

A Prescription for Failure

Health and Intellectual Property
in the Dominican Republic



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It is “an essential right to have treatment.”

- Dominican HIV/AIDS advocate, AIDS Free World

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Executive Summary

In the United States, trade policy is generally considered an economic issue. But for developing countries like the Dominican Republic, it can be a matter of life and death.

This report, the culmination of seven months of research by students at Georgetown University Law Center, seeks to shed light on how the intellectual property provisions of the Dominican Republic – Central America – United States Free Trade Agreement (DR-CAFTA) are being implemented in the Dominican Republic and the impact that the Agreement is likely to have on access to medicine there.

Although intellectual property protections are just one of many factors that impact the price of medicines, their effect can be significant. Strong intellectual property laws limit competition in the pharmaceutical market, and, in so doing, can keep the price of medicines considerably higher than they would otherwise be. For example, the introduction of generic HIV/AIDS medications contributed to a 99% reduction in the price of anti-retrovirals internationally over the last decade, and international generic competition reduced the price of the HIV/AIDS medication KALETRA® by fifty-five percent in the Dominican Republic.

High pharmaceutical prices can be devastating for the government and individuals. They strain already-stretched public health budgets and leave some patients with the choice of paying for medications out-of-pocket or forgoing treatment in order to fund life's other necessities. When life-saving medicines are priced out of reach in developing countries, people die.

The international community addressed the balance between intellectual property protection and public health in the 1995 Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) and the Doha Declaration in 2001. TRIPS, which is binding on all members of the World Trade Organization, mandates minimum intellectual property standards and allows for certain "flexibilities" (e.g. parallel importation and compulsory licensing) to protect public health. The Doha Declaration, pursued by developing countries in response to difficulties in accessing affordable medicines, affirms the rights of states to use these flexibilities and makes clear that TRIPS can and should be interpreted to protect public health.

In contrast, DR-CAFTA, like a number of other free trade agreements the United States has negotiated with developing countries, imposes intellectual property protections that require obligations beyond those required in TRIPS. These heightened obligations have limited competition in the pharmaceutical market and resulted in increased prices for life-saving medicines, with devastating effects on public health.

In the Dominican Republic, the cost of medicine is a concern for the government and consumers. The Dominican government spends one-fourth of its health budget purchasing medicines, and government health insurance only covers about one third of Dominicans. Thus, the burden of purchasing life-saving medicines falls largely on individual Dominicans. As the

Dominican Republic attempts to extend health insurance coverage to all, heightened intellectual property protections, such as those in DR-CAFTA, could increase the price of medicines in a manner that overwhelms government efforts and leaves the burden of purchasing life-saving medicines on individuals who often do not have the means to do so.

Further, although the Dominican Republic receives international funding, this support only subsidizes a limited number of drugs and diseases. This assistance, though generous, may not always be available or sufficient, and raises concerns about the ability of the Dominican government to protect public health in the event of an interruption or decrease in aid. Moreover, even with such funding, patients are not always able to secure the drugs they need because of high pharmaceutical prices. For example, interviews suggested that some Dominican HIV/AIDS patients may be kept on first-line drugs when they should be moved to expensive second-line treatments because of cost concerns.

The Dominican government's ability to address these public health challenges may be limited by the promotion of stringent intellectual property protections by the U.S. government and the multinational pharmaceutical industry. Further, concern was expressed that U.S. technical assistance to the Dominican Republic provides information about DR-CAFTA obligations without equal information about public health safeguards that could be implemented. Without information about public health safeguards, DR-CAFTA could be implemented in a manner that is potentially devastating for Dominican patients.

During the negotiations over DR-CAFTA, the United States used its strong bargaining position to include heightened intellectual provisions such as "patent extensions," which can lengthen the term of a patent to compensate for administrative delays; "data exclusivity," which limits the use of test data by generic manufacturers in seeking marketing approval; and "patent linkage," which requires the agency responsible for ensuring drug safety and efficacy to also verify the non-existence of a patent.

Similar requirements in other countries have led to delays in the introduction of generic competition and have had devastating effects on access to affordable medicines. If these obligations have a similar effect in the Dominican Republic, as is projected, the public health system could be threatened and lives could be lost.

In recognition of the negative consequences that these heightened intellectual property provisions have on developing countries, 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 trading partners to adopt certain heightened intellectual property obligations for pharmaceuticals and reaffirmed the U.S. commitment to the Doha Declaration. The free trade agreement that the United States signed with Peru already reflects this change in U.S. policy. Bringing Dominican obligations under DR-CAFTA in line with this new U.S. approach is needed if the country is to avert a public health crisis and lives are to be saved.

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 implementation in line with the New U.S. Trade Policy, specifically:
 - a. Patent extensions for pharmaceuticals should be made optional.
 - b. At a minimum, data exclusivity should be limited to “a reasonable period” for undisclosed and required data, and should protect only new chemical entities. Data exclusivity should also be subject to an exception to protect public health in accordance 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 and other trade partners 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 needs 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 further study and address the effects that intellectual property laws can have 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 and intellectual property negotiations.

I. Introduction

Each year, millions of people in developing countries die because they cannot afford medications.¹ Intellectual property rights are a key factor affecting medicine prices. While they are intended to provide incentives for innovation, they also create limited monopolies that allow high prices to be set and maintained for life-saving drugs.² As the United States presses for more stringent intellectual property protections in free trade agreements,³ it has a moral obligation to consider the life and death impact of its trade policy.

The struggles of individuals in the Dominican Republic are representative of the challenges faced by many in the developing world. Public health is just one of the many burdens governments bear. With limited resources stretched to cover pressing concerns ranging from crime control to clean water, developing countries like the Dominican Republic are often unable to provide their citizens with the medications they desperately need⁴ and many Dominicans are forced to pay for their own treatment costs.⁵ In 2001, the Dominican Republic enacted social security reform legislation intended to provide universal health coverage to all Dominican citizens.⁶ As the social security system covers more citizens and diseases, the Dominican government may be overwhelmed by the price of medications, thereby forcing private citizens to continue to pay for their own treatment.⁷ Patients may have to make difficult decisions such as choosing between medicine and food.⁸

Unfortunately, individuals in developing countries like the Dominican Republic are often the least able to afford the medication they need. Because a typical Dominican woman earns less

¹ See World Health Assembly, Public health, innovation and intellectual property, W.H.A. 60.30, at ¶ 3, 66nd Ass. (May 24, 2007) (“[A]ccess to medicines ... is hampered by ... lack of resources and prices that are beyond the reach of many in the developing world.”).

² Medecins Sans Frontieres, *The impact of patents on access to medicines*, <http://www.msfaccess.org/main/access-patents/introduction-to-access-and-patents/the-impact-of-patents-on-access-to-medicines/> (last visited Mar. 6, 2010).

³ See Office of the United States Trade Representative, *Trade Facts: USTR’s Mission to Protect U.S. Intellectual Property Rights*, http://www.ustr.gov/sites/default/files/uploads/factsheets/2007/asset_upload_file285_13523.pdf at ¶ 2 (Nov. 2007) (last visited Mar. 6, 2010).

⁴ See Josh Ruxin, et. al., *Emerging Consensus in HIV/AIDS, malaria, tuberculosis, and access to essential medicines*, 365 LANCET, 618, 618 (2005) (“[P]oorest countries face enormous hurdles to achieving the Millennium Development Goals for health, let alone the broader goal of health for all their citizens.”).

⁵ See MAGDALENA RATHE, ET AL., *MEDICAMENTOS Y PROPIEDAD INTELECTUAL: EVALUACION DEL IMPACTO DE LOS NUEVOS ESTANDARES DE DERECHOS DE PROPIEDAD INTELECTUAL EN EL PRECIO DE LOS MEDICAMENTOS: EL CASO DE LA REPUBLICA DOMINICANA*, at 20 (2009).

⁶ See Ley No. 87-01, *Ley que crea el Sistema Dominicano de Seguridad Social*, Santo Domingo, Dominican Republic, 2001.

⁷ See discussion *infra* Part III.

⁸ Interview with nurse, Buen Samaritano Hospital, January 14, 2010, La Romana, Dominican Republic (on file with authors). See also Disease Control Priorities Project, *Ensuring Supplies of Drugs and Vaccines in Developing Countries, Without Medicines Patients Die Needlessly*, <http://www.dcp2.org/file/220/dcpp-drugsandvaccines-web.pdf> (Oct. 2008) (last visited March 6, 2010) (“[I]n most developing countries, consumers typically pay out of pocket for drugs, often sacrificing months or years of income to get well....”).

than \$200 USD per month⁹ and likely has no health insurance,¹⁰ a diagnosis of Hepatitis B would be crippling to her health and her family. In Santo Domingo, the cost for a standard Hepatitis B treatment is \$337.11 USD *per week* (over \$19,400 USD for a full course).¹¹ Thus, a Dominican woman like the one described may be forced to find a way to pay for a drug that costs over seven times her annual income.¹² Without treatment, she will face liver failure and death.

Although patients may not know why their medicines are so expensive, intellectual property rights can dramatically affect drug prices.¹³ With this relationship in mind, intellectual property laws should be enacted with the understanding that innovation incentives must be balanced with the public interest in using and benefitting from new products and processes.¹⁴ Though desirable, these innovation incentives do not negate the need to accommodate public health concerns. Rather, public health should be a key consideration in setting optimal levels of intellectual property protection.

In 2007, the United States shifted its trade policy partly in recognition that certain types of intellectual property provisions, though perhaps incentivizing innovation, can undermine public health.¹⁵ This shift in trade policy (“New U.S. Trade Policy”) imposes less stringent protections on other developing countries. The Dominican Republic, however, has not been offered similar provisions.

This report analyzes the impact of intellectual property protection on access to medicines in the Dominican Republic, with a specific focus on the provisions of the Dominican Republic-Central American-United States Free Trade Agreement (DR-CAFTA).¹⁶ As the United States successfully advocates for higher levels of intellectual property protection,¹⁷ developing countries risk detrimentally shifting the delicate balance between intellectual property and public health and burdening those least able to pay. The right to the highest attainable standard of health is

⁹ This extrapolation is based on statistical data from the Oficina Nacional de Estadística, *available at* <http://www.one.gob.do/> (last visited Mar. 6, 2010).

¹⁰ In 2002, only 21% of Dominicans were covered by some type of health insurance. PAN-AMERICAN HEALTH ORGANIZATION, HEALTH SYSTEMS PROFILE: DOMINICAN REPUBLIC 19 (3rd ed. Oct. 2007) [hereinafter PAHO].

¹¹ Interview with health official, Secretaria de Estado de Salud Pública y Asistencia Social (SESPAS), January 14, 2010, Santo Domingo, Dominican Republic (on file with authors). According to the official, treatment for Hepatitis B in the Dominican Republic is Pegasys, a drug produced by Roche, and the weekly cost of Pegasys is about \$347.11 USD (12,600 RD) per week required for 56 weeks *Id.* The exchange rate used is 1 USD = 36.3000 RD.

¹² Calculation based on the cost of Pegasys for one year (\$337.11 USD per week x 52 weeks = \$17,529 USD) divided by total income (\$2400 USD).

¹³ United Kingdom Comm’n on Intellectual Prop. Rights, *Final Report*, http://www.iprcommission.org/graphic/documents/final_report.htm, at Ch. 2, 36 (Sept. 12, 2002) (last visited Mar. 6, 2010) (“The importance of prices of medicines to poor consumers in developing countries is perhaps obvious.”).

¹⁴ See U.S. Const. art. I, § 8, cl. 8 (intellectual property designed to “[p]romote ... progress”).

¹⁵ See discussion *infra* Part IV.

¹⁶ Dominican Republic-Central America-United States Free Trade Agreement, Aug. 5, 2004 [hereinafter DR-CAFTA] *available at* <http://www.ustr.gov/trade-agreements/free-trade-agreements/cafta-dr-dominican-republic-central-america-fta/final-text>.

¹⁷ See Office of the United States Trade Representative, *Intellectual Property*, <http://www.ustr.gov/trade-topics/intellectual-property> at ¶¶ 1-3 (noting that the Office “uses a wide range of bilateral and multilateral trade tools to promote strong intellectual property laws and effective enforcement worldwide”).

internationally recognized as one of the fundamental rights of every human being.¹⁸ While the Dominican Republic currently faces severe resource constraints and struggles to provide its citizens with the medications they desperately need, the effects of DR-CAFTA could have potentially deadly results. Increasing intellectual property protections at the expense of public health comes at a legal, moral and possibly mortal cost.

A. The Human Right to Health

The right to the highest attainable standard of health is internationally recognized as one of the fundamental rights of every human being. Article 25(1) of the Universal Declaration of Human Rights provides that “[e]veryone has the right to a standard of living adequate for the health and well-being of himself and his family, including . . . medical care”¹⁹ Similarly, Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) recognizes “the right . . . to the . . . highest attainable standard of physical and mental health.”²⁰ The right to health may implicate related human rights, including the right to life, education, work and the benefits of scientific progress.²¹

The right to health and related human rights are inextricably connected with the right to affordable medicines. The Committee on Economic, Social and Cultural Rights, which interprets the ICESCR, has indicated that the right to health includes economic accessibility.²² Such an obligation means that “health facilities, goods and services must be affordable for all” and “poorer households should not be disproportionately burdened with health expenses. . . .”²³

The Dominican Republic has legal obligations with respect to the right to health. On January 4, 1978,²⁴ the Dominican Republic acceded to the ICESCR and, as such, is bound by its provisions that require progressive realization of the right to health for its citizens.²⁵ Thus, the Dominican Republic must take steps toward the full realization of the right to health and refrain from

¹⁸ See discussion *infra* Part I.A.

¹⁹ Universal Declaration of Human Rights, G.A. Res. 217A, Art. 25(1), U.N. GAOR, 3d Sess., 1st plen. mtg., U.N. Doc A/810 (Dec. 12, 1948) [hereinafter UDHR].

