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2014

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Recommended Citation

Matthew E. Silverman, *The Case for Flexible Intellectual Property Protections in the Trans-Pacific Partnership*, 27 J.L. & Health 215 (2014)
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THE CASE FOR FLEXIBLE INTELLECTUAL PROPERTY PROTECTIONS IN THE TRANS-PACIFIC PARTNERSHIP

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I. INTRODUCTION

The United States and eleven other countries are currently in the end stages of negotiating the Trans-Pacific Partnership (TPP)—the largest free trade agreement (FTA) in U.S. history—which incorporates a range of trade topics, including the protection and enforcement of intellectual property rights (IPRs).¹ Although the negotiations have been highly secretive, negotiating texts of the agreement leaked as recently as November 2013 have suggested that the United States is proposing IPR provisions, specifically relating to patent protection, that are stronger and less

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¹ Alex Hern & Dominic Rushe, *WikiLeaks Publishes Secret Draft Chapter of Trans-Pacific Partnership*, THE GUARDIAN (Nov. 13, 2013), <http://www.theguardian.com/media/2013/nov/13/wikileaks-trans-pacific-partnership-chapter-secret>.

flexible than IPR provisions included within three of the four most recent U.S. FTAs.² This paper addresses and analyzes these leaked IPR provisions and makes the argument that in the best interest of global welfare and public-health policy, the United States should not be attempting to incorporate stronger IPR protections in the TPP.

Section 1 provides an introduction to the TRIPS agreement—the first international agreement to set minimum standards for the protection and enforcement of IPRs—and discusses the significance of the “Doha Declaration” in helping to clarify the need to interpret TRIPS from a public-health perspective. Section 2 describes the recent U.S. trend of seeking levels of IPR protection in its FTAs that exceed the minimum standards of TRIPS (referred to as “TRIPS-plus” provisions)—including patent term extensions, patent linkages, and enhanced data protection, as detailed in Section 3 of this paper. Section 4 describes the Bipartisan Trade Deal (BTD) of May 10, 2007, as an attempt by members of Congress to address concerns about the effect that these enhanced IPR protections have on developing countries’ ability to access life-saving medicines. Section 5 outlines the leaked U.S. TPP proposals relating to patent term extensions, patent linkages and data protection, and describes how they will impede TPP countries from gaining access to medicines. In order to better understand the issues and arguments that are at stake from both sides, Section 6 provides the arguments commonly put forth as to why strong patent protection is necessary, while Section 7 examines the significance of generic medicines being accessible in the global marketplace. Section 8 analyzes these arguments and draws the conclusion that, while patent protection of pharmaceuticals is important, it must be fairly balanced against the needs of the developing world to be able to access affordable, life-saving medicines. In conclusion, this paper puts forth the argument that the United States should honor its existing global-health commitments by seeking flexible IPR standards in the TPP to ensure that the health interests of the poorest and sickest people in the developing world are not undermined by the profit-maximizing interests of pharmaceutical companies.

II. THE TRIPS AGREEMENT AND THE “DOHA DECLARATION”

At the center of the international IPR system is the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).³ TRIPS sets minimum standards of protection and enforcement for copyrights, trademarks, patents and other forms of intellectual property.⁴ All WTO member countries are required to comply with these standards by modifying their national regulations to be consistent with the rules of the agreement.⁵ TRIPS strikes a balance between the “rights of patent holders to benefit from their inventions and

² *Id.*

³ SHAYERAH ILIAS, CONG. RESEARCH SERV., R40607, INTELLECTUAL PROPERTY RIGHTS AND ACCESS TO MEDICINES: INTERNATIONAL TRADE ISSUES 11 (2010).

⁴ *Id.* at 11.

⁵ Amal Nagah Elbeshbishi, *TRIPS and Public Health: What Should African Countries Do?* 49 AFRICAN TRADE POLICY CTR. WORK IN PROGRESS 1, 3 (2007), available at <http://www.uneca.org/sites/default/files/publications/49.pdf>.

the rights of countries to address health priorities through the provision of affordable medicines.”⁶

Among the debates about the implications of TRIPS is its impact on public health.⁷ Prior to TRIPS, developing countries regulated public health with little involvement from an international IPR system.⁸ Critics of TRIPS asserted that developed countries, which are the major producers of intellectual property, would be the prime beneficiaries of the agreement.⁹ Opponents also argued that TRIPS would raise the costs of public-health goods, constrain the ability of governments to provide health services to their populations, and hinder innovation and economic development for low-income countries.¹⁰ In an effort to alleviate developing countries’ concerns with TRIPS, trade ministers adopted a *Declaration on the TRIPS Agreement and Public Health* (the “Doha Declaration”) committing WTO member states to “interpret and implement the agreement to support public health and to promote access to medicines for all.”¹¹

The Doha Declaration was an important step toward making TRIPS more development friendly and emphasizing the need to interpret TRIPS from a public-health perspective.¹² Specifically, the Doha Declaration clarified that TRIPS does not and should not prevent WTO members from taking measures to protect public health.¹³ The IPR flexibilities allowed under TRIPS and the Doha Declaration are internationally recognized as important public policy and legal tools in the efforts to protect public health and promote access to medicines in the developing world.¹⁴

⁶ Ruth Lopert & Deborah Gleeson, *The High Price of “Free” Trade: U.S. Trade Agreements and Access to Medicines*, 41 J.L. MED. & ETHICS 199, 200 (2013).

