



The Role of Interest Groups in the Peru-United States Trade Promotion Agreement (PTPA)

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Table of Contents

TABLE OF CONTENTS	3
ABSTRACT	4
BACKGROUND	5
MODIFICATIONS MADE.....	7
PROBLEM.....	9
QUESTION.	14
OBJECTIVES.....	15
HYPOTHESIS	16
ON THE LITERATURE OF THE PTPA	17
THEORETICAL FRAMEWORK FOR INTEREST GROUP ANALYSIS.....	22
THE DEVELOPMENT OF THE PTPA.....	29
RATIFICATION PROCESS	43
PTPA TIMELINE.	54
UNDERSTANDING THE CHANGES MADE TO THE PTPA	55
INTEREST GROUPS INVOLVED	64
RETHINKING THE IMPACT OF PLURALISM.....	80
LONG-TERM PERSPECTIVE.....	86
BIBLIOGRAPHY	91

Abstract

This case study seeks to analyze the impact that interest groups had in shaping the modifications in Intellectual Property Rights (IPR) provisions contained in the U.S.-Peru Trade Promotion Agreement (PTPA). In its original form, the PTPA contained IPR provisions that were favorable to pharmaceutical interest groups, but after several political changes in the U.S. Congress in 2006, the trade agreement was reviewed again and saw some modifications in its IPR provisions. Ultimately, this study looks to highlight the negotiation process from start to finish to understand what political dynamics were in play and determine if interest groups were the primary actors in shaping these changes.

Key words: Peru, United States, free trade, trade agreement, intellectual property, pharmaceutical industry, interest groups

Background

For the past 20 years, the U.S. has pursued free trade policies with many developing countries, especially in the Latin American region. Trade liberalization has been a principal objective of U.S. foreign policy during this time period and has played a significant role in how the U.S. builds alliances and partnerships. Beyond reaping the benefits of opening up markets, these arrangements have allowed the U.S. to form alliances and incorporate other issues such as intellectual property, labor, and environmental standards into these agreements.

The Peru-United States Trade Promotion Agreement (PTPA) followed this same template of promoting economic liberalization, while incorporating controversial provisions such as Intellectual Property Rights (IPR) standards in the agreement's text. Discussed and negotiated during the mid-2000s, the trade agreement was eventually signed on April 12th, 2006 and was approved by the Peruvian legislature on June 28th, 2006. The U.S. Congress approved the trade agreement during 2007 after several modifications were made to the original agreement. The U.S. would soon come to an agreement with Peru on several of the legally-binding amendments to the PTPA that concerned environmental, labor, and IPR standards. Subsequently, the Peruvian Congress would vote 70-38 in favor of the modifications to the PTPA on June 27, 2007.¹

¹ Villarreal, M. Angeles. 2007. U.S.-Peru Economic Relations and the U.S.-Peru Trade Promotion Agreement. [online] CRS Report for

U.S. President George W. Bush would then sign the agreement with the modifications in question on December 14, 2007.² The trade agreement would later be implemented by the Bush Administration via proclamation on February 1, 2009.³

The retrospective changes made in this agreement were mostly in environmental, intellectual property, and labor matters. The most notable changes were the modifications in the IPR provisions of the trade agreement that dealt with patents. What made these changes interesting was that these provisions received a certain degree of pushback from Peruvian interest groups at the start of the trade agreement negotiations, but were then ignored after the Peruvian Congress ratified the agreement in 2006.

Congress<<https://www.fas.org/sqp/crs/row/RL34108.pdf> >[Accessed June November 16th, 2015.]

² Hornbeck, J.F. 2009. Free Trade Agreements: U.S. Promotion and Oversight of Latin American Implementation. Inter-American Development Bank. [online] <<http://idbdocs.iadb.org/wsdocs/getdocument.aspx?docnum=35030812>>[Accessed: June 20th, 2015].