²⁰ International Covenant on Economic, Social and Cultural Rights, G.A. Res. 2200A (XXI), U.N. GAOR, 21st Sess., Supp. No. 16, Art. 12, U.N. Doc A/6316 (Dec. 16, 1966) [hereinafter ICESCR].

²¹ Access to medicine may also implicate the right to “life,” “education,” and “work,” UDHR, *supra* note 19, at Art. 3, 25(1), 23 (right to “life,” “education, and “work), ICESCR, *supra* note 20, at Art. 15 (right to the benefits of scientific progress), and the rights of the child, Convention on the Rights of the Child, G.A. Res 44/25, U.N. GAOR, 44th Sess., Supp. No. 49, U.N. Doc. A/44/49 (Nov. 20, 1989) (right to the benefits of scientific progress).

²² Committee on Economic, Social and Cultural Rights, *General Comment 14: The Right to the Highest Attainable Standard of Health*, ¶ 12 (b), 22nd Sess., U.N. Doc. E/C.12/2000/4 (Aug. 11, 2000).

²³ *Id.*

²⁴ See United Nations Treaty Collection, Status of the International Covenant on Economic, Social and Cultural Rights, http://treaties.un.org/Pages/ViewDetails.aspx?src=TREATY&mtdsg_no=IV-3&chapter=4&lang=en, at Dominican Republic (last visited Mar. 6, 2010).

²⁵ See Vienna Convention on the Law of Treaties, U.N. Doc. A/Conf. 39/27, at Art. 11 (May 23, 1969) (“The consent of a State to be bound by a treaty may be expressed by signature . . . or accession.”).

adopting laws or policies that would diminish the availability or affordability of medicines.²⁶ As a party to the ICESCR, the Dominican Republic has three duties in relation to the right to health: 1) to “respect,” or refrain from interfering directly or indirectly, with the right to health; 2) to “protect” the right to health, which includes taking steps to ensure that non-state actors do not interfere with the right to health; and 3) to “fulfill” the right to health through appropriate legislative, administrative, judicial and other measures.²⁷

The United States signed the ICESCR in 1977 but has not ratified it,²⁸ and therefore must refrain from acts that “defeat the object and purpose of [the] treaty.”²⁹ In addition, the United Nations Special Rapporteur on the Highest Attainable Standard of Health has indicated that developed countries should not encourage developing countries to accept intellectual property standards that do not provide public health safeguards, especially in the context of a bilateral or multilateral trade agreement.³⁰ This obligation can reasonably be interpreted to prohibit signatories like the United States from attempting to constrain the ability of states to address pressing public health challenges through free trade agreements.

Thus, in addition to moral responsibilities, both the Dominican Republic and the United States have legal obligations with respect to the right to health.³¹ Findings in this report raise questions about whether such obligations are being met.

B. Methodology

The Georgetown Human Rights Action/Human Rights Institute Fact-Finding Team, a group of nine students and two professors from the Georgetown University Law Center, conducted a fact-finding mission in the Dominican Republic. The primary goal of the mission was to determine how DR-CAFTA is being implemented in the Dominican Republic and the potential future impact of the Agreement on the right to health. Although factors ranging from

²⁶ Committee on Economic, Social and Cultural Rights, *General Comment 14: The Right to the Highest Attainable Standard of Health*, ¶ 32 22nd Sess., U.N. Doc. E/C.12/2000/4 (Aug. 11, 2000). (“[T]here is a strong presumption that retrogressive measures taken in relation to the right to health are not permissible.”). [hereinafter CESCR].

²⁷ *Id.* at ¶ 39. (“States Parties should ensure that the right to health is given due attention in international agreements In relation to the conclusion of other international agreements, States Parties should take steps to ensure that these instruments do not adversely impact on the right to health.”)

²⁸ See United Nations Treaty Collection, *supra* note 24, at United States.

²⁹ Vienna Convention on the Law of Treaties, *supra* note 25, at Art. 18. Though the United States is not a party to the Vienna Convention, its provisions have been recognized the Department of State as customary international law. Evan Criddle, *The Vienna Convention on the Law of Treaties in U.S. Treaty Interpretation*, 44 VA. J. INT’L L. 431, 443 (2004).

³⁰ Paul Hunt & Rajat Khosla, *The human right to medicines*, 8 INT’L J. HUM. RTS., 98, 105 (June 2008) (“In the context of medicines, this responsibility means that no rich State should encourage a developing country to accept intellectual property standards that do not take into account the safeguards and flexibilities included under the TRIPS agreement. In other words, developed States should not encourage a developing country to accept ‘TRIPS-Plus’ standards in any bilateral or multilateral trade agreement.”)

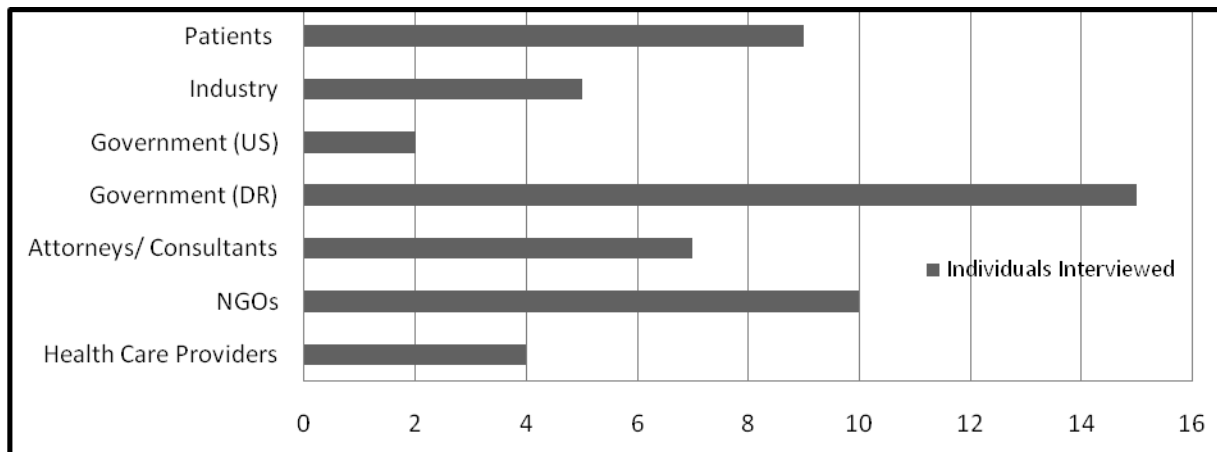
³¹ See World Health Organization, Comm’n on Intellectual Prop. Rights, Innovation and Public Health, *Public health, innovation and intellectual property right: report of the Commission on Intellectual Property Rights, Innovation and Public Health*, at 9 (2006) (“The moral obligation [to provide access to medicines for all] is backed by a legal imperative.”).

discrimination to quality of medications affect health in the Dominican Republic, the project focused exclusively on intellectual property rights. The mission's focus was selected by the members of the student group Georgetown Human Rights Action from a number of student proposals. Team members were selected from applications solicited from the student body as a whole. Funding for the project was provided by the Human Rights Institute at the Georgetown University Law Center.

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 Team also interviewed representatives of civil society and academia in the United States, who consulted in the development of the research project.

The "fact-finding" occurred primarily during interviews conducted from January 11th through January 15th, 2010, in Santo Domingo and La Romana, Dominican Republic. In total, the Team interviewed fifty-two individuals in the Dominican Republic, including patients, healthcare providers, American and Dominican government officials, members of non-governmental organizations, representatives from the multinational and domestic pharmaceutical industries, and Dominican lawyers. Interviews were generally held in the interviewee's office or in a health care facility. Informed consent was obtained for all interviews.

Interviews Conducted in the Dominican Republic
January 11 to January 15, 2010



Upon returning to the Washington, D.C., the Team consolidated its findings and recommendations into this report.

II. Intellectual Property & Public Health

Increased intellectual property protections, such as those in DR-CAFTA, can raise the price of medicines.³² Upward pressure on drug prices is particularly devastating in developing countries, such as the Dominican Republic, where resources are limited and purchasing high-priced pharmaceuticals can divert funding from other pressing priorities.³³ Although intellectual property is only part of a broad set of issues that affect access to medicines,³⁴ its impact on price remains a serious concern.

Intellectual property rights are legal monopolies over creations of the mind.³⁵ Patents may be the most recognized form of intellectual property protection, but this protection comes in a number of different shapes and sizes.³⁶ Regardless of the specific type of intellectual property right, all such rights operate by excluding competition, and thereby allow patent-holding companies to charge higher prices than those that would exist on an open market.³⁷

Pharmaceutical companies argue that their high prices are justified to reimburse investment in discovery,³⁸ but the actual cost of developing a new medicine is contested and may not be as high as industry claims.³⁹ A recent study shows that U.S. pharmaceutical companies spend twice as much on marketing as on research and development.⁴⁰ And, in 2008, the pharmaceutical industry's profits were nearly twice that of the oil and gas industry.⁴¹ Although high prices may create powerful incentives for creation, they also act as barriers to the right to health by placing

³² United Kingdom Comm'n on Intellectual Prop. Rights, *supra* note 13, at 37.

³³ See Carsten Fink, *Enforcing Intellectual Property Rights: an Economic Perspective*, in *The Global Debate on the Enforcement of Intellectual Property Rights and Developing Countries*, Issue Paper No.22, at xv (ICTSD, 2009).

³⁴ See, e.g., World Health Organization, *supra* note 31, at 6 (noting that health outcomes depend on many factors such as economic growth, income distribution, nutrition, education, public health measures, and medicine).

“[I]nnovation for ‘medicines and other products’ must be situated within a wider picture of efforts across sectors to improve health and development.” *Id.* at 7.

³⁵ See Earl W. Kintner & Jack L. Lahr, *An Intellectual Property Law Primer* 7–11 (Clark Boardman Company, Ltd. 1982) (1975).

³⁶ See, e.g., discussion *infra* Part IV.B.

³⁷ World Health Organization, *supra* note 31, at 20 (noting that the validity of justification for patents is context-specific because “where most consumers of health products are poor ... the monopoly costs associated with patents can limit the affordability of patented health-care products required by poor people in the absence of other measures to reduce prices or increase funding”).

³⁸ Companies claim that the research and development of a successful drug costs between 800 million to one billion dollars. Brochure from Pharmaceutical Research and Manufacturers of America, *Drug Discovery and Development: Understanding the R&D Process* 10 (2007), available at http://www.innovation.org/drug_discovery/objects/pdf/RD_Brochure.pdf.

³⁹ See Bob Young & Michael Surrusco, *Rx R&D Myths: The Case Against the Drug Industry's R&D Scare Card*, PUBLIC CITIZEN CONGRESS WATCH 2-12, July 2001, available at <http://www.citizen.org/documents/ACFDC.PDF>.

⁴⁰ Marc-André Gagnon & Joel Lexchin, *The Cost of Pushing Pills: A New Estimate of Pharmaceutical Promotion Expenditures in the United States*, 5-1 PLoS Medicine 29, 32 (Jan. 2008) (discussing the disparity in estimates of money spent on research and development and estimating that more than twice is spent on promotion as is spent on research and development).

⁴¹ See Fortune 500, *Top industries: Most profitable*,

<http://money.cnn.com/magazines/fortune/fortune500/2009/performers/industries/profits/> (last visited Mar. 6, 2010).

medicines beyond the reach of many people in developing countries.⁴² Serious moral and legal questions may be raised when life-saving drugs cost many times a person's annual income.

The connection between intellectual property obligations and public health has been vigorously debated by civil society, industry, and international organizations.⁴³ Two major international documents address intellectual property rights and public health concerns: the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS)⁴⁴ and the Declaration on TRIPS and Public Health (Doha Declaration).⁴⁵ Whether these international documents achieve an appropriate balance between intellectual property rights and public health is a matter still widely debated.⁴⁶ However, when the international community or individual states introduce additional obligations that go beyond TRIPS and that contravene the flexibilities for public health that are affirmed under the Doha Declaration, such as in the case of DR-CAFTA, the consequences can be dire. The high prices for medicines that may result can be a death sentence to impoverished individuals in developing countries.

A. TRIPS: Establishing International Intellectual Property Standards

TRIPS, signed in 1995,⁴⁷ introduced minimum international intellectual 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 it has an exceedingly far reach.⁴⁸ TRIPS, largely the result of U.S. efforts,⁴⁹ marked the first time that states were required to patent pharmaceutical products and processes.⁵⁰ Prior to TRIPS, governments had broad flexibility to adopt the intellectual property regimes of their choosing and many states excluded pharmaceuticals from patentability.⁵¹ Thus, subjecting life-saving medicines to a twenty-year

⁴² See Médecins Sans Frontières, *Drug Patents Under the Spotlight: Sharing Practical Knowledge about Pharmaceutical Patents*, <http://apps.who.int/medicinedocs/pdf/s4913e/s4913e.pdf>, at 2 (March 2003); see also CESCR, *supra* note 26, at ¶ 12 (b).

⁴³ See Peter M. Gerhart, *Symposium: The International Intellectual Property Regime Complex: The Tragedy of TRIPS*, 2007 MICH. ST. L. REV. 143, 145 (2007) (addressing the “diverse” literature on international intellectual property law that has “grown enormously” since TRIPS and revolves around the topics of efficacy and fairness).

⁴⁴ Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C – Results of the Uruguay Round, 33 I.L.M. 1197 (1994) [hereinafter TRIPS].

⁴⁵ World Trade Organization, Ministerial Declaration of 14 November 2001, WT/MIN(01)/DEC/11, 41 I.L.M. 746 [hereinafter Doha Declaration].

⁴⁶ See Peter M. Gerhart, *Slow Transformations: The WTO as a Distributive Organization*, 17 AM. U. INT'L L. REV. 1045, 1079-81 (2002) (arguing that the Doha Declaration “tips the balance of the WTO toward flexibility and recognition”).

⁴⁷ World Trade Organization, *Understanding the WTO: The Organization, Members and Observers*, http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm (last visited Mar. 6, 2010).