⁷ ILIAS, *supra* note 3, at 12.

⁸ *Id.*

⁹ *Id.*

¹⁰ *Id.*

¹¹ *Id.* at 13.

¹² Elbeshbishi, *supra* note 5, at 3.

¹³ *Id.*

¹⁴ MÉDECINS SANS FRONTIÈRES, INT’L ACCESS CAMPAIGN, TRADING AWAY HEALTH: HOW THE U.S.’S INTELLECTUAL PROPERTY DEMANDS FOR THE TRANS-PACIFIC PARTNERSHIP AGREEMENT THREATEN ACCESS TO MEDICINES 5 (Aug. 2012), <http://aids2012.msf.org/wp-content/uploads/2012/07/TPP-Issue-Brief-IAC-July2012.pdf> [hereinafter *Trading Away Health*]. A WTO case illustrating the flexibility available in TRIPS involved a dispute between Canada and the European Communities on the “Bolar” exception, allowing generic drug manufacturers to produce, and/or import and use, quantities of a patented product necessary to conduct tests needed to obtain regulatory approval before the expiration of a patent. Under TRIPS, governments can make limited exceptions to patent rights, provided certain conditions are met. These exceptions cannot “unreasonably” conflict with the “normal” exploitation of the patent and must not unreasonably prejudice the legitimate interests of the patent owner, taking into account the legitimate interest of third parties (Article 30). This provision covers a range of exceptions. For example, there are countries that provide for a “research” or “experimental use” exception to allow researchers to use a patented invention more fully. In addition, Article 30 permits countries to allow manufacturers of generic drugs to use a patented invention without the patent owner’s permission and before the patent protection expires for the purpose of obtaining marketing approval from public-

III. "TRIPS-PLUS" IN U.S. FREE TRADE AGREEMENTS

In recent years, the United States has increasingly focused on FTAs as a tool to promote stronger international IPR protections.¹⁵ In negotiating FTAs since the implementation of TRIPS, the United States Trade Representative (USTR) has frequently sought levels of IPR protection that exceed the minimum standards of TRIPS (so-called "TRIPS-plus" provisions).¹⁶ These new and higher IPR standards arguably favor the short-term business interests of U.S. pharmaceutical companies at the expense of public-health interests in developing countries.¹⁷

The United States' pursuit of TRIPS-plus protections for pharmaceutical patents in recent FTAs is well recognized.¹⁸ This pursuit has been driven, at least in part, by a desire to achieve levels of protection it anticipated from TRIPS but failed to secure.¹⁹ The U.S. pharmaceutical industry viewed TRIPS as falling short of its objectives, and as a result, there has generally been a progressive increase in IPR protection for pharmaceuticals in U.S. FTAs since TRIPS.²⁰

Proponents of stronger IPR provisions in FTAs argue that they ultimately promote access to medicines for developing countries by encouraging innovation.²¹ However, the incorporation of TRIPS-plus provisions in recent U.S. FTAs has attracted criticism from public-health advocates and developing countries, which have expressed concerns that the enhanced protections run contrary to the spirit of the Doha Declaration and severely limit access to life-saving medicines in the developing world.²² Both of these arguments are addressed in greater detail in Section 8 of this paper.

health authorities—thereby allowing generic producers to market their versions almost as soon as the patent expires. This provision, sometimes called the "regulatory exception" or "Bolar" provision, has been upheld as conforming to TRIPS in a WTO dispute ruling. In a report adopted on April 7, 2000, a WTO dispute-settlement panel stated that Canadian law was consistent with TRIPS in allowing manufacturers to do so. Elbeshbishi, *supra* note 5, at 4.

¹⁵ SHAYERAH ILIAS & IAN FERGUSSON, CONG. RESEARCH SERV., RL34292, INTELLECTUAL PROPERTY RIGHTS AND INTERNATIONAL TRADE 24 (2011).

¹⁶ ILIAS, *supra* note 3, at 20.

¹⁷ Elbeshbishi, *supra* note 5, at 6.

¹⁸ Lopert & Gleeson, *supra* note 6, at 199.

¹⁹ *Id.*

²⁰ *Id.*

²¹ ILIAS, *supra* note 3, at 21.

²² *Id.* at 20. The impact of TRIPS-plus provisions has been demonstrated in empirical studies. For example, Oxfam determined that the imposition of TRIPS-plus provisions in the Jordan-U.S. FTA resulted in a twenty percent overall increase in medicine prices between 2001 and 2006, and led to the delayed introduction of generic equivalents for seventy-nine percent of new medicines produced by twenty-one pharmaceutical companies between 2002 and mid-2006. Lopert and Gleeson, *supra* note 6, at 202.