³ US Peru TPA Home. 2009. The U.S. and Peru signed the U.S.-Peru Trade Promotion Agreement (USPTA). [online]<<http://www.export.gov/peru/u.s.perutradepromotionagreement/index.asp>>[Accessed: June 18th, 2015].

Modifications Made

As mentioned before, certain modifications were made to the Free Trade Agreement (FTA) that reflected the complaints and misgivings that Peruvian civil society groups raised. These changes were finally put in place in 2007 through a Democratic controlled Congress which, on paper at least, placed more emphasis on measures that protected the environment, labor rights, and public health.⁴

The following changes include:

1. Patent Extension Term Limits

The original FTA with Peru contained provisions on patent term extensions. The modified agreement makes extension of patents due to delays in the patent or marketing approval process voluntary. In exchange, Peru would commit itself to processing applications in a reasonable and timely manner, with U.S. aid and cooperation. What was traditionally an obligation since the NAFTA negotiations, patent extensions to compensate for delays in the patent-or marketing-approval process were no longer obligatory. This illustrated a significant shift towards IPR liberalization and allowed for domestic companies and the generic industry to play on a more level playing field in the pharmaceutical market.

⁴ Braun, Johanna von (2012), *The Domestic Politics of Negotiating International Trade: Intellectual Property Rights in US-Colombia and US-Peru Free Trade Agreements*. London, Routledge, 2012. 276-278 p.

2. Limit Data Exclusivity Terms

The original agreement stipulated that the data exclusivity period of 5 years would begin when the pharmaceutical product entered the market, with a potential grace period of 5 years. The new arrangement changes the language of “at least 5 years” to just 5 years. If said product was approved within 6 months of an application for marketing approval, the 5-year period begins at the time that the product was approved in the U.S.

3. Inclusion of the Doha Declaration in FTA Text

In the original agreement, the Doha Declaration was not included in the text. Under the modified agreement, the Doha Declaration was included so as to serve as a reference for resolving conflicts that could potentially compromise public health standards. It requires that both parties commit to the principles laid out by the Doha Declarations and allow Peru to take necessary measures to protect public health.

All in all, these modifications marked a loosening of the enforcement of the IPR provisions in the FTA. What was traditionally an obligation to comply with in the past, patent term extensions and similar measures became slightly more voluntary and flexible.

Problem

Since the passage of TRIPS (The Agreement on Trade-Related Aspects of Intellectual Property Rights) by the World Trade Organization (WTO) in 1994, intellectual property has been fully integrated into the international trading system.⁵ This new international order has set minimum standards for IPR protections among WTO members.

From that point forward, IPRs have been increasingly included in trade agreements. TRIPS obligates WTO members to provide protections of copyrights, trademarks, and patents. In the same vein, TRIPS establishes a framework for dispute resolutions and settlements concerning compliance failures and other disputes between conflicting members.

Over the years, the U.S. has made it a point to protect and extend the copyrights of certain works such as Hollywood films, music, and software.⁶ Many of the aforementioned interest groups have pushed for stronger protection of IPRs not only in the domestic sphere but also in the international realm. Even with TRIPS standards in place, the U.S. has sought to expand IPRs through

⁵ Council for Trade-Related Aspects of Intellectual Property Rights. Office of the United States Trade Representative. [online] <<https://ustr.gov/trade-agreements/wto-multilateral-affairs/-world-trade-organization/council-trade-related-aspects-in.>> [Accessed June 18th, 2015.]

⁶De Micco, Pascale. 2014. The US and EU free trade agreements with Peru and Colombia: A comparison. [online] <http://www.europarl.europa.eu/RegData/etudes/briefing_note/join/2014/522326/EXPO-INTA_SP%282014%29522326_EN.pdf> [Accessed August 14, 2015.]

bilateral agreements. These newer standards, known as TRIPS-Plus or TRIPS +, look to go beyond the scope of TRIPS and implement more stringent standards.⁷

It is no surprise that these efforts have encountered a certain degree of backlash in the past few years. Most pushback has come against extended patent protections of pharmaceuticals. According to many public health advocates, these types of extensions restrict access to vital medicines in developing countries.