⁴⁸ World Trade Organization, *Understanding the WTO: The Agreements, Intellectual property: protection and enforcement*, http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm (last visited Mar. 6, 2010).

⁴⁹ DANIEL C.K. CHOW & EDWARD LEE, INTERNATIONAL INTELLECTUAL PROPERTY: PROBLEMS, CASES AND MATERIALS 270-71 (2006).

⁵⁰ *Id.*

⁵¹ *Id.*

patent monopoly was a dramatic shift in international intellectual property protection.⁵²

However, in an attempt to balance these new obligations, TRIPS also recognizes the right of states to “adopt measures necessary to protect public health,”⁵³ and grants considerable freedom in implementing intellectual property provisions through so-called “TRIPS flexibilities.”⁵⁴ These flexibilities legally allow states to provide for the public health of their citizens.⁵⁵ For example, states have some flexibility in how they define what inventions meet the *criteria* to obtain a patent.⁵⁶ 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.⁵⁷ 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.⁵⁸ These flexibilities are designed to allow states to implement intellectual property provisions in a way that does not undermine the right to health.⁵⁹ DR-CAFTA, negotiated in 2004, significantly erodes the ability to utilize these flexibilities by requiring intellectual property protections that go beyond a country’s TRIPS obligations.⁶⁰

B. Doha Declaration: Reinforcing TRIPS’ Public Health Commitment

Although TRIPS guaranteed the use of some public health safeguards, developed countries like the United States continued to pressure developing countries to strengthen intellectual

⁵² See ELLEN F.M. ’T HOEN, *THE GLOBAL POLITICS OF PHARMACEUTICAL MONOPOLY POWER: DRUG PATENTS, ACCESS, INNOVATION, AND THE APPLICATION OF THE WTO DOHA DECLARATION ON TRIPS AND PUBLIC HEALTH* 7 (AMB Publishers 2009).

⁵³ TRIPS, *supra* note 44, at Art. 8(1).

⁵⁴ See J.H. Reichman, *From Free Riders to Fair Followers: Global Competition Under the TRIPS Agreement*, 29 N.Y.U. J. INT’L L. & POL. 11, 28 (1997) (concluding that TRIPS “leaves developing countries ample ‘wiggle room’ in which to implement national policies favoring the public interest in free competition”); JAYASHREE WATAL, *INTELLECTUAL PROPERTY RIGHTS IN THE WTO AND DEVELOPING COUNTRIES* 7 (2001) (highlighting the “constructive ambiguity” in TRIPS).

⁵⁵ See James Thuo Gathii, *The Legal Status of the Doha Declaration on TRIPS and Public Health Under the Vienna Convention on the Law of Treaties*, 15 HARV. J.L. & TECH. 291, 301 (2002) (indicating that the language of the Doha Declaration, “cast in terms of members’ rights to protect public health introduces an interpretation not expressly provided in the TRIPS Agreement”).

⁵⁶ See TRIPS, *supra* note 44, at Art. 27(1). Patents must be available for products or processes that are “new, involve an inventive step and are capable of industrial application.” *Id.* However, the meaning and level of “inventive” could differ between Member States, creating room for flexibility in interpretation.

⁵⁷ See *id.* at Art. 6.

⁵⁸ See *id.* at Arts. 30-31. Generally, compulsory licenses are thought to fall under Article 31. See, e.g., Christopher Garrison, *Exceptions to Patent Rights in Developing Countries*, ISSUE PAPER NO. 17 at 2 (UNCTAD - ICTSD Project on IPRs and Sustainable Development 2006). However, use under Article 30 is also without permission of the right holder. See TRIPS, *supra* note 44, at Art. 30.

⁵⁹ See Doha Declaration, *supra* note 45 at ¶ 4 (“[T]he TRIPS Agreement does not and should not prevent Members from taking measures to protect public health... we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.”).

⁶⁰ See generally DR-CAFTA, *supra* note 16; see also World Health Organization, *supra* note 31, at 22 (identifying the “growing number of bilateral and free trade agreements which include higher standards of protection that erode these flexibilities”). See discussion *infra* Part IV.B.

property protections and refrain from using these flexibilities to protect public health.⁶¹ Many of these pressure tactics, such as trade disputes and litigation in Brazil, Thailand, and South Africa, garnered high-profile media criticism.⁶² In the wake of these controversies, developing countries used the 2001 WTO Ministerial Conference in Doha, Qatar as a platform to bring access to medicines to the forefront of the World Trade Organization.⁶³

The resulting binding interpretative text, the Doha Declaration, affirms the sovereign right of governments to fully utilize TRIPS flexibilities, including compulsory licensing and parallel importation, to protect public health.⁶⁴ The Declaration states that TRIPS can and should be interpreted to protect public health and promote access to affordable medicines.⁶⁵ However, in the years since the Declaration, developing countries have been subjected to pressure in the form of bilateral and multilateral trade agreements, like DR-CAFTA, that increase intellectual property rights at the expense of public health.⁶⁶

C. Competition: Driving Down Drug Prices

Competition in pharmaceutical markets generally lowers the price of medicines.⁶⁷ For example, the introduction of generic anti-retroviral medication to treat HIV/AIDS is credited with contributing to the 99% reduction in the cost of HIV/AIDS treatments over the past decade.⁶⁸ With the introduction of competition, brand-name manufacturers are forced to lower prices in order to maintain a profitable market share.⁶⁹

⁶¹ T HOEN, *supra* note 52, at 20-24. *Contra* Press Release, Office of United States Trade Representative [hereinafter USTR], USTR Zoellick says World has Chosen Path of Hope, Openness, Development and Growth (Nov. 14, 2001) (noting that the Office of the U.S. Trade Representative immediately praised the Declaration as a “landmark political declaration” and “a good example of developed and developing nations advancing common goals”).

⁶² T HOEN, *supra* note 52, at 21-29.

⁶³ See Gathii, *supra* note 55, at 296.

⁶⁴ Doha Declaration, *supra* note 45, at ¶¶ 4-5.

⁶⁵ *Id.* at ¶¶ 3-4.

⁶⁶ See STAFF OF H. COMM. ON GOV'T. REFORM, 109TH CONGRESS., TRADE AGREEMENTS AND ACCESS TO MEDICATIONS UNDER THE BUSH ADMINISTRATION, at 6 (Comm. Print 2005) (finding that “contrary to the Doha Declaration, U.S. trade negotiators have repeatedly used the trade agreements to restrict the ability of developing nations to acquire medicines at affordable prices”).

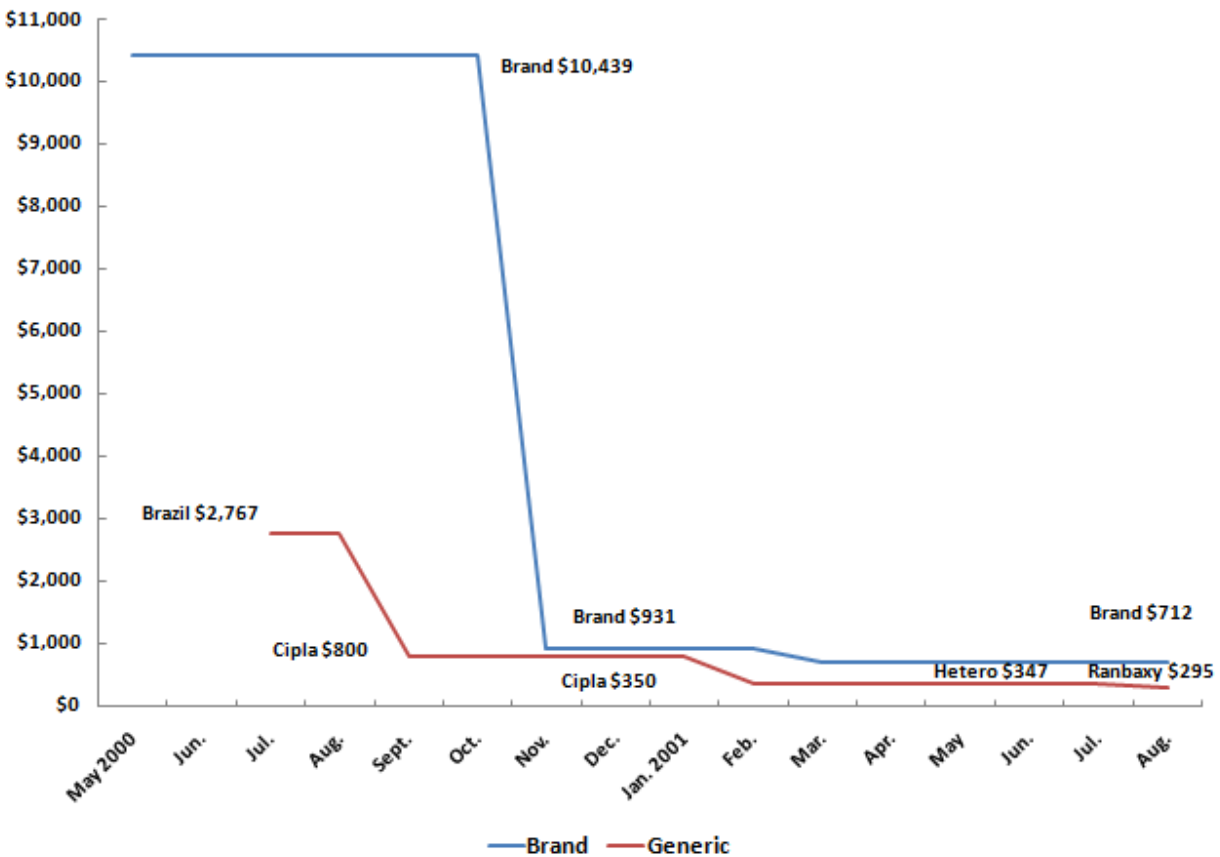
⁶⁷ Theodore C. Bailey, *Innovation and Access: The Role of Compulsory Licensing in the Development and Distribution of HIV/AIDS Drugs*, 2001 I.L. TECH. & POL'Y 193, 204 (2001). “The difference between a monopolistic and a competitive market can have a profound effect on the price of a drug, as evidenced by the drastic drop in price that occurs when patent protection for drugs cease.” *Id.*

⁶⁸ Medecins Sans Frontieres, *supra* note 2, at ¶ 4.

⁶⁹ *Id.* at ¶¶ 2-4 (“The most effective and sustainable way to bring down the price of a drug is through competition between manufacturers.”).

The Effects of Generic Competition⁷⁰

Cost of Triple-Combination AIDS Treatment May 2000 - August 2001



Compulsory licensing is one tool that harnesses the power of competition to break the lock of intellectual property monopolies and lower the price of medicines. For example, the Dominican government could grant a compulsory license to a third party, such as a generic drug manufacturer, to produce Hepatitis B or HIV/AIDS medication.⁷¹ The patent holder would receive some payment for the license⁷² and the additional production source would inject competition into the market, which may reduce high medicine prices.⁷³ The Dominican government has never issued a compulsory license, though it has considered doing so in the past.⁷⁴

⁷⁰ Data from Médecins Sans Frontières (2001) “A matter of life and death: The role of patents in access to essential medicines” http://www.doctorswithoutborders.org/publications/reports/2001/doha_11-2001.pdf (last visited Mar. 22, 2010). The graph depicts the effect of generic competition on the lowest world price per patient per year of stavudine (d4T) + lamivudine (3TC) + nevirapine triple combination therapy.

⁷¹ T Hoen, *supra* note 52, at 39.

⁷² TRIPS, *supra* note 44, at Art. 31(b).

⁷³ See Bailey, *supra* note 67, at 204.

⁷⁴ See discussion *infra* Part IV.C.

KALETRA® in the Dominican Republic: Competition Through Compulsory Licenses

In the Dominican Republic, the price of KALETRA® (Lopinavir/Ritonavir), an HIV/AIDS medication produced by Abbott Laboratories, dropped by approximately 55% with the introduction of international generic competition in the form of a compulsory license. Currently, 70% of HIV patients in the Dominican Republic use the drug combination in KALETRA®. When the Dominican government began purchasing KALETRA® from the patent holder, the average price internationally was \$183 USD per month of treatment, an amount equivalent to an average Dominican's monthly income. However, after a compulsory license was issued by the Thai government in 2007, the price was reduced to \$83 USD as a result of indirect competition.

Sources: Medicins Sans Frontiers: Untangling the Web – lopinavir/ritonavir (LPV/r), <http://utw.msffaccess.org/drugs/lopinavir-ritonavir> (last visited March 21, 2010), Press Release, World Health Organization, WHO Welcomes Abbott's Decision to Reduce the Price of Second-Line Antiretroviral Therapy (Apr. 10, 2007).

Increasing intellectual property protections could result in the Dominican Republic being unable to take advantage of international generic competition. Pharmaceutical companies only face competition in countries where intellectual property provisions allow generic alternatives.⁷⁵ For example, Abbott Laboratories reduced the price of KALETRA® in the Dominican Republic when faced with a Thai compulsory license.⁷⁶ Had KALETRA® been patented in the Dominican Republic, the price of KALETRA® could have remained prohibitively high because Abbott would not have been forced to compete with the generic alternative.⁷⁷ Thus, if attention is not paid to domestic intellectual property protections, Dominicans may not reap the benefits of generic competition internationally.

The negative ramifications of overly protective intellectual property laws exist despite differences between the Dominican pharmaceutical manufacturing market and that of the developed world. Because of limitations in the Dominican market such as small size and the presence of branded generics (i.e. generic pharmaceuticals with advanced marketing campaigns),⁷⁸ some Dominican-produced generics may not realize the same low price levels as unbranded or internationally-produced generics.⁷⁹ Thus, addressing intellectual property

⁷⁵ THE WORLD BANK, *BATTLING HIV/AIDS: A DECISION MAKER'S GUIDE TO THE PROCUREMENT OF MEDICINES AND RELATED SUPPLIES* 112 (Yolanda Tayler, ed., 2004) (“If a medicine or supply is not protected by intellectual property rights (such as a patent) in the country of importation, intellectual property rights will not constitute an obstacle for the procurement authority.”).

