committee on Ways and Means of the U.S. House of Representatives and the Office of the United States Trade Representative announced a New U.S. Trade Policy in May 2007. This New U.S. Trade Policy withdrew obligations on trade partners that were negotiating trade agreements with the United States at the moment (Peru, Colombia, Panama) to adopt certain heightened intellectual property obligations for pharmaceuticals and reaffirmed the U.S. commitment to the Doha Declaration. Peru has already benefited from this change in U.S. policy. Dominicans, however, do not receive the same benefits and are forced to implement heightened intellectual property obligations that have negative consequences for public health.

11. How is the United States currently involved in implementing the intellectual property provisions of DR-CAFTA in the Dominican Republic?

This promotion of intellectual property provisions of DR-CAFTA currently largely occurs through the United States Agency for International Development (“USAID”), which funds, selects and hires consultants to provide training and guidance to Dominican authorities on DR-CAFTA implementation. The generic industry in particular expressed concern that this USAID guidance is biased towards interpreting and implementing DR-CAFTA in a way that promotes strong intellectual property protection without providing equal information about safeguards that can be used to promote public health. This bias could be critically damaging if decision-makers in the Dominican Republic are not aware of the legal flexibilities to protect public health that exist in U.S. law. For example, Dominican government officials expressed confusion about the requirements needed to issue a compulsory license, and many of those interviewed were unaware of public health safeguards that exist in U.S. law or New U.S. Trade Policy. Without accurate and balanced training about what DR-CAFTA provisions require, the Dominican government may not be able to use pro-public health flexibilities, which limits the government’s ability to respond to public health needs.

12. What are the key recommendations of the Georgetown *A Prescription for Failure* Report?

To promote access to affordable pharmaceuticals in the Dominican Republic, the Georgetown Human Rights Action/ Human Rights Institute Fact-Finding Team makes the following recommendations to the **Government of the United States of America:**

1. The United States should bring DR-CAFTA provisions in line with New U.S. Trade Policy, specifically:
 - a. Patent extensions for pharmaceuticals should be made optional.
 - b. Data exclusivity should be limited to “a reasonable period” and protect only new chemical entities. Data exclusivity should be subject to an exception to protect public health in accord with the Doha Declaration.
 - c. Patent linkage systems should be optional, clearly allowing countries to place the burden on patent holders to enforce their rights.
2. The United States should ensure that training and funding are provided in a way that strengthens the Dominican Republic’s capacity to implement pro-public health policies, including training on public health safeguards such as those provided in TRIPS and U.S. law in addition to DR-CAFTA obligations.
3. The United States should publicly recognize the right of the Dominican Republic to use TRIPS flexibilities consistent with U.S. commitments under the Doha Declaration. In future negotiations, the United States should refrain

from promoting intellectual property provisions that inhibit a government's ability to advance public health.

To promote access to affordable pharmaceuticals in the Dominican Republic, the Georgetown Human Rights Action/Human Rights Institute Fact-Finding Team makes the following recommendations to the **Government of the Dominican Republic**:

1. The Dominican Republic should utilize TRIPS flexibilities where necessary to protect public health. To this end, the Dominican Republic should consider:

- a. Identifying public health situations that merit the use of TRIPS flexibilities.
- b. Clarifying and publicizing the procedures for obtaining a compulsory license.
- c. Providing training on TRIPS flexibilities to relevant government agencies and civil society.

2. The Dominican Republic should strengthen its understanding of the effects of the intellectual property on access to medicine in the Dominican Republic. To this end, the Dominican Republic should consider:

- a. Commissioning a study on access to medicine in the Dominican Republic.
- b. Promoting more active involvement of health officials in trade negotiations.