IV. PATENT TERM EXTENSIONS, PATENT LINKAGES, AND DATA PROTECTION

The most prominent TRIPS-plus patent provisions in U.S. FTAs are patent term extensions, patent linkages, and data protection.²³

Patent Term Extensions. Many U.S. FTAs include provisions for mandatory patent term extensions beyond the TRIPS obligation of patent protection terms of twenty years from the filing date.²⁴ Extensions are allowed in cases of “unreasonable” delays in the issuance of patents due to the regulatory review or administrative process.²⁵ Patent holders contend that such extensions allow them to recoup the costs of research and development (R&D) of new products, while critics argue such extensions delay the entry of generic drugs into the marketplace.²⁶

Patent Linkages. Patent linkage refers to the attachment of regulatory approval for the marketing of a drug with the status of a patent.²⁷ If a patent exists, the U.S. Food and Drug Administration (FDA) and its counterparts in other countries may only grant marketing approval for a generic drug that is patented in the country with the permission of the patent holder.²⁸ Patent linkage is a common provision in U.S. FTAs.²⁹ Patent linkage is considered to be TRIPS-plus because under TRIPS generic drug manufacturers are able to apply for marketing approval *without* the patent owner’s permission and prior to the expiration of the patent, thereby reducing the time it takes for the generic drugs to enter the marketplace once the patent expires.³⁰

Data Protection. To bring a patented drug to market, a pharmaceutical company must demonstrate through costly clinical trials that the drug is both safe and effective.³¹ In cases where the patent holders must submit undisclosed data regarding

²³ ILIAS & FERGUSSON, *supra* note 15, at 26. Other prominent TRIPS-plus provisions include compulsory licensing and parallel importation. A compulsory license is a government authorization for third parties (such as a company or the government itself) for the manufacture or use of a product under patent without the permission of the rights-holder. TRIPS permits signatories to issue compulsory licenses for patented devices and provide compensation to the owner of the patent and does not limit the situations in which such licenses may be issued. The third party must have attempted to obtain permission from the patent holder; however, this requirement is waived in times of national emergency or other extenuating circumstances. *Id.* at 27. Parallel importation refers to goods imported into a country without permission of the rights-holder after those goods were legitimately sold elsewhere. Some developing countries contend that this practice is an alternative method for governments to increase access to medicines in the absence of a compulsory license. Pharmaceutical companies have voiced concerns that parallel importation threatens their ability to engage in price differentiation between different markets. *Id.* at 28.

²⁴ *Id.* at 26.

²⁵ *Id.*

²⁶ *Id.*

²⁷ *Id.* at 27.

²⁸ *Id.*

²⁹ *Id.*

³⁰ *Id.*

³¹ J.F. HORNBECK, CONG. RESEARCH SERV., RL32540, THE U.S.-PANAMA FREE TRADE AGREEMENT 22 (2012).

the safety or effectiveness of these drugs in order to market them, TRIPS requires WTO members to take measures to protect such data from disclosure and unfair commercial use; TRIPS does not prescribe any specific time period for this protection.³² However, recent U.S. FTAs generally require a five-year period of marketing exclusivity for the patent holder, which typically begins from the date the product is approved in the country.³³ Under this TRIPS-plus provision, generic drug manufacturers wanting to market and distribute their drug while the data exclusivity period is in effect must conduct their own clinical trials and submit their own findings to the national drug regulatory authority (they cannot rely on the findings submitted by the patent holder).³⁴ Increased data protection/exclusivity, therefore, raises the cost of manufacturing generic drugs and delays access to these drugs.³⁵

V. INTELLECTUAL PROPERTY RIGHTS IN THE BIPARTISAN TRADE DEAL

The steady increase of IPR protections in U.S. FTAs that occurred after TRIPS saw a change in 2007 with the implementation of the Bipartisan Trade Deal (BTD).³⁶ In May 2007, Congress and the Bush Administration concluded a bipartisan agreement on trade policy that addressed some members' concerns about the implications of enhanced IPRs on the ability of developing countries to meet public-health needs.³⁷ In particular, Democrats in Congress sought to ensure that pending FTAs allowed trading partners the flexibility to meet their international IPR protection and enforcement obligations while being able to promote access to life-saving medicines.³⁸ The BTD allowed developing countries flexibility in the application of the three TRIPS-plus provisions described in Section 3 above—patent term extensions, patent linkages, and data protection—where necessary to protect

³² *Id.* at 27.

³³ *Id.*

³⁴ *Id.*

³⁵ *Id.*

³⁶ Lopert & Gleeson, *supra* note 6, at 202.

³⁷ ILLIAS & FERGUSON, *supra* note 15, at 25.

³⁸ *Id.*

The administration's agreement with the Congressional leadership preserves a strong overall level of protection for intellectual property in developing country free trade agreements, including those most recently notified to Congress. Within this overall framework of strong intellectual property protection, the agreement reached with the Congressional leadership aims to incorporate certain flexibilities. These modifications are aimed at further ensuring that developing country free trade agreement partners are able to achieve an appropriate balance between fostering innovation in, and promoting access to, life-saving medicines. The results are fully in line with this Administration's long-standing trade policy objectives in the area of intellectual property.

public health.³⁹ This flexibility has been incorporated in the recent U.S. FTAs with Peru, Panama and Colombia in the following ways:

- Patent term extensions for pharmaceutical products are optional, rather than mandatory.
- Marketing approval for a generic drug is not tied with the patent status of its brand-name drug.
- Data exclusivity terms of five years may be reduced by a minimum of six months in practice.⁴⁰

For example, under the Panama FTA, if a company files to market a new drug in Panama after making an initial filing in another country, such as the United States, and Panama approves the drug within six months of that filing, the data exclusivity term begins at the time the drug was approved in the United States, not Panama.⁴¹ This provision is intended to speed up the entry of generics into Panama's market by encouraging drug companies and foreign governments to engage in the approval process as quickly and efficiently as possible.⁴² Because this "six-month rule" effectively reduces the data exclusivity term in Panama, drug companies are encouraged to file as soon as possible to maximize the time their data may be