⁷⁶ See discussion *infra* KALETRA® in the Dominican Republic: Competition Through Compulsory Licenses

⁷⁷ See THE WORLD BANK, *supra* note 75, at 12 (“If generic medicines are available from foreign suppliers, this does not necessarily mean that they can be lawfully imported because the originator may hold a patent “in-country” and may try to use it to block importation.”).

⁷⁸ Interview with representative of the generic industry, Industrias Farmacéuticas Dominicana (INFADOMI), January 11, 2010, Santo Domingo, Dominican Republic (on file with authors).

⁷⁹ See N. GREGORY MANKIW, *PRINCIPLES OF MICROECONOMICS* 384-85 (Thompson South-Western 2007). The use of brand names allows manufacturers to differentiate their products and charge a higher price than they could charge for undifferentiated goods. *Id.*

protections internationally, particularly in generic source countries like India and Brazil, is critical.⁸⁰ However, although a complete solution must be international, intellectual property protections in the Dominican Republic are an important piece of the public health puzzle. When countries like the Dominican Republic increase their intellectual property protections, they can cease to be able to import lower-priced generics that may be available on the international market.

⁸⁰ See e.g., Medicines Sans Frontiers, *People Living with HIV/AIDS: India must not sacrifice us in trade agreement with Europe*, Press Release, [http://www.msfaccess.org/media-room/press-releases/press-release-detail/?tx_ttnews\[tt_news\]=1604&cHash=bc2335a5ff](http://www.msfaccess.org/media-room/press-releases/press-release-detail/?tx_ttnews[tt_news]=1604&cHash=bc2335a5ff), at ¶ 4 (Mar. 12, 2010) (last visited Mar. 15, 2010) (“As the source of 92 percent of the AIDS medicines used in developing countries today, India is the pharmacy of the developing world. So the impact of [a potential free trade agreement between India and the European Union] also stretches far beyond India....”).

III. An Increasing Burden: The Struggle to Provide Dominicans with Medicines

Although Dominicans face a number of challenges that impact the right to health,⁸¹ unaffordable medicines are a major concern for patients, health care professionals and the government.⁸² Over eighty percent of spending on pharmaceuticals is paid for out of pocket by Dominican patients.⁸³ According to one doctor, “[patients] have enough money to find out what is wrong with them and what medicines they need but not enough money to buy [medications]. . . . [S]ometimes they can’t afford the whole course of medicine so they just buy [enough medication for] a day or two.”⁸⁴ Even with private health insurance coverage, one patient suffering from anemia was forced to pay \$100 USD for ten iron injections.⁸⁵ Though her treatment calls for daily injections, she can only afford to take them every other day.⁸⁶ Because the price of medications can be a life and death matter, countries should consider the public health implications of their trade policy.

A. The Dominican Government

In an attempt to better manage the many burdens on the Dominican health system, the Dominican Republic passed health reform legislation⁸⁷ and created a social security system to provide universal health insurance coverage to Dominican citizens.⁸⁸

Although the 2001 legislation tasked the Dominican government with providing universal social security by 2012,⁸⁹ less than one-third of Dominicans are currently covered.⁹⁰ Despite the fact that not all Dominicans are covered, the government already spends one-quarter of its health budget on pharmaceuticals.⁹¹ With expanded social security coverage, that amount will need to drastically increase, or patients will be forced to forego treatment. Further, each patient is

⁸¹ See Ruxin, *supra* note 4, at 620. Patients and civil society also indicated that Dominicans suffer from a number of barriers such as lack of health system infrastructure, stigmatization, etc. Interview with HIV/AIDS advocate, Red Dominicana de Personas que Viven con VIH/SIDA (REDOVIH), January 12, 2010, Santo Domingo, Dominican Republic (on file with authors).

⁸² Interview with health official, Comisión Ejecutiva para la Reforma del Sector Salud (CERSS), January 14, 2010, Santo Domingo, Dominican Republic (on file with authors).

⁸³ See RATHE, *supra* note 5, at 20.

⁸⁴ Interview with nurse, Buen Samaritano Hospital, *supra* note 8.

⁸⁵ Interview with HIV/AIDS advocate, REDOVIH, *supra* note 81.

⁸⁶ *Id.*

⁸⁷ See Ley No. 42-01 Ley General de Salud, Santo Domingo, Dominican Republic, 2001, Art. 127-129; PAHO, *supra* note 10, at 29. The law created the *Sistema Nacional de Salud* (SNS) (national health system), *Plan Básico de Salud* (PBS) (basic health plan), and *Seguro Familiar de Salud* (family health insurance program).

⁸⁸ See Ley No. 87-01, *supra* note 6.

⁸⁹ RATHE, *supra* note 5, at 22; see also PAHO, *supra* note 10, at 29.

⁹⁰ Interview with social security official, El Seguro Nacional de Salud, January 15, 2010, Santo Domingo, Dominican Republic (on file with authors). Currently, only 3 million (out of 10 million people) are covered. *Id.* While the Social Security system has not yet covered all Dominicans the roughly 30% of the population covered by the program is a significant increase from the 5.4% covered in 1996. See PAHO, *supra* note 10, at 19. In the same year, only 12.4% of Dominicans had private health insurance coverage. *Id.*

⁹¹ RATHE, *supra* note 5, at 20.

currently limited to roughly \$90 USD per year for drug purchases, an amount often insufficient when dealing with life-threatening diseases.⁹² Thus, out-of-pocket expenses for Dominicans may remain significant regardless of the success of Dominican social security.

The Dominican government will face even greater burdens as chronic diseases like cancer and heart disease become increasingly common in addition to infectious diseases like dengue fever and tuberculosis.⁹³ Because chronic diseases often require long treatments with drugs that are protected by intellectual property laws, providing medicines to treat these conditions can be extremely expensive.⁹⁴ For example, a full course of breast cancer drugs costs over \$33,000 USD in the Dominican Republic.⁹⁵ A Dominican health official characterized the amounts spent on such high-cost chronic diseases as unsustainable.⁹⁶

The high price of medicine is a common thread that runs through the health challenges the Dominican Republic faces. The inability to pay for high-priced pharmaceuticals forces healthcare providers, government and individuals to make heart-breaking choices.

- One healthcare provider indicated that her hospital “didn’t even want a mammogram machine until [the facility] could offer cancer drugs.”⁹⁷
- An official with the Dominican government pointed to waiting lists for some of the most expensive medications that treat life-threatening diseases and are prohibitively expensive for most Dominicans. The waiting lists were implemented because the government could not afford to provide medicines for all patients in need.⁹⁸
- Further, the few patients lucky enough to qualify for government assistance for catastrophic diseases such as cancer must travel two to three times a month to Santo Domingo for their medications. These trips can be especially burdensome because patients may have to travel long distances while severely ill with only limited funds to pay for such travel. The frequent trips are necessary because high prices mean that the limited drugs the Dominican government can purchase must be carefully rationed.⁹⁹
- A cancer patient in Santo Domingo stated that she was only able to pay for her first

⁹² *Id.* at 23.

⁹³ PAHO, INDICADORES BASICOS DE SALUD, REPUBLICA DOMINICANA 2008 5 (2008). Infectious diseases caused over ten percent of deaths in men and women in 2005. *Id.* at 4. HIV/AIDS is of particular concern, with an estimated rate of 5.5 persons infected per 100,000 in 2007, and much higher rates in tourist areas such as Puerto Plata, which has an incidence of 24.6 persons infected per 100,000 citizens. *Id.* at 9. Worldwide, deaths from chronic diseases are projected to be more than two times the death rate from communicable diseases by 2015. WORLD HEALTH ORGANIZATION, *supra* note 31, at 4.

⁹⁴ Interview with health official, SESPAS, *supra* note 11.

⁹⁵ *Id.*

⁹⁶ *Id.*

⁹⁷ Interview with nurse, Buen Samaritano Hospital, *supra* note 8.

⁹⁸ See interview with health official, SESPAS, *supra* note 11.

⁹⁹ *Id.* See also interview with HIV/AIDS advocate, La Junta Directiva de Coalición, January 12, 2010, Santo Domingo, Dominican Republic (on file with authors).

course of treatment with the help of family and friends. “[I]t was a big sacrifice for them . . . I hated to be a burden . . . because they have their own commitments.”¹⁰⁰

- Other patients are forced to choose between feeding their families and treating their illness.¹⁰¹ One healthcare provider characterized it as a losing proposition between “[buying] medication and buying lunch.”¹⁰²

The Efavirenz Dilemma

Efavirenz (EFV) is the generic name of an important antiretroviral drug for HIV treatment produced by Bristol-Myers Squibb and Merck under the brand name SUSTIVA® and STOCRIN®. Interviews in the Dominican Republic report that EFV is patented. Because EFV is patented, the Dominican Republic cannot benefit from lower prices internationally.

Brand-name EFV costs over **three times more** than the generic version available internationally.

Because the Dominican government cannot afford to purchase EFV on the limited funds provided by international donors, it purchases nevirapine (NVP), a drug similar to EFV but whose price has decreased dramatically as a result of generic competition. However, NVP may cause life-threatening liver damage and weaken the immune system if given to some patients too early in the progression of their disease.

One Dominican health official remarked that EFV is the preferable treatment because the government can initiate potentially life-saving treatment sooner and it avoids safety concerns associated with NVP.

Because the government is forced to supply NVP, Dominican patients wait longer to begin treatment for HIV/AIDS, leaving patients with immune systems that are potentially weakened. These standards of initiating treatment for HIV/AIDS are lower in the Dominican Republic than standards set in World Health Organization guidelines and in developed countries.

Source: Interview with health official, Comision Ejecutiva para la Reforma del Sector Salud, in Santo Domingo, Dominican Republic, January 14, 2010 (on file with authors); Rapid Advice: Antiretroviral Therapy for HIV Infection in Adults and Adolescents 10-11, World Health Organization (November 2009).

¹⁰⁰ Interview with patient, Instituto Oncológico, January 15, 2010, Santo Domingo, Dominican Republic (on file with authors).

¹⁰¹ See United Kingdom Comm’n on Intellectual Prop. Rights, *supra* note 13, at 36 (“[I]f a sick person has to pay more for a pharmaceutical product as a result of a patent, it means that he or she will have less to spend on other essentials of life such as food or shelter.”).

¹⁰² Interview with nurse, Buen Samaritano Hospital, *supra* note 8.

B. International Donors

International funding currently plays a critical role in keeping the Dominican health system afloat. This funding heavily subsidizes a limited number of medications. In particular, the Global Fund finances the purchase of most HIV/AIDS, malaria, and tuberculosis medications in the Dominican Republic.¹⁰³ Although such funding is beneficial, there are serious questions about the long-term sustainability of this model.

First, international assistance covers only a limited number of medications and diseases. Dominicans face diseases that can be just as deadly as those singled out by international donors such as HIV/AIDS, malaria, and tuberculosis.¹⁰⁴ To a Dominican patient who is dying of Hepatitis B, for example, international assistance is of little comfort. Even patients who benefit from receiving free HIV/AIDS medications do not receive all the medications they need. Specifically, international aid provides only a limited amount of medication for the opportunistic infections that are often part and parcel of HIV/AIDS.¹⁰⁵ Therefore, international assistance cannot be the only solution to the problem of high-priced medicine.

Second, the medications selected for international funding are often limited due to price concerns. It has been reported that one way the Dominican government may be controlling the cost of medications that treat more advanced stages of AIDS, is by limiting the testing of HIV/AIDS patients.¹⁰⁶ By testing these patients less frequently, those who should be receiving more advanced treatment may be forced to wait for appropriate medication even though their immune systems may be more compromised.¹⁰⁷ In addition, HIV/AIDS patients in the Dominican Republic are reportedly kept on first-line drugs, where generic competition exists, when they should be moved to more expensive second and third-line treatments.¹⁰⁸ Although

¹⁰³ See The Global Fund to Fight AIDS, Tuberculosis and Malaria, <http://www.theglobalfund.org/programs/grant/?compid=158&grantid=239&lang=en&CountryId=DMR>. [hereinafter Global Fund]. The Dominican Republic has received Global Fund grants since 2004, and six grant recipients have requested a total of \$179,983,639 USD to date. *Id.* Thus far, the Global Fund has approved funding of \$108,121,868 USD to combat the spread of these infectious diseases in the Dominican Republic. *Id.*

¹⁰⁴ See discussion *supra* Part III.A (discussing the impact of the increasing prevalence of chronic diseases in the Dominican Republic).

¹⁰⁵ Interview with representative, Consejo Presidencial del SIDA (COPRESIDA), January 14, 2010, Santo Domingo, Dominican Republic (on file with authors).

¹⁰⁶ Interview with HIV/AIDS advocate, Alianza Solidaria para la Lucha contra el VIH/SIDA (ASOLSIDA), January 13, 2010, Santo Domingo, Dominican Republic (on file with authors).

¹⁰⁷ See Médecins Sans Frontières, *HIV/AIDS Treatment: Optimize Now, or Pay More Later...*, <http://www.msf.ca/news-media/news/2009/07/hiv-aids-treatment-optimize-now-or-pay-more-later/>, at ¶ 4 (Jul. 20, 2009) (“Unlike older first-line drugs, most second- and third-line drugs are patented and priced out of reach for patients in developing countries.”); see also National Institute of Allergy and Infectious Diseases, *How HIV Causes AIDS*, <http://www3.niaid.nih.gov/topics/HIVAIDS/Understanding/howHIVCausesAIDS/>, at ¶¶ 1-2 (“HIV destroys CD4 positive (CD4+) T cells, which are ... crucial to maintaining the function of the human immune system. As HIV attacks these cells, the person infected with the virus is less equipped to fight off infection and disease ... Antiretroviral medicines can help reduce the amount of virus in the body, preserve CD4+ T cells and dramatically slow the destruction of the immune system.”).