In response, the Doha Declaration was crafted in 2001 with purpose of defining the limits of IPR protections in trade agreements. Additionally, it aimed to promote access to medicines for all. Many public interest groups have turned to this declaration when facing trade agreements that contain TRIPS-Plus standards.⁸

One of the most notable cases of this development was the Peru-United States Trade Promotion Agreement (PTPA). In 2004, the Andean Free Trade Agreement's first round of negotiations commenced, which set out to create a substantive free trade agreement between the U.S. and other South American

⁷ Médecins Sans Frontières. 2011. TRIPS, TRIPS Plus and Doha. [online] <<http://www.msfaccess.org/content/trips-trips-plus-and-doha>> [Accessed May 20, 2015.]

⁸ WTO. 2011. Declaration on the TRIPS agreement and public health. [online] <https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm> [Accessed May 22, 2015.]

countries such as Bolivia, Colombia, Ecuador, and Peru.⁹ After Bolivia did not show up at the start of negotiations and Ecuador had to withdraw for domestic reasons, the U.S. decided to negotiate these agreements individually with Colombia and Peru.

The Peruvian agreement was pretty standard. It contained provisions that liberalized commerce between the two countries in matters of tariffs, investment, goods, and services. In addition, this agreement contained provisions that protected IPRs. The provisions covered a wide range of protections in the areas of copyrights, trademarks, patents, and data exclusivity.

Although the Peruvian public viewed the agreement favorably, points of contention arose in matters of intellectual property. Concerns were raised about the patent extension and data exclusivity provisions. Not only did these provisions face opposition from the Peruvian generic pharmaceutical industry, they also received strong pushback from civil society organizations. The latter were mostly concerned about how the aforementioned measures could possibly restrict access to basic medicines and other related products. The former had more of an economic interest at stake and saw these provisions as measures that could potentially cut into their profits.

⁹ Villarreal, M. Angeles. 2005. Andean-U.S. Free-Trade Agreement Negotiations. [online] CRS Report for Congress<<http://fpc.state.gov/documents/organization/57960.pdf>>[Accessed June 9th, 2015.]

Despite the concerns raised, Peru ended up signing the agreement in 2006. However, in 2007, U.S. Congressional Democrats modified the agreement to reflect some of their concerns with matters of labor rights, environmental standards, and public health. With regards to TRIPS-Plus provisions, the White House showed willingness to tone down these measures in an agreement established in 2007.¹⁰ This change of direction was aimed towards bilateral trade agreements with developing countries, with Peru being the first country to have these modifications implemented.

The aforementioned modifications included allowing developing countries flexibility in the application of patent term extension, patent linkage, and data protection in cases where it was necessary to protect public health.

Although most of the TRIPS framework stayed in place, the TRIPS-Plus provisions—data exclusivity and patent term extensions—were excluded in the final version of the agreement. Additionally, text from the Doha Declaration was included in the agreement to reflect the concerns of balancing intellectual property rights with public health measures. This marked the beginning of a

¹⁰ Lopert, Ruth and Gleeson, Deborah. 2013. The High Price of “Free” Trade: U.S. Trade Agreements and Access to Medicines. [online] Journal of Law, Medicine, and Ethics
<<http://apps.who.int/medicinedocs/documents/s20165en/s20165en.pdf>
>[Accessed June 11th, 2015.]

notable trend of pushback towards IPR provisions included in subsequent FTAs such as the Colombian and Panamanian trade agreements.¹¹

The main problem being analyzed in this case study are the modifications made to this very agreement. This study looks to not only analyze the modifications but also determine what types of interest group pressure, if any existed, or political dynamics helped bring about these changes.