³⁹ Lopert & Gleeson, *supra* note 6, at 202. The BTDA entailed the following flexibilities with regard to IPR protections:

- Clarification that the period of protection for test data for pharmaceuticals by developing country FTA partners will generally not extend beyond the period that such protection is available for the same product in the United States, coupled with a provision that will encourage our partners to process marketing approval applications for innovative drugs in a timely manner.
- Clarification that developing country FTA partners may implement exceptions to normal rules for protecting test data if necessary to protect public health.
- A more flexible approach, for developing country partners, to restoring patent terms to compensate for processing delays. This flexibility is accompanied by new provisions stipulating that trading partners will make best efforts to process patent and marketing approval applications expeditiously.
- More flexibility in terms of the types of procedures that developing country partners may implement to prevent the marketing of patent-infringing products.
- Integration within the intellectual property chapter of a recognition that nothing in the chapter affects the ability of our FTA partners to take necessary measures to protect public health by promoting access to medicines for all, and a statement affirming mutual commitment to the 2001 Doha Declaration on the TRIPS Agreement and Public Health.

BIPARTISAN TRADE DEAL, *supra* note 37, at 3.

⁴⁰ ILIAS & FERGUSSON, *supra* note 15, at 27.

⁴¹ HORNBECK, *supra* note 31, at 22.

⁴² *Id.*

protected in Panama after receiving market approval.⁴³ Countries are therefore encouraged to put in place an efficient drug-certification process because they must approve within the sixth-month rule to benefit from it.⁴⁴

Despite the BTDA's purpose of easing IPR protection, in an effort to balance the pharmaceutical companies' interests with the need for greater access to affordable medicines in the developing world, Congress noted that the intellectual property chapters of U.S. trade agreements would nevertheless continue to "represent an enhancement of IPR protection for pharmaceutical products in those markets" by continuing to: protect pharmaceutical test data; require the establishment of procedures for patent holders to effectively enforce their rights against infringing products; limit grounds for patent revocation; and retain the option for patent term extension to be applied in cases of unreasonable delays.⁴⁵ The extent to which the IPR provisions in the BTDA will serve as a future template is unclear—specifically, whether or not these standards will be used for all future FTAs or if they will be used according to the income status of the United States' trading partners.⁴⁶ For instance, while the IPR provisions of the BTDA were incorporated into the free trade agreements with Peru, Panama and Colombia (low-income/developing countries),⁴⁷ the United States did not significantly scale down the patent protections in its recent trade agreement with South Korea (a middle-income/developed country)⁴⁸—despite South Korean per capita GDP being little more than half that of the United States.⁴⁹

Some stakeholders have encouraged Congress to reconsider the IPR provisions in the BTDA as they relate to current and future FTA negotiations.⁵⁰ Specifically, the U.S. pharmaceutical industry has aggressively lobbied against the IPR provisions in the BTDA being incorporated within the ongoing Trans-Pacific Partnership (TPP) negotiations,⁵¹ as discussed in Section 5 below. On the other hand, global-health advocates and producers of generic medicines have largely embraced the BTDA and encouraged even further weakening of patent protections in an effort to increase access to medicines.⁵²

VI. PHARMACEUTICAL IPRs IN THE TRANS-PACIFIC PARTNERSHIP

The United States is presently in the final stages of negotiating the Trans-Pacific Partnership (TPP)—a free trade agreement encompassing twelve countries that will

⁴³ *Id.*

⁴⁴ *Id.* In addition, there is language in the intellectual property chapter of the U.S.-Panama FTA stating that, in cases of epidemics, extreme urgency, or national emergency, a waiver from the data exclusivity laws would be allowed. *Id.*

⁴⁵ Lopert & Gleeson, *supra* note 6, at 202.

⁴⁶ ILIAS, *supra* note 3, at 26.

⁴⁷ *Id.*

⁴⁸ ILIAS & FERGUSON, *supra* note 15, at 25.

⁴⁹ Lopert & Gleeson, *supra* note 6, at 202.

⁵⁰ ILIAS, *supra* note 3, at 26.

⁵¹ *Trading Away Health*, *supra* note 14, at 8.

⁵² ILIAS, *supra* note 3, at 26.

“set the standard for 21st-century trade agreements going forward.”⁵³ The TPP text will likely become the template for future U.S. trade agreements with the capacity to set “*de facto* global standards.”⁵⁴

U.S. Trade Representative Michael Froman has signaled that the United States is leaning toward an approach in TPP negotiations that would establish more flexible pharmaceutical IPR protections for developing countries than for developed countries.⁵⁵ In remarks on October 29, 2013, Froman invoked the BTD as support for IPR flexibility within the agreement, stating “[w]hat the [BTD] signaled was that there are developed countries, there are developing countries, and there are approaches that may strike that balance between ensuring access to medicines on one hand and ensuring strong protection for innovation on the other.”⁵⁶

There has long been speculation that the United States may ultimately settle on an approach in TPP that applies more flexible IPR standards to developing countries than to developed ones.⁵⁷ One U.S. industry source indicated that brand-name drug manufacturers would not reject such a proposal outright, as long as developing countries would be required to meet higher IPR standards at a later date.⁵⁸

However, leaked drafts⁵⁹ of the U.S. negotiating positions in the TPP suggest that the United States may be backing away from the more flexible IPR standards under the BTD and demanding more aggressive IPR protections.⁶⁰ Most recently, a leaked version of the TPP chapter on intellectual property (published on November 13,

⁵³ *Trading Away Health*, *supra* note 14, at 1. The TPP countries currently negotiating are Australia, Brunei Darussalam, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, Vietnam, and the United States. South Korea and Taiwan have expressed interest in joining TPP negotiations. Srinivasa Madhur, *China-Japan-Korea FTA: A Dual Track Approach to a Trilateral Agreement*, 28 J. ECON. INTEGRATION 376, 381 (2013).