¹⁰⁸ See interview with HIV/AIDS advocate, REDOVIH, *supra* note 81; see interview with HIV/AIDS advocate, ASOLSIDA, *supra* note 106 (discussing how the Dominican Republic uses CD4 levels, an immune system indicator used to tell when a patient should be moved from first-line medicines to a more aggressive treatment, is set at a

the consequences of such actions can mean death,¹⁰⁹ patients may not be given the best possible medicines because affordably-priced generics are not available. Thus, even international assistance is forced to contend with the barrier of price.

Finally, international funding may not always be available to the Dominican Republic. One government attorney working on health reform efforts noted that there is no guarantee that the Global Fund will renew its grants.¹¹⁰ And a health official acknowledged that the Dominican government will be responsible for providing medicines for these diseases when assistance ends or is interrupted.¹¹¹ Significant doubts exist about the government's ability to adequately compensate for a loss of international assistance.¹¹² One HIV/AIDS advocate recalled how civil society scrambled to find funds in anticipation of providing anti-retroviral medication when international funding renewal appeared to be in jeopardy in 2009.¹¹³ Further, according to some interviews, the Dominican government has been forced to borrow medicines from poorer countries like Haiti or purchase medicines at a higher price from the name-brand manufacturer to ensure continued treatment.¹¹⁴ One Dominican HIV/AIDS advocate stated that “[i]f international funding runs out, treatment runs out.”¹¹⁵

International assistance is a double-edged sword. Although it plays a critical role in saving the lives of Dominicans, if funding were stopped or decreased, the consequences could be dire. Because the Dominican government cannot rely on unlimited international aid, it must find its own solution to the problem of life-saving medicines priced out of reach.

lower level than international standards: “CD4 testing is set at 250 in the Dominican Republic while the international standard is 350”).

¹⁰⁹ Médecins Sans Frontières, *supra* note 107, at ¶ 3 (discussing the need for “robust first-line treatment” and “access to affordable second- and third-line treatment combinations” and noting that “[n]one of this is happening now, which means that thousands of patients are back on AIDS death row.”).

¹¹⁰ Interview with attorney, Comisión Ejecutiva para la Reforma del Sector Salud, January 13, 2010, Santo Domingo, Dominican Republic (on file with authors) (“When the Global Fund ends, we are supposed to get continuation grant – but what does that guarantee? This is a topic of public health.”).

¹¹¹ Interview with health advisor, Executive Branch of the Dominican Republic, January 13, 2010, Santo Domingo, Dominican Republic (“[W]hen the Global Fund runs out it will fall on us [to fill this void].”).

¹¹² Interview with HIV/AIDS advocate, REDOVIIH, *supra* note 81; interview with HIV/AIDS advocate, ASOLSIDA, *supra* note 106 (noting that the government would not treat access to medicines as a priority). However, some expressed a belief that the government would be able to compensate for a reduction in international assistance because demand for second- and third-line treatments is not significant for some diseases such as tuberculosis. Interview with tuberculosis advocate, Asociación Dominicana Pro-Bienestar de la Familia, January 12, 2010, Santo Domingo, Dominican Republic (on file with authors).

¹¹³ Interview with HIV/AIDS advocate, AIDS Free World, January 11, 2010, Santo Domingo, Dominican Republic (on file with authors).

¹¹⁴ Interview with health official, CERSS, *supra* note 82. According to a leading HIV/AIDS advocate, a shipment of generic anti-retroviral medication from India was delayed in 2009, and the Dominican government was forced to borrow medicines from Haiti to ensure continued treatment. Interview with HIV/AIDS advocate, REDOVIIH, *supra* note 81.

¹¹⁵ Interview with HIV/AIDS advocate, REDOVIIH, *supra* note 81.

IV. U.S. Pressure: Compounding the Price Problem

Despite its commitment to the Doha Declaration,¹¹⁶ the United States has pursued free trade agreements, like DR-CAFTA, that increase intellectual property levels¹¹⁷ and, in the process, threaten to undermine access to medicines. In some instances, these increased obligations are being implemented in ways that are even more stringent than the highly developed intellectual property protections in the United States.¹¹⁸

DR-CAFTA is expected to increase pharmaceutical prices in the Dominican Republic over the next two decades,¹¹⁹ which will likely undermine the Dominican government's efforts to provide life-saving medicines and force individual Dominicans to continue purchasing medicine at unaffordable prices. Ultimately, U.S. promotion of heightened intellectual property protections could exacerbate existing public health difficulties in the Dominican Republic.

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 protection.¹²⁰ These tactics often exploit the disparities in bargaining power caused by the dependence of many developing countries, like the Dominican Republic, on trade with the United States.¹²¹ During DR-CAFTA negotiations, this dependence resulted in the Dominican government accepting TRIPS-plus intellectual property provisions.¹²² Today, the United States continues to promote these already heightened obligations through training and technical assistance that fails to inform the Dominican government of the more public health conscious approaches it may take, including those the United States itself employs.¹²³ These intellectual property efforts favor multinational pharmaceutical companies at the expense of public health and may be interfering with the Dominican Republic's ability to uphold the right to health of its citizens.

¹¹⁶ See discussion *supra* Part II.B (discussing the Doha Declaration and its affirmation of the right of governments to fully utilize TRIPS flexibilities to protect public health and promote access to affordable medicines).

¹¹⁷ See Carsten Fink & Patrick Reichenmiller, *Tightening TRIPS: Intellectual Property Provisions of U.S. Free Trade Agreements*, World Bank, Trade Note 20, at 1 (Feb. 7, 2005) <http://siteresources.worldbank.org/INTRANETTRADE/Resources/Pubs/TradeNote20.pdf>.

¹¹⁸ See Frederick M. Abbott, *Intellectual Property Provisions of Bilateral and Regional Trade Agreements in Light of U.S. Federal Law*, Issue Paper No. 12 at 1 (2006) (emphasizing that developing countries that accept intellectual property commitments must recognize that U.S. intellectual property law is a “sophisticated system of checks and balances” with exceptions to patent holder's rights). If a developing country fails to implement sufficient exceptions, their intellectual property commitments will be more excessive than both TRIPS and U.S. law. *Id.*

¹¹⁹ RATHE, *supra* note 5, at v.

¹²⁰ See generally Rahul Rajkumar, *The Central American Free Trade Agreement: An End Run Around the Doha Declaration on TRIPS and Public Health*, 15 ALB. L.J. SCI. & TECH. 433 (2005) (discussing mechanisms commonly used by the United States to pressure countries into accepting TRIPS-plus provisions).

¹²¹ See generally United States and Dominican Republic Trade Data, 2008, *infra* graphic Part IV.A.

¹²² See discussion *infra* Part IV.A (discussing the trade dependence and pressure placed on the Dominican Republic to accept TRIPS-plus provisions in DR-CAFTA).

¹²³ See discussion *infra* Part IV.C (discussing the United States' continued influence on the Dominican Republic to promote the use and enforcement of TRIPS-plus provisions in DR-CAFTA).

Despite this pressure on the Dominican Republic to accept and implement heightened intellectual property provisions in DR-CAFTA, the United States has recognized that these provisions have negative consequences for developing countries and undermine the public health protections affirmed in the Doha Declaration.¹²⁴ Partly in recognition of these negative consequences, the Ways and Means Committee of the U.S. House of Representatives and the Office of the United States Trade Representative revisited pending free trade agreements to substantially revise some of these standards and reaffirmed U.S. commitment to the Doha Declaration.¹²⁵ This change in policy (“New U.S. Trade Policy”) has been offered to Colombia, Peru, and Panama in free trade agreements that incorporate these more favorable provisions in addition to revised labor and environmental provisions.¹²⁶ Dominicans, however, do not benefit from the New U.S. Trade Policy and are forced to implement heightened intellectual property obligations that are no longer in line with U.S. policy and may have negative consequences for public health.

A. Unequal Partners: The Non-Negotiation of Intellectual Property in DR-CAFTA

The Dominican government negotiated DR-CAFTA with one primary goal: preserving its vital trade relationship with the United States.¹²⁷ This trade imbalance is reflected in the reliance of the Dominican Republic on the United States as a market.¹²⁸ According to one former DR-CAFTA negotiator, as the Dominican government watched Central American countries enter further into free trade negotiations with the United States, it became fearful of losing U.S. market share to its neighbors and joined negotiations.¹²⁹

¹²⁴ *E.g.* STAFF OF H. COMM. ON GOV'T. REFORM, 109D CONGRESS., TRADE AGREEMENTS AND ACCESS TO MEDICATIONS UNDER THE BUSH ADMINISTRATION, at i (Comm. Print 2005) (finding that “contrary to the Doha Declaration, U.S. trade negotiators have repeatedly used the trade agreements to restrict the ability of developing nations to acquire medicines at affordable prices”); Letter to Susan Schwab from Reps. Waxman, Allen, McDermott, Doggett, Schakowsky, Start, DeGette, Van Hollen, Lee, Blumenauer, Lewis and Emanuel (Mar. 12, 2007) (copy on file with author) (“Regrettably, recent U.S. free trade agreements [FTAs] appear to undermine ... commitment [to the Doha Declaration] with provisions that strip away flexibilities to which countries are entitled under TRIPS.”).

¹²⁵ *See* U.S. GEN. ACCOUNTING OFFICE, INTELLECTUAL PROPERTY: U.S. TRADE POLICY GUIDANCE ON WTO DECLARATION ON ACCESS TO MEDICINES MAY NEED CLARIFICATION, <http://www.gao.gov/products/GAO-07-1198>, 41-42 (Sept. 2007) (discussing “congressional concern over IP provisions and access to medicines addressed in bipartisan trade deal”).

¹²⁶ *See* Brook K. Baker, *Ending Drug Registration Apartheid: Taming Data Exclusivity and Patent/Registration Linkage*, 34 AM. J. L. & MED. 303, 335-36 (2008); *see, e.g.*, United States-Peru Trade Promotion Agreement, Art. 17-18, April 12, 2006, *available at* <http://www.ustr.gov/trade-agreements/free-trade-agreements/peru-tpa/final-text>, at Art. 16.9.6(b)-(c) [hereinafter Peru FTA] (incorporating new labor and environmental provisions).

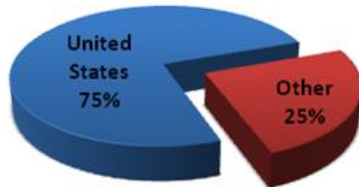
¹²⁷ *See* interview with former DR-CAFTA negotiator, January 11, 2010, Santo Domingo, Dominican Republic (on file with authors); interview with former DR-CAFTA negotiator for intellectual property and telecommunications, January 15, 2010, Santo Domingo, Dominican Republic (on file with authors).

¹²⁸ *See generally* “Dominican Republic and United States Trade Data, 2008” at 23.

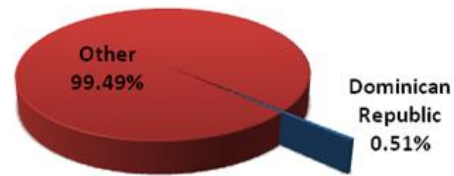
¹²⁹ *See* interview with former DR-CAFTA negotiator, *supra* note 127 (noting that the Dominican Republic was not interested in a trade agreement with the United States until it found out Central America was negotiating one).

Dominican Republic and United States Trade Data, 2008

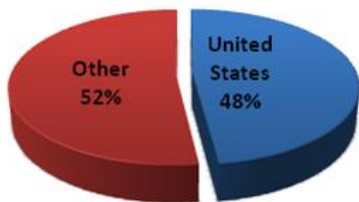
Dominican Exports



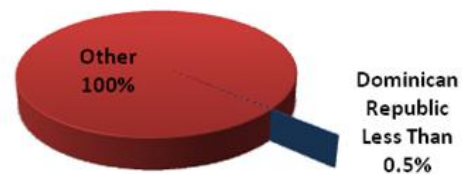
U.S. Exports



Dominican Imports



U.S. Imports



Sources: United States Department of State, *Dominican Republic Profile*, <http://www.state.gov/r/pa/ei/bgn/35639.htm>, ¶ 4 (June 2009) (last visited Mar. 6, 2010); United States Census Bureau, *Foreign Trade Statistics, Trade with Dominican Republic: 2008*, <http://www.census.gov/foreign-trade/balance/c2470.html#2010> (Mar. 11, 2009) (last visited Mar. 6, 2010); United States Census Bureau of Economic Analysis, *U.S. International Trade in Goods and Services January 2010*, <http://www.bea.gov/newsreleases/international/trade/2010/pdf/trad0110.pdf>, Exhibit 1 (Mar. 11, 2010).

Further weakening the Dominican government’s bargaining power was the late stage at which it began trade discussions. Negotiations between the United States and the Dominican Republic lasted just three months,¹³⁰ largely because the other participating Central American countries had already completed a substantial portion of the agreement.¹³¹ Several former DR-CAFTA negotiators reported that Dominican negotiators were relatively inexperienced.¹³² One noted that “we needed handholding as a country and as negotiators [during this process].”¹³³ Further, DR-CAFTA’s intellectual property provisions were not negotiated until the final round, which may have influenced Dominican acquiescence to unfavorable terms because negotiators did not want to risk provisions on textiles and sugar that had already been agreed upon.¹³⁴ The

¹³⁰ Press Release, USTR, *U.S. & Dominican Republic Conclude Trade Talks Integrating the Dominican Republic into CAFTA*, at ¶ 7 (March 15, 2004)

¹³¹ See SICE Foreign Trade Information System, *Central America-Dominican Republic-United States*, http://www.sice.oas.org/TPD/USA_CAFTA/USA_CAFTA_e.ASP (last visited Mar. 6, 2009). (listing the participating Central American nations: Costa Rica, El Salvador, Guatemala, Honduras, and Nicaragua).

¹³² Interview with former DR-CAFTA negotiator, *supra* note 127; interview with former DR-CAFTA negotiator for intellectual property and telecommunications, *supra* note 127.

¹³³ Interview with former DR-CAFTA negotiator, *supra* note 127.