¹¹ Cho, Sungjoon. 2007. The Bush Administration and Democrats Reach a Bipartisan Deal on Trade Policy. [online] American Society of International Law <<http://www.asil.org/insights/volume/11/issue/15/bush-administration-and-democrats-reach-bipartisan-deal-trade-policy>> [Accessed June 15th, 2015.]

Question

The modifications to this agreement were by no means radical, but they did mark a notable policy change in the realm of free trade. It is clear that pro-pharmaceutical interest groups suffered setbacks in this arrangement. What this case study aims to do is to understand why there were changes made to this FTA. In addition, it will aim to determine if interest groups played a substantial role in the changes made to this FTA.

Did the actions of interest groups throughout the ratification process bring about changes to the IPR provisions in the PTPA? Were there other factors that played a role in generating these changes?

Objectives

The main objective of this study is to determine if interest groups played a substantial role in determining certain policy changes concerning the IPR provisions in the PTPA. To get a thorough understanding of these changes, the PTPA itself and the rounds and discussions that led to its eventual ratification will also be covered in this study. In addition, the controversial points of the IPR provisions in the trade agreement will be analyzed. Interest groups will also be observed throughout the case study to determine if they had any substantial impact on the modifications made to the FTA's IPR provisions.

Specific objectives include:

1. Analyze the PTPA itself to understand the context it was negotiated in and see what was specifically modified.
2. Analyze the process that effectively led to the modification of the IPR provisions in the PTPA.
3. Identify the interest groups involved during the ratification process of the PTPA and determine if they had a significant impact in the modifications of the IPR provisions.
4. Determine if there existed other factors that could explain why these modifications occurred.

Hypothesis

Ultimately, it was successful political pressure from anti-IPR interest groups that led to the modification of this trade agreement. This case demonstrated that pluralistic interest group theory can allow for positive outcomes that benefit humbler interest groups. When there is enough interest group pressure and a system of pluralistic completion, smaller and less powerful groups have the chance of making impactful change. This, in turn, acts as a system of checks and balances among interest groups and prevents one interest group or a small number of interest groups from accumulating too much power in the political process.

Interest group theory alone did not account for all of these changes. In tandem with a Democratic Congress that was more skeptical of liberalization, these interest groups were able to take advantage of the current political climate and push their reformist agenda. Democrats made sure to reform certain aspects of the IPR provisions in the trade agreement as a way to demonstrate their competence in governance and also to stem the tide of economic liberalization that President George W. Bush presided over during his administration. Without the Democrats coming into power in the U.S. Congress in 2006, these modifications to the PTPA may have not come into a fruition. It was the teamwork and complementary efforts of the interest groups involved and Democrat Congressmen that ultimately realized these changes.

On the Literature of the PTPA

Johanna Von Braun's *The Domestic Politics of Negotiating International Trade: Intellectual Property Rights in US-Colombia and US-Peru Free Trade Agreements* is the most notable work that covers the negotiation process of the PTPA and its IPR provisions. The main inspiration for this study came from Von Braun's seminal work where she highlighted the domestic origins and development of the IPR negotiations of the Colombia and Peru FTAs during the decade of the 2000s. Von Braun focused mostly on domestic politics and the impact they have on the outcomes for international treaties and other forms of international cooperation between countries.

This publication does a good job in identifying the multitude of actors involved during these negotiations and how they positioned themselves throughout this period. Its main strength lies in how it starts from the domestic level and works its way up to the international level in explaining how policymaking is determined on the international stage. Von Braun effectively shows how domestic politics plays a major role in international negotiations and how private interests that advocated for IPR protections at the domestic level have just as much of an incentive to jump into the international lobbying arena.

Another key strength of Von Braun's work is her chronological detailing of the PTPA negotiations and ratification process. This study will draw heavily from

her work in this respect, since it gives a very clear timeline of the most important developments throughout the negotiation phases.