⁵⁴ Lopert & Gleeson, *supra* note 6, at 206–07.

⁵⁵ *Froman Signals Flexible Approach to Drug IP in TPP, Hatch Opposes*, INSIDE U.S. TRADE (Nov. 1, 2013), <http://insidetrade.com/Inside-US-Trade/Inside-U.S.-Trade-11/01/2013/froman-signals-flexible-approach-to-drug-ip-in-tpp-hatch-opposes/menu-id-710.html> [hereinafter *Froman Signals*].

⁵⁶ *Id.* Senate Finance Committee ranking member Orrin Hatch (R-UT) took issue with Froman’s position at an October 30, 2013, hearing. Hatch disagreed with Froman’s notion that there is a tension between strong intellectual property protections for drugs and ensuring access to medicines, stating: “[t]o the contrary, strong intellectual property spurs innovation and is therefore essential to providing access to innovative medicines.” *Id.*

⁵⁷ *Id.*

⁵⁸ *Id.*

⁵⁹ The TPP has largely been conducted in secrecy; the negotiating texts have not been made available for public consumption, and Congress has had relatively limited access to the texts, as compared to trade agreement negotiations under previous Administrations.

⁶⁰ Lopert & Gleeson, *supra* note 6, at 208; *Trading Away Health*, *supra* note 14, at 1. Speaking the same day as the leak, Froman repeatedly emphasized that the United States is trying to promote access to medicines as well as protect innovation through the TPP negotiations. Matthew Schewel, *Leaked TPP IP Chapter Reveals Details of Conflicting Drug Proposals*, INSIDE U.S. TRADE (Nov. 14, 2013), <http://insidetrade.com/Inside-US-Trade/Inside-U.S.-Trade-11/15/2013/leaked-tpp-ip-chapter-reveals-details-of-conflicting-drug-proposals/menu-id-710.html>.

2013, by the anti-secrecy website *Wikileaks*) reveals the details of a counterproposal on pharmaceutical IPR protections tabled by five TPP countries⁶¹ that omits three protections for pharmaceutical IPRs that are known to be significant pieces of the U.S. proposals in TPP.⁶² Not surprisingly, these proposals involve patent term extensions, patent linkages and data protection.⁶³ The following is a discussion of the U.S. proposals with regard to these three IPR protections within TPP (as gleaned from leaked negotiating texts), including their potential impact on restricting access to medicines in TPP countries.

A. Proposal #1 – Patent Term Extensions

The United States' proposal in the TPP would require countries to grant patent term extensions of at least five years to compensate for administrative delays in the regulatory or patent approval process.⁶⁴ Even though the BTD recognized the negative impact of patent term extensions on access to medicines, and made them optional for countries negotiating trade agreements with the United States, the United States is proposing that patent term extensions in the TPP be *mandatory*.⁶⁵ Patent term extensions will create extra years in which a patent holder can maintain a monopoly position and continue to charge artificially high prices for a drug, free from generic competition, thereby further delaying the entry of affordable medicines into the marketplace of TPP countries.⁶⁶

B. Proposal #2 – Patent Linkages

The United States has proposed that patent linkage be required of TPP countries, thereby imposing restrictive conditions for the registration of generic medicines in developing TPP countries and creating a new and burdensome role for national regulatory authorities.⁶⁷ With this proposal, the United States is renegeing on the BTD, which made patent linkage *optional* for countries negotiating trade agreements with the United States.⁶⁸ Patent linkage provisions will delay the entry of generics into TPP countries.⁶⁹ By requiring regulatory authorities to police patents, patent linkages “hinder generic drug registration while circumventing patent dispute processes between the patent holder and the patent authorities.”⁷⁰

⁶¹ These countries are Canada, Chile, Malaysia, New Zealand, and Singapore. Schewel, *supra* note 60.

⁶² *Id.*

⁶³ *Id.*

⁶⁴ *Trading Away Health*, *supra* note 14, at 13.

⁶⁵ *Id.*

⁶⁶ *Id.*

⁶⁷ *Id.*

⁶⁸ *Id.*

⁶⁹ *Id.* at 14.

⁷⁰ *Id.*

C. Proposal #3 – Data Protection

The United States has proposed at least five years of data exclusivity for new chemical entities and at least three years of data exclusivity for drugs containing an already approved active ingredient.⁷¹ U.S. pharmaceutical companies have lobbied for the data exclusivity period for “biologics” to be set at a minimum of twelve years.⁷² Because biologics are structured differently than traditional chemical medicines, they require a different regulatory approval process.⁷³ This would be the first time the United States has included a proposal on biologics in a trade agreement.⁷⁴ If included within the TPP, such a proposal would severely delay the entry of “biosimilars” (generic biologics) into the marketplace.⁷⁵ It is unclear if the United States will adhere to the flexible IPR protections included in the BTDA and trade agreements with Peru, Colombia, and Panama (as discussed in Section 4 above), including the “six-month rule” and allowances for data exclusivity waivers in cases of epidemics and other national health emergencies.⁷⁶