¹³⁴ See SONIA GUZMÁN DE HERNÁNDEZ, *LA INTRAHISTORIA DEL DR-CAFTA* 113 (Corripio 2006); interview with former DR-CAFTA negotiator, *supra* note 127. *But see* former DR-CAFTA negotiator for intellectual property and telecommunications, *supra* note 127 (asserting that the Dominican Republic was able to negotiate some changes in the form of a few amendments, notes, and side letters even if they were unable to make large changes to the text).

enticement of these benefits and inexperience of the negotiators may have prevented the Dominican Republic from negotiating significant changes in intellectual property provisions.

The United States acknowledged that it would pursue heightened intellectual property protections in DR-CAFTA.¹³⁵ These protections have been characterized as some of the most onerous among other U.S. free trade agreements with developing countries,¹³⁶ and surpass obligations under TRIPS.¹³⁷ Yet, despite the United States' stated desire to include heightened intellectual property protection, parties to DR-CAFTA signed a Memorandum of Understanding as part of the Agreement stating that DR-CAFTA's intellectual property chapter does not affect a country's ability to take "necessary measures to protect public health by promoting access to medicines for all."¹³⁸

Although the legal effects of this Memorandum are untested, U.S. activities during and after DR-CAFTA negotiations call into question its commitment to the document's principles. One DR-CAFTA negotiator reported that the United States focused on protecting the multinational pharmaceutical industry during the negotiations.¹³⁹ Since the negotiation of DR-CAFTA, the United States has provided technical assistance on DR-CAFTA implementation that may not fully embrace or inform the Dominican Republic about safeguards that could be implemented to address public health concerns. By promoting policies that may raise the price of medicines in the Dominican Republic, the United States may be interfering with the Dominican Republic's ability to realize the right to health for its citizens.

B. Beyond TRIPS, Beyond the New U.S. Trade Policy: DR-CAFTA Intellectual Property Provisions

DR-CAFTA imposes several intellectual property provisions that go beyond those contained in TRIPS and the New U.S. Trade Policy. These provisions could negatively affect public health in the Dominican Republic and are compounded by U.S. technical assistance on DR-CAFTA implementation that may not present the public health safeguards present in U.S. law to the Dominican government. Without these safeguards, Dominican law may sometimes go beyond highly developed U.S. intellectual property law. This combination of DR-CAFTA provisions and U.S. technical assistance could drive up the price of medicines in a way that is devastating for the lives of many ordinary Dominicans.

¹³⁵ Letter to the House Notifying Intent to Negotiate Free Trade Talks with Dominican Republic from the United States Trade Representative to the Honorable J. Dennis Hastert, Speaker, U.S. House of Representatives, at 3 (Aug. 4, 2003) (noting noted that the Dominican Republic should "build on the foundations established in [TRIPS] and other international intellectual property agreements").

¹³⁶ U.S. GEN. ACCOUNTING OFFICE, *supra* note 125, at Figure 2 (comparing DR-CAFTA provisions to other free trade agreements).

¹³⁷ See discussion, *infra* Part IVB (discussing the TRIPS-plus obligations in DR-CAFTA).

¹³⁸ DR-CAFTA, *supra* note 16 at Understanding Regarding Certain Public Health Measures, Aug. 5, 2004 (stating that the intellectual property chapter of DR-CAFTA does not affect a country's ability to take "necessary measures to protect public health by promoting access to medicines for all").

¹³⁹ See interview, former DR-CAFTA negotiator for intellectual property and telecommunications, *supra* note 127.

This report focuses on three DR-CAFTA provisions that impose obligations beyond TRIPS: 1) patent extensions, 2) data exclusivity, and 3) patent linkage.¹⁴⁰ In examining these provisions, comparisons are made between the Dominican law implementing DR-CAFTA,¹⁴¹ TRIPS and U.S. law. These comparisons show that the Dominican Republic may be missing opportunities to implement intellectual property protections in a manner that protects the right to health.

1. Patent Extensions

Patent extensions increase the protected term of a patent.¹⁴² Extensions are designed to compensate for government delays in granting a patent application or approving a drug for market.¹⁴³ Compensation is given by extending the patent holder's monopoly over the pharmaceutical product.¹⁴⁴ However, by extending this monopoly, a patent extension further delays the entry of competition into the market and, thus, may keep prices artificially high.¹⁴⁵

The patent extension provision in DR-CAFTA imposes obligations on the Dominican Republic that exceed those contained in TRIPS. Although 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.¹⁴⁶ Thus, the patent extension provision in DR-CAFTA creates additional protections for pharmaceutical companies not contemplated by TRIPS.

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 a regulatory delay cannot exceed fourteen years from marketing approval,¹⁴⁷ while this limit does not exist in Dominican law.¹⁴⁸ Thus, the Dominican law implementing DR-CAFTA may not protect public health to the same degree.

The problem of patent extensions is particularly acute in developing countries. In the United States, it takes over three years on average to complete the patent application process.¹⁴⁹ In developing countries like the Dominican Republic, which have far fewer resources at their

¹⁴⁰ Each provision is explained in detail in the text. Additional information is available in Annex B.

¹⁴¹ Ley No. 424-06, *Ley de Implementación del Tratado de Libre Comercio entre la República Dominicana, Centroamérica, y los Estados Unidos de América del 20 noviembre de 2006* [Implementation Law of DR-CAFTA], GAC. OF. No. 10393, 22 de noviembre de 2006 (Dom. Rep.) [hereinafter "Dominican law"].

¹⁴² Cynthia M. Ho, *A New World Order for Addressing Patent Rights and Public Health*, 82 CHI.-KENT L. REV. 1469, 1498 (2007).

¹⁴³ Carlos M. Correa, *Bilateralism in Intellectual Property: Defeating the WTO System for Access to Medicines*, 36 CASE W. RES. J. INT'L L. 79, 85 (2004).

¹⁴⁴ DR-CAFTA, *supra* note 16, at Art. 15.9(6).

¹⁴⁵ See STAFF OF H. COMM. ON GOV'T. REFORM, *supra* note 66, at 8.

¹⁴⁶ DR-CAFTA, *supra* note 16, at Art. 15.9(6).

¹⁴⁷ 35 U.S.C. §§ 156(a), (c)(3) (2006).

¹⁴⁸ Ley No. 20-00 sobre Propiedad Industrial [Law on Industrial Property], GAC. OF. No. 10044, 10 de mayo de 2000, Art. 27 Párr. I (1)-(2), as amended by Dominican Law, Art. 2 (Dom. Rep.).

¹⁴⁹ Terry Carter, *A Patent on Problems: New PTO Chief has Strong Backing – and a Huge Backlog of Work*, ABA. J. Mar. 2010, at 42, 44.

disposal than the United States,¹⁵⁰ administrative delays in the patent office and drug regulatory authority are not uncommon.¹⁵¹ Thus, patent extensions impose a double burden on developing countries by effectively punishing them for their lack of resources by extending monopolies that increase drug prices and further strain government budgets.

Patent extensions affect public health by forcing patients to wait even longer than the twenty-year term established by TRIPS for generic medicines and the competition they bring to the market.¹⁵² DR-CAFTA has not been in effect long enough in the Dominican Republic to see how patent extensions will be granted and their impact.¹⁵³ However, the United States has recognized the potential negative consequences of patent extensions, which are now optional for developing countries under the New U.S. Trade Policy.¹⁵⁴ Unfortunately, the Dominican Republic has yet to benefit from this favorable shift in policy.

2. Data Exclusivity

Data exclusivity is a form of intellectual property protection for pharmaceutical safety, efficacy and quality data.¹⁵⁵ 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.¹⁵⁶ 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.¹⁵⁷ But, data that is protected by an exclusivity regime cannot be used or relied upon by a third party, such as a generic manufacturer, for a period time.¹⁵⁸ If generic manufacturers cannot rely on this data, they must either wait until the data exclusivity expires or hold their own clinical research trials, which are often prohibitively expensive and can raise ethical questions by duplicating

¹⁵⁰ The United States Patent and Trademark Office employed 6,243 patent examiners at the end of fiscal year 2009. United States Patent and Trademark Office, PERFORMANCE AND ACCOUNTABILITY REPORT FISCAL YEAR 2009 11 (USPTO 2009), available at <http://www.uspto.gov/about/stratplan/ar/index.jsp>. The Dominican Republic's Oficina Nacional de la Propiedad Industrial has fifteen total employees, six of which examine patents. See interview with patent office officials, Oficina Nacional de la Propiedad Industrial (ONAPI), January 12, 2010, Santo Domingo, Dominican Republic (on file with author).

¹⁵¹ See CARLOS CORREA, INTEGRATING PUBLIC HEALTH CONCERNS INTO PATENT LEGISLATION IN DEVELOPING COUNTRIES 83 (South Centre 2000); ANDY GRAY, ACCESS TO MEDICINES AND DRUG REGULATION IN DEVELOPING COUNTRIES: A RESOURCE GUIDE FOR DFID 1-3 (London 2004).

¹⁵² See *All Costs, No Benefits: How TRIPS-plus intellectual property rules in the US-Jordan FTA affect access to medicines*, Oxfam Briefing Paper, at 27, March 2007.

¹⁵³ See interview with representatives, Fundación Plenitud, January 11, 2010, Santo Domingo, Dominican Republic (on file with author).

¹⁵⁴ See, e.g., Peru FTA, *supra* note 126, at Art. 16.9.6(b)-(c); see also María Fabiana Jorge, *New U.S. Trade Policy: A turning point?*, 5 J. GENERIC MED. 5, 6 (2007) (noting that countries "may" instead of "shall" implement patent extensions for delays in marketing approval or granting a patent for pharmaceuticals under the amended free trade agreements).

¹⁵⁵ See Correa, *supra* note 143, at 85.

¹⁵⁶ G. Lee Skillington & Eric M. Solovy, *The Protection of Test and Other Data Required by Art 39.3 of the TRIPS Agreement*, 24 NW. J. INT'L L. & BUS. 1, 6 (2003).

¹⁵⁷ Ellen R. Shaffer & Joseph E. Brenner, *A Trade Agreement's Impact On Access To Generic Drugs*, 28 HEALTH AFFAIRS 959 (2009).

¹⁵⁸ See Sandra Adamini et al., *Policy Making on Data Exclusivity in the European Union: from Industrial Interests to Legal Realities*, 34 J. HEALTH POL. POL'Y & L. 979, 980 (2009).

unnecessary testing on human beings for commercial purposes.¹⁵⁹ Thus, data exclusivity prevents generic manufacturers from entering the market, providing competition and driving down prices.

Data exclusivity is completely independent from patents and creates an additional layer of monopoly protection.¹⁶⁰ Whereas patents reward innovation, data exclusivity rewards investment and effort.¹⁶¹ Protecting data is particularly problematic in developing countries because brand-name pharmaceutical manufacturers typically attempt to sell their products in developed markets like the United States before attempting to extract profit from developing countries.¹⁶² A pharmaceutical manufacturer could wait until patent protections or data exclusivity in developed countries expired, and then use data exclusivity to receive an additional term of monopoly in developing countries like the Dominican Republic.¹⁶³ The result is that the developing nations, which have the greatest need for lower cost drugs, may have to wait the longest to obtain them.¹⁶⁴

Data exclusivity provisions in DR-CAFTA can be characterized as exceeding those in TRIPS.¹⁶⁵ TRIPS requires countries to protect undisclosed data from unfair commercial uses and certain types of disclosure.¹⁶⁶ TRIPS leaves governments with broad discretion in implementing data protection regimes,¹⁶⁷ and, consequently, allows for public health considerations.¹⁶⁸ The United States, however, has chosen to adopt a more extensive data exclusivity regime that flatly requires five years of protection for new products containing a new chemical entity and three

¹⁵⁹ Jerome H. Reichman, *Rethinking the Role of Clinical Trial Data in International Intellectual Property Law: The Case for a Public Goods Approach*, 13 MARQ. INTELL. PROP. L. REV. 1, 5, n.12 (2009) (noting that “repeating a preexisting trial [because of data exclusivity protection] raises ethical questions, because it would deny some patients access to medicines known to be effective purely for commercial purposes” while also recognizing that “generic trials might also provide drugs to patients who otherwise could not afford them”).

¹⁶⁰ See Reichman, *supra* note 159, at 5.

¹⁶¹ See GlaxoSmithKline, *Global Public Policy Issues*, Position Paper, <http://www.gsk.com/policies/GSK-on-regulatory-data-protection.pdf> (Dec. 2007) (last visited Mar. 6, 2010) (justifying data exclusivity because this monopoly on clinical research data “represents a fair return for industry being expected to share confidential data and a fair reward for the investment and effort involved in collating the data”).

¹⁶² U.S. GEN. ACCOUNTING OFFICE, *supra* note 125, at 39.

¹⁶³ *Id.*

¹⁶⁴ *Id.* at 38-39.

¹⁶⁵ Medecins Sans Frontieres, *Doha Derailed: Extra Burdens – IP provisions not required by TRIPS*, http://www.msf.org/msfinternational/invoke.cfm?component=report&objectid=3A6F7274-E541-48ED-BFAE87D7879201FE&method=full_html, at ¶¶5-6 (Sept. 2003). *But see* Skillington & Solovy, *supra* note 156, at 33 (discussing the position of the General Counsel of the Office of the United States Trade Representative that “unfair commercial use” was understood to mean that “data will not be used to support, clear or otherwise review other applications for marketing approval for a set amount of time unless authorized by the original submitter of the data.”). However, the “interpretation of exactly this term is highly disputed among WTO members.” Ingo Meitinger, *Implementation of Test Data Protection According to Article 39.3 TRIPS*, 8-2 J. WORLD INTELL. PROP. 123, 124 (2005).