Data exclusivity for biologics will result in higher prices and delay the introduction of affordable, generic versions of these medications in TPP countries.⁷⁷ Examples of these effects have been shown in instances where data exclusivity provisions were implemented in national laws.⁷⁸ Jordan implemented data exclusivity under its FTA with the United States.⁷⁹ A 2007 study found that of 103 medicines registered and launched since 2001 that had no patent protection in Jordan, at least seventy-nine percent had no competition from a generic equivalent as a consequence of data exclusivity.⁸⁰ The study also found that prices of these drugs were up to eight hundred percent higher than in neighboring Egypt.⁸¹ A 2010 study determined that once Guatemala enacted data exclusivity, some drug prices rose as much as 846%.⁸² In the United States, the price of colchicine (a treatment used mainly for gout) rose more than 5000% after data exclusivity was enacted.⁸³

⁷¹ *Id.* at 12.

⁷² *Id.*

⁷³ *Id.*

⁷⁴ *Id.* Some members of Congress oppose the inclusion of data exclusivity relating to biologics in the TPP. The Federal Trade Commission has recommended eliminating data exclusivity for biologics in the United States. *Id.*

⁷⁵ *Id.*

⁷⁶ *Id.*

⁷⁷ *Id.*

⁷⁸ *Id.*

⁷⁹ *Id.*

⁸⁰ *Id.*

⁸¹ *Id.*

⁸² *Id.*

⁸³ *Id.* Colchicine has been in use for thousands of years, costs little to produce, and cannot be patented. Therefore, generic versions of the drug have been widely available since the nineteenth century. However, a new monopoly on colchicine was created in 2009 when the

VII. WHY PATENT PROTECTION OF PHARMACEUTICALS IS IMPORTANT

A patent is a “time-limited, legal, exclusive right granted for the invention of new products, processes, organisms, designs, and plants that allows the right holder to exclude others from making, using, or selling the protected invention for a period of twenty years.”⁸⁴ The financial returns generated by the exclusive monopolies provided by patents are believed to enable pharmaceutical companies to recoup the costs of R&D, earn profits, and invest in future innovations.⁸⁵ As such, the pharmaceutical industry is dependent on the protection of patents.⁸⁶

New drugs cost pharmaceutical companies approximately one billion dollars to discover, develop, and gain regulatory approval.⁸⁷ R&D is costly in the pharmaceutical industry because most drug candidates fail to reach the market—less than one percent of the compounds examined in pre-clinical stages are cleared for testing on humans.⁸⁸ Moreover, manufacturing plants are expensive (costing between fifty million and two hundred million dollars), and unique manufacturing requirements usually mean they are suitable for only one product.⁸⁹ All of these R&D costs are compensated for by the profits generated from patent-protected products.⁹⁰

Without patent protection, imitators can “free-ride” on the innovator’s regulatory approval and duplicate the drugs for a small fraction of what it cost to produce the original.⁹¹ Imitators of the original drug (generics) need only demonstrate that there is “bioequivalence” to the original brand in order to receive market registration.⁹² This process costs one million to two million dollars and takes only a few years.⁹³ The prospect of success for generics is very likely, as reflected by the fact that many

FDA accepted clinical data from a one-week trial of the drug and granted data exclusivity to a leading pharmaceutical company, URL Pharma. That company subsequently sued to force other manufacturers off the market and raised prices from \$0.09 to \$4.85 per pill. *Id.*

⁸⁴ ILIAS, *supra* note 3, at 3.

⁸⁵ *Id.* at 4. Dave Ricks, senior vice president at Eli Lilly, stated “[n]ew products come from the incentive to develop them through the promise of rewards through intellectual property . . . Without those rewards, it’s difficult to see where those new medicines would come from to begin with.” *Froman Signals*, *supra* note 55.

⁸⁶ ILIAS, *supra* note 3, at 3.

⁸⁷ EMMANUEL HASSAN, OHID YAQUB, & STEPHANIE DIEPEVEEN, RAND CORP., INTELLECTUAL PROPERTY AND DEVELOPING COUNTRIES: A REVIEW OF THE LITERATURE 26 (2010), available at http://www.rand.org/content/dam/rand/pubs/technical_reports/2010/RAND_TR804.pdf.

⁸⁸ *Id.*

⁸⁹ *Id.*

⁹⁰ *Id.*

⁹¹ *Id.*

⁹² *Id.*

⁹³ *Id.*

generics typically receive FDA approval and enter the market within a short period of time after the patent expires on the original drug.⁹⁴

VIII. THE SIGNIFICANCE OF GENERIC MEDICINES

Generic medicines—copies of patented drugs whose patents have typically expired—help to lower the price of pharmaceuticals in the global marketplace.⁹⁵ As stated previously, generic manufacturers do not generally have to repeat research and clinical trials conducted by the originating pharmaceutical companies in order to obtain regulatory approval, but rather only need to demonstrate the “bioequivalence” of their product to the original, patented drug.⁹⁶ Without this requirement, generic medicines are able to enter the market more quickly and at lower prices once the patents have expired.⁹⁷ Generic medicines also play the role of market competitors, encouraging brand-name pharmaceutical companies to lower the prices of their drugs and possibly develop newer, improved drugs.⁹⁸