¹⁶⁶ TRIPS, *supra* note 44, at Art. 39.3. TRIPS specifies that undisclosed data is protected if it involves considerable effort to originate and its submission was required by regulatory authorities to register new chemical entities. *Id.*

¹⁶⁷ World Health Organization, *WTO and the TRIPS Agreement*, at ¶ 6, http://www.who.int/medicines/areas/policy/wto_trips/en/index.html (last visited Mar. 6, 2010);

¹⁶⁸ See *id.* at ¶ 7.

years of protection for new uses or indications.¹⁶⁹ It has attempted to promote this more extensive data exclusivity regime in other countries through free trade agreements like DR-CAFTA.¹⁷⁰ Under DR-CAFTA, data submitted for regulatory approval is given at least five years of protection regardless of the purpose of its use.¹⁷¹ Further, some products that do not contain a new chemical entity are protected when they would not be under TRIPS.¹⁷² Thus, where generics would have an opportunity to enter the market under TRIPS (e.g. under a compulsory license) DR-CAFTA could unilaterally prohibit entry for at least five years. This extension of the monopoly may have life or death consequences for patients who are unable to obtain lower-priced medicines.

Studies show that one of the main factors in increasing the price of medicines in developing countries is data exclusivity.¹⁷³ Perhaps unsurprisingly then, interviews with individuals who work with intellectual property and pharmaceuticals revealed that data protection is the most contentious of the three DR-CAFTA provisions studied in this report.¹⁷⁴

Recognizing in part the problematic nature of data exclusivity provisions for developing countries, the New U.S. Trade Policy contains a TRIPS-plus data exclusivity obligation that is more amenable to public health concerns.¹⁷⁵ For example, under New U.S. Trade Policy, data exclusivity is limited to new “chemical entities” rather than a new “product,”¹⁷⁶ a distinction that limits the pharmaceuticals that qualify for protection.¹⁷⁷ Additionally, the period of data exclusivity is shifted from “at least five years” to a reasonable period, normally five years.¹⁷⁸ Further, the New U.S. Trade Policy establishes a public health exception that authorizes countries to take measures to protect public health notwithstanding data exclusivity.¹⁷⁹ These changes in U.S. policy significantly improve the balance between economic incentives and public health considerations over the provisions contained in DR-CAFTA.

¹⁶⁹ 21 U.S.C. §§ 355(c)(3)(E)(ii)-(iii) , 355(j)(5)(F)(ii).

¹⁷⁰ U.S. GEN. ACCOUNTING OFFICE, *supra* note 125, at 27.

¹⁷¹ DR-CAFTA, *supra* note 16, at Art. 15.10(1)(a).

¹⁷² Compare *id.* with TRIPS, *supra* note 44, at Art. 39.3.

¹⁷³ See, e.g., Oxfam America, *supra* note 152, at 6; Shaffer et. al., *supra* note 157, at 957.

¹⁷⁴ Interview with representative, Asociacion de Representantes de Importadores de Medicamentos, January 12, 2010, Santo Domingo, Dominican Republic (on file with author); interview with representative of the generic industry, INFADOMI, *supra* note 78.

¹⁷⁵ See U.S. GEN. ACCOUNTING OFFICE, *supra* note 125, at 41-42.

¹⁷⁶ Compare DR-CAFTA, *supra* note 16, at Art. 15.10.1(a) with Peru FTA, *supra* note 126, at Art.16.10.2(a).

¹⁷⁷ Jorge, *supra* note 154 at 6-7 (noting that New U.S. Trade Policy limits data exclusivity protection to “new chemical entities”).

¹⁷⁸ Peru FTA, *supra* note 126, at Art.16.10.2(b). See also Jorge, *supra* note 154 at 7 (noting that this shift from “at least five years” represents a “very significant change” because data exclusivity will have “clear limits as it is in the U.S.”).

¹⁷⁹ Peru FTA, *supra* note 126, at Art.16.10.2(e) (creating a public health exception to data exclusivity in accordance with the Doha Declaration).

3. Patent Linkage

Patent linkage refers to a system where drug regulatory bodies are linked with patent enforcement.¹⁸⁰ If a drug is patented, the drug regulatory agency generally cannot approve the generic version of the drug for purchase and must inform the patent owner that someone else has tried to obtain approval to sell the drug.¹⁸¹ 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.¹⁸² 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.¹⁸³

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.¹⁸⁴ 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.¹⁸⁵

Although the United States adopted a patent linkage system,¹⁸⁶ U.S. law contains significant safeguards that can be used to protect public health.¹⁸⁷ For example, U.S. law requires patent owners to identify and list patents in the publicly available Orange Book, a public database where patents and data exclusivity are listed,¹⁸⁸ and to affirmatively enforce their patent in court after being informed of a generic manufacturer's attempt to gain marketing approval.¹⁸⁹ An additional safeguard under U.S. law incentivizes generic production by limiting marketing approval delays of generic products to no more than thirty months.¹⁹⁰ Further, the U.S. law provides for an even greater incentive for 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.¹⁹¹ Even though the U.S. patent linkage system has

¹⁸⁰ Abbott, *supra* note 118, at 10.

¹⁸¹ DR-CAFTA, *supra* note 16, at Art. 15.10(2)(a)-(b).

¹⁸² *Id.*

¹⁸³ Abbott, *supra* note 118, at 11.

¹⁸⁴ DR-CAFTA, *supra* note 16, at Art. 15.10(2)(a)-(b).

¹⁸⁵ STAFF OF H. COMM. ON GOV'T. REFORM, *supra* note 66, at 9.

¹⁸⁶ 35 U.S.C. § 271(e)(2).

¹⁸⁷ Abbott, *supra* note 118, at 11.

¹⁸⁸ See 21 U.S.C. § 355(b)(1) (requiring applicants to submit for publication the patent numbers and expiration dates of "any patent which claims the drug for which the applicant submitted the application or which claims a method of using such adrug and with respect to which a claim of patent infringement could reasonably be asserted").

¹⁸⁹ 35 U.S.C. § 271(e)(5). Patent owners have a forty-five day window of opportunity from when they are notified to enforce their patent by taking legal action against the generic manufacturer. *Id.*

¹⁹⁰ 21 U.S.C. § 355(j)(5)(B)(iii).

¹⁹¹ *Id.* § 355(j)(5)(B)(iv).

faced criticism for hindering generic competition,¹⁹² these flexibilities in U.S. law are an example of the highly developed nature of U.S. intellectual property law that tries to establish a balance between patent holders and consumers.¹⁹³

In contrast, the Dominican Republic has implemented only one of these flexibilities in Dominican law: establishment of a public register that lists patented pharmaceutical products.¹⁹⁴ A generic manufacturer in the Dominican Republic does not have similar mechanisms contained in U.S. law to challenge the patent in order to accelerate generic marketing approval. Without the opportunity and incentive for generic manufacturers to challenge patents under Dominican law, the drug regulatory authority may assume that patents are valid and block the marketing approval of a drug even if the patent is likely invalid.¹⁹⁵ By failing to implement critical safeguards, the Dominican Republic creates a complex patent linkage system that will impose administrative and legal burdens that could provide patent holders with more protection than under U.S. law.¹⁹⁶

Recognizing the unique burdens patent linkage places on drug regulatory authorities in developing countries, the New U.S. Trade Policy reverses the trend of tasking drug regulatory agencies with enforcing patents.¹⁹⁷ Under the New U.S. Trade Policy, patent holders must be notified that another person seeks to market a product covered under the patent.¹⁹⁸ After this notification, the patent holder may be required to seek enforcement to prevent marketing approval of the allegedly infringing product.¹⁹⁹ Thus, the burden of patent enforcement is placed on the patent holder to seek available remedies, and not on the drug regulatory authority to enforce patents.²⁰⁰ Further, provisions in recent free trade agreements explicitly recognize that generic manufacturers can challenge pharmaceutical patent validity or applicability.²⁰¹ These changes in U.S. policy significantly improve the balance between patent holders and public health from the provisions contained in DR-CAFTA.

¹⁹²Even the flexibilities in U.S. law may not prevent abuse by patent holders. See U.S. Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study*, 14 <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf> (July 2002) (last visited Mar. 6, 2010) (concluding that the Orange Book was abused by patent holders because some owners filed suspect patent applications simply to prevent the marketing of generic medicines). The study also highlighted that 72% of the generic applications were experiencing legal actions by the brand-name patent holders and that several abuses of the system that led to patent evergreening and generic entry delay onto the market up to 5 years. *Id.*

¹⁹³ See Abbott, *supra* note 118, at vii (noting that “intellectual property rights and related regulatory standards deemed appropriate for the United States may not be appropriate for developing countries” because free trade agreements fail to reflect the interplay between rules, limitations and exceptions that establish a balance between patent holders and consumers in U.S. law).

¹⁹⁴*Supra* note 192.

¹⁹⁵ Abbott, *supra* note 118, at 11.

¹⁹⁶ Abbott, *supra* note 118, at 11.

¹⁹⁷ See, e.g., Jorge, *supra* note 154, at 7-8 (discussing differences between current patent linkage regimes and the benefits under the New U.S. Trade Policy).

¹⁹⁸ See Peru FTA, *supra* note 126, at Art. 16.10(3)(b).

¹⁹⁹ *Id.* at Art. 16.10(3)(a), (c).

²⁰⁰ See Jorge, *supra* note 154, at 8 (noting that linkage provisions under the New U.S. Trade Policy put the “responsibility back on the patent holder so that he/she has to act if he/she considers that a patent may be infringed”).

²⁰¹ Peru FTA, *supra* note 126 at Art. 16.10(4)(c).

C. Beyond TRIPS, Beyond the New Trade Policy: DR-CAFTA Implementation

Despite the change in U.S. trade policy, the United States continues to promote the use and enforcement of TRIPS-plus provisions in the Dominican Republic that go beyond obligations in U.S. law and the New U.S. Trade Policy.²⁰² This promotion 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.²⁰³

The Dominican 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.²⁰⁴ 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. Demonstrating this lack of knowledge, Dominican government officials expressed confusion about the requirements needed to issue a compulsory license.²⁰⁵ And, many of those interviewed were unaware of public health safeguards that exist in U.S. law or the New U.S. Trade Policy.²⁰⁶ Without accurate education and balanced training about what DR-CAFTA provisions require, the Dominican government may choose not to use pro-public health flexibilities, which limits the government’s ability to respond to public health needs.

²⁰² See interview with representatives, United States Agency for International Development (USAID), January 12, 2010, Santo Domingo, Dominican Republic (on file with authors).

²⁰³ See, e.g., *id.*; interview with patent office officials, ONAPI, *supra* note 150; interview with trade officials, La Dirección de Comercio Exterior (DICOEX), January 13, 2010, Santo Domingo, Dominican Republic (on file with authors).

²⁰⁴ See interview with representative of the generic industry, INFADOMI, *supra* note 78; see generally Liliana Otero, *Medicamentos y DR-CAFTA: Compromisos Asumidos por República Dominicana*, (July 2008) (reproduced by Chemonics International Inc. for USAID’s DR-CAFTA implementation Project) (discussing DR-CAFTA implementation in terms of heightened intellectual property obligations without providing comparable information about legal mechanisms that could be used to balance intellectual property protections with public health).

²⁰⁵ Many expressed the belief that a compulsory license can only be granted in an emergency situation. *E.g.*, interview with representatives, Fundación Plenitud, *supra* note 153 (stating that the government believes there must be an emergency to grant a compulsory license); interview with trade officials, DICOEX, *supra* note 203 (expressing her understanding that the use of flexibilities is “limited to cases of national emergencies”). *But see* interview with intellectual property attorney, January 12, 2010, Santo Domingo, Dominican Republic (on file with authors) (stating that data exclusivity and patent linkage provisions in DR-CAFTA would not block a compulsory license).

²⁰⁶ See interview with representative of the generic industry, INFADOMI, *supra* note 78; interview with HIV/AIDS advocate, La Junta Directiva de Coalición, *supra* note 99.

Although the willingness to provide financial assistance and capacity-building is commendable, the United States loses credibility by directing Dominican authorities how to implement Dominican law without providing balanced information about flexibilities that the Dominican Republic can use to protect the public's health.

The Pharmaceutical Industry: Regional Lobbying

Dominican government officials report that powerful pharmaceutical companies also attempt to influence Dominican policy in ways that could undermine the right to health.

In 2009, the Dominican Republic and eight Central American countries considered organizing a regional drug purchasing program for thirty-six high-priced drugs. Because each country has little individual purchasing power, the regional drug purchasing program would have enabled the countries to pool their resources for additional bargaining and purchasing power with multinational pharmaceutical companies. This effort was supported by the finding that only thirteen drugs consume ninety percent of the region's public health budget.

In response to these efforts, a pharmaceutical lobbying organization sent a letter to the government of each country questioning the strategy and arguing that these measures might violate international and national legal obligations. The lobbying organization, FEDEFARMA, represents companies such as Eli Lilly, Merck, Sanofi Aventis and Pfizer.

Sources: Letter, 2009 PAHO Reunión del Sector Salud de Centroamérica y República Dominicana (on file with authors)

V. Forecasting the Effects of DR-CAFTA in the Dominican Republic

TRIPS-plus provisions such as those found in DR-CAFTA can profoundly impact access to medicines.²⁰⁷ 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.²⁰⁸ 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, after its free trade agreement with the United States.²⁰⁹ 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.²¹⁰ Research indicates that the Dominican Republic is also likely to experience an increase in pharmaceutical prices because of DR-CAFTA.²¹¹

The price of pharmaceuticals in the Dominican Republic is expected to increase by nine to fifteen percent by 2027 as a result of DR-CAFTA based on a recent study by Fundación Plenitud and the Pan-American Health Organization.²¹² The majority of this price increase is attributed to the effects of data exclusivity.²¹³ 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 prices could be deadly for Dominican patients who are affected in many different ways. A nurse in the Dominican Republic explained that patients currently cannot afford to take “anything that is non-generic” on a daily basis.²¹⁴ 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.”²¹⁵ 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 grants from international donors.²¹⁶

Dominican government officials and civil society also expressed concern about the sustainability of the Dominican Republic’s public health programs if prices increase as projected.²¹⁷ One health official noted that the Dominican government currently spends over \$10 million USD on

²⁰⁷ See, e.g., Oxfam America, *supra* note 152, at 7; Shaffer et. al., *supra* note 157, at 961.

²⁰⁸ Oxfam America, *supra* note 152, at 12.

²⁰⁹ *Id.* at 2.

²¹⁰ Shaffer et. al., *supra* note 157, at 961.

²¹¹ See RATHE, *supra* note 5, at v.

²¹² *Id.*

²¹³ *Id.* at 62.

²¹⁴ Interview with nurse, Buen Samaritano Hospital, *supra* note 8.

²¹⁵ Interview with HIV/AIDS advocate, ASOLSIDA, *supra* note 106.

²¹⁶ See interview with health official, CERSS, *supra* note 82.

²¹⁷ Interview with health official, SESPAS, *supra* note 11.

pharmaceuticals that treat chronic diseases, and that this spending is unsustainable.²¹⁸ Other countries that have implemented heightened intellectual property provisions as a result of free trade agreements with the United States faced similar problems. For example, in Jordan, the rise in pharmaceutical prices has threatened the sustainability of public health programs.²¹⁹ The Dominican government could also be forced to spend resources on training and the implementation of TRIPS-plus provisions to the detriment of other public health needs. Patent linkage, for example, forces the Dominican drug regulatory agency to spend resources on patent verification and notification. This burden is in addition to its public health responsibilities, which include assuring the safety, efficacy and quality of pharmaceuticals.²²⁰ With scarce resources, the implementation of DR-CAFTA itself further strains the Dominican budget from health priorities and requires additional resources to ensure that DR-CAFTA is implemented in a way that safeguards the right to health.

Outdated TRIPS-plus provisions in DR-CAFTA could critically limit the Dominican Republic's ability to uphold the right to health for its citizens. Further, price increases threaten to overwhelm the Dominican government's efforts to implement meaningful social security protection for its citizens. Without such reform, Dominican citizens will continue to struggle to pay for drugs they cannot afford. Though the United States has extended more favorable intellectual property provisions to other developing countries, Dominicans do not currently benefit from this shift in U.S. trade policy. Instead, Dominicans will face rising drug prices under DR-CAFTA.²²¹ The Dominican Republic should also be able to benefit from these less stringent intellectual property provisions that better allow developing countries to uphold the right to health.

²¹⁸ *Id.* (estimating that \$11.2 million USD (406 million RD) was spent in the chronic disease department in 2009). The exchange rate used is 1 USD = 36.3000 RD.

²¹⁹ Oxfam America, *supra* note 152, at 3.

²²⁰ Interview with health official, SESPAS, *supra* note 11.

²²¹ RATHE, *supra* note 5, at 62.

VI. Conclusion

The Dominican Republic will face increasing difficulties in protecting public health because of the heightened intellectual property provisions in DR-CAFTA and its implementing legislation. The human right to health, as contained in the International Covenant on Economic, Social and Cultural Rights, creates obligations for both the United States and the Dominican Republic. Heightened intellectual property provisions in DR-CAFTA and subsequent state practices may implicate the moral and legal obligations of both countries to uphold the right to health.

Currently, the Dominican Republic is unable to provide medications for all citizens. More than eighty percent of spending on pharmaceuticals is out of pocket despite an often inadequate average annual income of about \$3000 USD.²²² And, although the Dominican government is in the process of attempting to increase insurance coverage for its citizens, the public health budget is already strained and the medicine expenditure for each patient may be insufficient for many,²²³ raising further questions about the reform's viability. Further, the Dominican government relies heavily on international donors to provide for some life-saving medicine, a reliance that likely cannot be sustained.²²⁴

The future may not be more promising: the effects of DR-CAFTA have the potential to exacerbate these current pressing public health challenges. The TRIPS-plus intellectual property provisions in DR-CAFTA will likely have a profound impact on access to medicines and may hinder efforts by the Dominican Republic to protect public health. These provisions could significantly limit the Dominican Republic's ability to safeguard public health through internationally recognized legal flexibilities that were guaranteed under TRIPS and reaffirmed by the Doha Declaration. These provisions could also limit generic competition, allowing pharmaceutical companies to set and keep prices of new and already expensive drugs artificially high. Consistent with studies from other countries on the effects of TRIPS-plus provisions, the provisions in DR-CAFTA will likely increase pharmaceutical prices in the Dominican Republic.

The consequences of TRIPS-plus provisions, like those in DR-CAFTA, have been recognized as harming developing countries by keeping lower priced drugs from those who need them.²²⁵ Under the New U.S. Trade Policy, developing countries have been offered more favorable intellectual property provisions which make patent extensions optional and allow for a more flexible data exclusivity and patent linkage regime.²²⁶ Despite this recognition that heightened intellectual property provisions undermine public health protection, the United States' policy in

²²² See *id* at 20 (noting that eighty percent of spending on pharmaceuticals is out of pocket); see also Oficina Nacional de Estadística, Empleo por Rangos de Ingresos y Sexo, según año 2004-2007, available at <http://www.one.gob.do/> (last visited Mar. 6, 2010). The average income of a Dominican citizen in 2007 ranges from \$1,333.33 USD (48,000.12 RD) to \$3000.00 USD (72,000 RD). *Id.*

²²³ See discussion *supra* Part III.

²²⁴ See discussion *supra* Part III.B.

²²⁵ STAFF OF H. COMM. ON GOV'T. REFORM, *supra* note 66, at i.

²²⁶ Jorge, *supra* note 154, at 6-8.

the Dominican Republic has not similarly shifted. Further, U.S. technical assistance in the Dominican Republic may undermine the balance between intellectual property protections and public health by failing to provide information about pro-public health safeguards that could be implemented in Dominican law.

The United States has the capacity to save lives in the Dominican Republic by promoting a pro-public health trade policy. With this capacity comes the moral responsibility to consider the life and death impact of intellectual property provisions on Dominicans. Our recommendations provide possible ways to address this critical issue and alleviate this significant burden on the Dominican Republic.

VII. Recommendations

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 implementation in line with New U.S. Trade Policy, specifically:
 - a. Patent extensions for pharmaceuticals should be made optional.
 - b. At a minimum, data exclusivity should be limited to “a reasonable period” for undisclosed and required data, and should protect only new chemical entities. Data exclusivity should also be subject to an exception to protect public health in accordance 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 and other trade partners 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 needs 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 further study and address the effects that intellectual property laws can have 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 and intellectual property negotiations.

APPENDIX I. Organizations Consulted in the Dominican Republic

Hospitals and Clinics

- Hospital El Buen Samaritano, La Romana, Dominican Republic
- Hospital General Plaza de la Salud, Santo Domingo, Dominican Republic
- Instituto Oncológico, Santo Domingo, Dominican Republic

Dominican Government

- Comisión Ejecutiva para la Reforma del Sector Salud (CERSS)
- Consejo Presidencial del SIDA (COPRESIDA)
- Consejo Nacional de Salud (CNS)
- Presidencia de la Republica
- La Dirección de Comercio Exterior (DICOEX)
- Oficina Nacional de la Propiedad Industrial (ONAPI)
- La Programa de Medicamentos Esencial/ Central de Apoyo Logístico (PROMESE-CAL)
- Secretaria de Estado de Relaciones Exteriores (SEREX)
- Secretaria de Estado de Salud Pública y Asistencia Social (SESPAS)
- El Seguro Nacional de Salud (SENASA)

United States Government

- United States Agency for International Development (USAID)
- United States Commercial Service (USCS)

Industry Representatives

- Asociación de Industrias Farmacéuticas Dominicana (INFADOMI)
- Asociación de Representantes de Importadores de Medicamentos (ARAPF)

Non-Governmental Organizations

- AIDS Free World
- Alianza Solidaria para la Lucha contra el VIH/SIDA (ASOLSIDA)
- Asociación Dominicana Pro-Bienestar de la Familia (PROFAMILIA)
- Consejo Presidencial del SIDA (COPRESIDA)
- La Junta Directiva de Coalición
- Fundación Plenitud
- Fundación Global Democracia y Desarrollo (FUNGLODE)
- Fundación Grupo Paloma
- Red Dominicana de Personas que Viven con VIH/SIDA (REDOVIH)

Other Professionals

- Dominican legal practitioners, trade negotiators, medical practitioners, government consultants.

APPENDIX II. Comparison of Intellectual Property Provisions

Patent Extensions:

TRIPS Agreement	DR Law No. 20-00	DR-CAFTA	DR Law No. 424-06	U.S. Hatch Waxman Act
No patent extensions.	No patent extensions.	<p>Art. 15.9(6)(a)-(b)</p> <p>Patent term extensions due to delays in regulatory review: an extension of the patent term shall be granted to compensate the patent owner for unreasonable curtailment of the effective patent term resulting from a delay in the marketing approval process.</p> <p>Patent term extensions due to delays in the grant of a patent: the term of a patent shall be extended to compensate for unreasonable delays that occur in granting the patent. Unreasonable delay shall at least include a delay in the issuance of a patent of more than 5 years from the date of filing of the application, or 3 years after a request for examination of the application has been made, whichever is later, provided that periods attributable to actions of the patent applicant need not be included in the determination of such delays.</p>	<p>Art. 2:</p> <p>Patent term extensions due to delays in regulatory review: the term of a patent shall be extended for unreasonable delays in regulatory review, defined as more than 2.5 years since the request for marketing approval.</p> <p>Patent term extensions due to delays in the grant of a patent: the term of a patent shall be extended for unreasonable delays in the granting of a patent, defined as more than 5 years from filing or 3 years from the request of examination, whichever is later.</p>	<p>35 U.S.C. § 156</p> <p>Patent term extensions due to delays in regulatory review: the portion of the patent term during which the patentee is unable to market product while awaiting government approval is restored.</p> <p>35 U.S.C. § 154</p> <p>Patent term extensions due to delays in the granting of a patent: the portion of patent term during which the patentee is unable to market the product while awaiting government approval if more than 3 years from filing is restored. Exceptions: delay requested by the applicant, interference procedure, appeals, etc.</p> <p>Conditions & Limitations:</p> <ul style="list-style-type: none"> - Applicant must file the request with the U.S. patent office within 60 days of the product approval by the agency. - Only one 5 year extension period can be sought per product. - The restoration period cannot be longer than five years and the total effective patent protection, including the restoration period, must not exceed fourteen years following FDA approval.

Data Exclusivity:

TRIPS Agreement	DR Law No. 20-00	DR-CAFTA	DR Law No. 424-06	Hatch Waxman Act
<p>Article 39.3:</p> <p>Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilizes 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.</p>	<p>Art. 179:</p> <p>No data exclusivity but contains unfair commercial use protection.</p> <p>Where the marketing authority requires the presentation of secret data or information, these are protected from unfair commercial use by third parties. The secret data or information is protected against disclosure. An exception is when it is necessary to protect the public or when adequate measures have been adopted to ensure that the data or information are protected against their unfair commercial use by third parties.</p>	<p>Art. 15.10:</p> <p>Parties are prohibited from granting marketing approval for a generic product that relies on the originator’s data or marketing approval for at least five years from the date of approval in the Party.</p> <p>A Party may require that the person providing the information in the other territory seek approval in the territory of the Party within five years of obtaining marketing approval in the other territory.</p> <p>Each Party shall protect such undisclosed information against disclosure except where necessary to protect the public. No Party may consider information within the public domain as undisclosed data. If any undisclosed information concerning safety and efficacy information is disclosed, the Party is still required to protect such information from unfair commercial use.</p>	<p>Art. 32(1):</p> <p>An applicant who files for marketing approval for a product containing a new chemical entity or active moiety receives data protection for at least five years from the date of approval of the product. Regulatory approval may not be granted to a second applicant that relies on data supplied by the first applicant. The Party submitting marketing approval information must seek approval in the Dominican Republic within five years of obtaining marketing approval in another territory.</p> <p>The information will be protected from disclosure, except when necessary to protect public health. No Party may consider information within the public domain as undisclosed data. If any undisclosed information concerning safety and efficacy information is disclosed, the Party is still required to protect such information from unfair commercial use.</p>	<p>21 U.S.C. § 355:</p> <p>An applicant who files for marketing approval for a product containing a new chemical entity or active moiety receives data protection for five years from the date of approval of the product. Regulatory approval may not be granted to a second applicant that relies on data supplied by the first applicant.</p> <p>An applicant who files for marketing approval for a product containing a new use or indication when the applicant has conducted essential, new clinical trials receives data protection for three years.</p>

Patent Linkage:

Trips Agreement	DR Law No. 20-00	DR-CAFTA	DR Law No. 424-06	Hatch Waxman Act
None.	None.	<p>Art. 15.10.2(a):</p> <p>Parties shall implement patent linkage systems in their marketing approval process to prevent a generic from marketing a product covered by a patent.</p> <p>The patent owner shall be informed of the request and the identity of any such other person who requests approval to enter the market during the term of a patent identified as claiming the approved product or its approved use.</p>	<p>Art. 32:</p> <p>A drug manufacturer seeking marketing approval of a new pharmaceutical product must provide the government with a list of patents that protect the product or its approved use in the DR. The Dominican government is charged with establishing a public register listing the patents that involve pharmaceutical products.</p> <p>If a patent exists, marketing approval is not allowed unless:</p> <ul style="list-style-type: none"> A.) A notarized sworn statement is provided indicating that there is no patent in effect in the Dominican Republic protecting the product or use; B.) Written authorization is provided from the patent holder; C.) Or, a notarized sworn statement is provided indicating that the applicant shall not enter the market prior to patent expiration. <p>The Dominican government is also obligated to inform the patent holder of the application and identify the person seeking marketing approval during the life of the patent.</p>	<p>21 U.S.C. § 355</p> <p>New drug applications must include patent information. Patent lists are published in an online “Orange Book.”</p> <p>Under U.S. law, if a patent exists there is a fourth option for generic manufacturers that does not exist under DR Law 424-06. Generics may provide a statement by which they challenge the patent validity or application. Patent holders receive a maximum 30-month stay of marketing approval where generics are challenging existing patents and only if the patent holder initiates litigation against generic applicants within 45 days.</p> <p>Generic applicants that successfully challenge a patent receive 180 days of exclusivity.</p>