“In the field of health, generic competition saves lives.”⁹⁹ The price of HIV treatment has dropped ninety-nine percent over the last ten years (from over ten thousand dollars for one year’s treatment in 2000, to less than one hundred fifty dollars per person, per year today) as a result of generic-drug production in India, Brazil, and Thailand, where these drugs were not patented.¹⁰⁰ By 2008, more than eighty percent of donor-funded purchases of anti-retroviral drugs for use in developing countries were generic drugs from India, including ninety-one percent of those formulated for children.¹⁰¹ This effect on drug prices has been crucial in expanding HIV/AIDS treatment to more than eight million people in the developing world.¹⁰²

All of the prominent international treatment initiatives for developing countries¹⁰³ rely on affordable generic drugs as a critical component of their sustainable treatment programs.¹⁰⁴ In 2010, the *United States President’s Emergency Plan for AIDS Relief (PEPFAR)* saved \$380 million through the purchase of generic versus originator anti-retroviral drugs.¹⁰⁵ More than eighty percent of AIDS drugs

⁹⁴ *Id.* at 26–27.

⁹⁵ *Id.*

⁹⁶ *Id.*

⁹⁷ *Id.*

⁹⁸ *Id.*

⁹⁹ *Trading Away Health*, *supra* note 14, at 4.

¹⁰⁰ *Id.*

¹⁰¹ *Id.*

¹⁰² *Id.*

¹⁰³ *Id.* These initiatives include the Global Fund, PEPFAR, UNITAID, and UNICEF. *Id.*

¹⁰⁴ *Id.*

¹⁰⁵ *Id.*

that Médecins Sans Frontières¹⁰⁶ uses across the world are generics from India.¹⁰⁷ The organization also uses generic drugs to treat malaria, tuberculosis, and a range of other infectious diseases in developing countries.¹⁰⁸

IX. PATENT PROTECTION AND ACCESS TO MEDICINES

The preceding sections of this paper presented arguments commonly put forward by the pharmaceutical industry to support stronger patent protection—specifically, that such protection is necessary because it allows pharmaceutical companies to recoup R&D costs and create profits that in turn spur pharmaceutical innovation. This section analyzes this argument and concludes that stronger patent protection of pharmaceuticals fails to encourage innovation in the developing world and serves to further impede access to medicines.¹⁰⁹

The argument that stronger patent protection is necessary to stimulate innovation, thereby leading to better global-health outcomes, is both overemphasized and misrepresented.¹¹⁰ This argument is overemphasized in that increased spending on R&D does not necessarily result in “genuine innovation.”¹¹¹ Many new drugs promoted by the pharmaceutical industry as innovations are actually “me-too” drugs—minor structural modifications to existing drugs that offer little or no additional benefit as compared to the original.¹¹² This practice of developing “me-too” drugs lends support to the argument that enhanced patent protection may actually discourage true innovation by creating financial incentives for insignificant changes to existing drugs.¹¹³

The argument that stronger patent protection stimulates innovation, thereby leading to better global-health outcomes, is misrepresented in that the evidence for this argument exists primarily in the *developed* world.¹¹⁴ While there is a correlation between stronger patent protection and R&D/innovation for drug which treat diseases that are prevalent in wealthy countries, research has shown that this correlation does not exist for the development of drugs to treat diseases that primarily affect the developing world (so-called “neglected diseases”).¹¹⁵

Less than ten percent of global spending on health R&D is directed toward the major health problems of ninety percent of the world’s population—often referred to as the “10/90 gap.”¹¹⁶ Low rates of R&D investment in neglected diseases may be

¹⁰⁶ Médecins Sans Frontières (Doctors Without Borders) is an international humanitarian organization that delivers emergency aid to people affected by armed conflict, epidemics, natural disasters, and exclusion from health care in nearly seventy countries. *Id.*

¹⁰⁷ *Id.* at 1.

¹⁰⁸ *Id.*

¹⁰⁹ HASSAN, YAQUB & DIEPEVEEN, *supra* note 87, at xv–xvi.

¹¹⁰ Lopert & Gleeson, *supra* note 6, at 210.

¹¹¹ *Id.*

¹¹² *Id.*

¹¹³ *Id.*

¹¹⁴ HASSAN, YAQUB & DIEPEVEEN, *supra* note 87, at xvi.

¹¹⁵ Lopert & Gleeson, *supra* note 6, at 210.

¹¹⁶ ILIAS, *supra* note 3, at 5.

one of many factors contributing to poor health conditions in developing countries.¹¹⁷ Some neglected tropical diseases are common in the developing world as a result of poverty-related conditions—including poor sanitation, unsafe drinking water, and a lack of basic health-care infrastructure.¹¹⁸

Funding for neglected diseases has increased in recent years; however, to attribute this increase to stronger IPR protection is difficult because other factors are likely to have played a more prominent role.¹¹⁹ When it was first identified in 1990, the “10/90 gap” led to considerable media exposure, political momentum, and increased research with regard to a few high-profile diseases.¹²⁰ This rise in R&D was arguably due to increased funding by the philanthropic sector, not the private sector.¹²¹ In 2007, only nine percent of neglected-disease funding came from the private sector.¹²² Therefore, while funding for neglected diseases has increased in recent years, this increase can be primarily attributed to public and philanthropic efforts focused on a few diseases in the public spotlight, rather than to strengthened IPRs catalyzing private-sector funding for neglected diseases.¹²³

The premise behind the pharmaceutical industry’s argument that stronger patent protection spurs innovation only holds true in situations where “markets offer sufficient financial incentives for a return on investment.”¹²⁴ Many developing countries simply cannot provide this type of market; therefore, the financial incentive for pharmaceutical companies is non-existent.¹²⁵ In light of this understanding and the evidence to support it, the premise that the public health of developing countries will benefit in the long term from stronger IPRs today ultimately fails.¹²⁶

X. CONCLUSION

One-third of the global population does not have access to essential medicines.¹²⁷ In the poorest parts of Asia and Africa, this statistic is closer to fifty percent.¹²⁸

¹¹⁷ *Id.*

¹¹⁸ *Id.*

¹¹⁹ HASSAN, YAQUB & DIEPEVEEN, *supra* note 87 at 32.

¹²⁰ *Id.* By 2004, there were sixty-three neglected-disease projects. *Id.*

¹²¹ *Id.*

¹²² *Id.*

¹²³ *Id.* at 32–33.

¹²⁴ ILIAS, *supra* note 3, at 4.

¹²⁵ *Id.* As the WHO Commission on Intellectual Property, Innovation, and Public Health concluded in 2006: “for diseases affecting millions of poor people in developing countries, patents are not a relevant factor or effective in stimulating R&D and bringing new products to the market.” *Trading Away Health*, *supra* note 12, at 7.

¹²⁶ “Assertions are often made about the advantages of TRIPS-plus protection but there has been little evidence of the beneficial effects of TRIPS-plus measures either in the form of increased foreign investment or increased innovation.” *Trading Away Health*, *supra* note 12, at 18 (citing U.N.D.P. & U.N.A.I.D.S, ISSUE BRIEF, THE POTENTIAL IMPACT OF FREE TRADE AGREEMENTS ON PUBLIC HEALTH (2012)).

¹²⁷ HASSAN, YAQUB & DIEPEVEEN, *supra* note 87 at xv.

Stronger patent protection not only fails to stimulate innovation that benefits the health of these people, it impedes their access to medicines by raising the costs of drugs and delaying the entry of generics into the global marketplace.¹²⁹ For those who rarely have health insurance, and often pay for drugs out of their own pockets, lack of access to affordable medicines can be the difference between life and death.¹³⁰ When patent protections are eased, competition between drug manufacturers allows for the poorest and sickest people in the world to have greater access to affordable and life-saving medicines.¹³¹ The public-health effect in the developing world created by this improved access is hard to overstate, as detailed in Section VIII of this paper. If through the TPP negotiations the United States is successful in renegeing on the patent flexibilities included in the BTM, it will undoubtedly lead to restricted access to medicines—and ultimately deficient public-health outcomes—in the developing world.¹³²

The leaked IPR proposals offered by the United States during TPP negotiations do not only threaten access to affordable medicines worldwide, they also compromise international public-health safeguards and U.S. global-health commitments.¹³³ Along with the Doha Declaration and the IPR flexibilities included in the BTM, an increase in international patent protection in the Trans-Pacific Partnership undermines other U.S. commitments to ensuring affordable access to life-saving medicines, including the following:

- *The Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property* (2008 World Health Assembly Resolution 61.21), in which the United States agreed, that countries are required to “take into account, where appropriate, the impact on public health when considering adopting or implementing more extensive intellectual property protection than required by TRIPS.”¹³⁴
- *The 2011 UN Political Declaration on HIV/AIDS* requires UN members, including the United States, to “ensure that intellectual property rights provisions in trade agreements do not undermine [TRIPS] flexibilities.”¹³⁵

¹²⁸ *Id.*

¹²⁹ ILIAS, *supra* note 3, at 6.

¹³⁰ *Trading Away Health*, *supra* note 14, at 5.

¹³¹ *Id.*

¹³² Lopert & Gleeson, *supra* note 6, at 211. “We are concerned . . . that the balance is once again shifting away from . . . access to affordable medicines and towards the greater protection of intellectual property rights for brand-name pharmaceutical companies in the developing world, a move that would jeopardize treatment goals and millions of lives.” *Trading Away Health*, *supra* note 14, at 19 (Letter from Jan Schakowsky et al., Representatives, United States House of Representatives, to Ron Kirk, Ambassador, United States Trade Representative (Aug. 2, 2011)).

¹³³ *Trading Away Health*, *supra* note 14, at 7.

¹³⁴ *Id.* at 7–8.

¹³⁵ *Id.* at 8.

- The Obama Administration has declared ending the AIDS epidemic a policy goal through initiatives such as *PEPFAR* and *The Global Fund*.¹³⁶ However, without continued access to new and affordable generic drugs, this goal will be unreachable.¹³⁷

In both principle and practice, it is necessary for pharmaceutical innovations to be encouraged and patent-protected. However, this necessity is not absolute and should be balanced with the interests of global welfare. The objective of increasing pharmaceutical profits, with the expectation that such financial returns will eventually trickle down to the poorest and sickest on Earth in the form of life-saving medicines, has not been accomplished and is bad public policy going forward.¹³⁸ In order to facilitate access to affordable medicines in the developing world and comply with its international public-health commitments, the United States should not impose increased IPR protections in the Trans-Pacific Partnership; at a minimum, it should honor the IPR flexibilities incorporated within the Bipartisan Trade Deal and the spirit of the Doha Declaration.¹³⁹

¹³⁶ *Id.*

¹³⁷ *Id.*

¹³⁸ Lopert & Gleeson, *supra* note 6, at 218.

¹³⁹ *Trading Away Health*, *supra* note 14, at 3.