In the same vein as Von Braun, Alfredo Ferrero's *Historia de un Desafío* effectively conveys a chronology of important events that led to the ratification of the PTPA. Ferrero's perspective as the Minister of Commerce revealed very valuable information on the events and negotiations that took place during the trade agreement process. His work provides a more precise chronology of the negotiation rounds and the obstacles that Peru faced, be it internationally or domestically, in trying to get this agreement passed. *Historia de un Desafío* also provides an in-depth political context of what transpired before and after the PTPA negotiations. The PTPA negotiations were by no means an isolated set of events, and Ferrero's work gives readers an idea of the overarching political trends and developments that were taking place in this time period.

José Raúl Perales' *La política comercial del Perú en el contexto regional* yielded some important insights on the political context of Peru during the 1990s up to the negotiation phases of the PTPA. Additionally, this publication highlighted various institutional features of the Peruvian government that made its pro-trade goals considerably easier to implement in this time period. Lastly, there were good observations of how Peru did not have many veto actors or institutions that could potentially derail the Peruvian government's free trade agenda. Perales' work gives readers an understanding of the institutional

dynamics in play that allowed Peru to pass the PTPA without much resistance at the domestic level.

Despite the heavy influence of Von Braun in this work, this work ultimately seeks to analyze the PTPA more exclusively but through a narrower interest group perspective. This study will incorporate a theoretical framework that draws from pluralist and neopluralist theories of interest group involvement in the political process.

Frank Baumgartner and Beth Leech's *Basic Interests* provides a concise overview of basic interest group theory and how interest groups affect the policymaking process. The main strength of this piece of literature is its clear portrayal of group theory and how pluralistic theory has evolved over the years. The crux of pluralistic theory lies in the assumption that the "best political outcomes would arise as a result of group conflict" and that the state should serve as an impartial arbiter among competing interest groups.¹² This study will rely heavily on the pluralistic assumption of interest group dynamics to demonstrate how interest groups were involved and how they ultimately shaped policymaking during the negotiations.

¹² Baumgartner, Frank R. & Leech, Beth L. (1998), *Basic Interests: The Importance of Groups in Politics and in Political Science*, Princeton: Princeton Press. 46p.

Kenneth Godwin, Erik Godwin, and Scott Ainsworth made a very valuable contribution to the development of interest group theory in their seminal work *Lobbying and Policymaking: The Public Pursuit of Private Interests*. This work introduces a more updated version of pluralism, neopluralism, that aims to rectify some of the flaws of previous pluralist analyses. Neopluralism builds off of traditional pluralist theory assumptions that policymaking involves various interest groups pitted against each other in order to exert influence on public policy. It does concede that certain interest groups do wield disproportionate power and can influence policy better than others. In addition, neopluralism takes into account the importance of elections and political parties as other mediums that interest groups can use to affect policy change directly and indirectly. This focus on elections and political parties is one of the more powerful insights of neopluralism that is particularly relevant to the PTPA. This perspective will be used in this case study to see if neopluralism is better at explaining the changes to the PTPA than traditional pluralistic theory.

Mancur Olson's *The Logic of Collective Action* yielded very powerful insights on the nature of interest group organization. Olson's perspective was considerably pessimistic in regards to how interest groups organize. He believed that producer groups would have considerable advantages in mobilizing political campaigns and lobbying given the low costs for them to organize. On the other hand, broader interest groups that supposedly represented the interests of the public at large would have more difficulty in organizing due to the higher

organization costs. According to Olson, the way that groups would overcome this hurdle is by providing selective benefits to members and potential members in order for them to feel incentivized to act and organize. This case study will use Olson's perspective as a counter-example to see if the original hypothesis still holds when put under further scrutiny.

Under the lens of interest group organization, this study will offer a more robust analysis of the PTPA's negotiations and what factors contributed to the modifications, specifically interest group pressure, and determine if this dynamic was the most decisive factor in causing these modifications. This case will focus on both Peruvian and American interest groups and how they interacted and positioned themselves during the negotiations.

There are many misconceptions and misunderstandings on how the lobbying process works and what type of impact it has on policymaking. This study will give readers an in-depth look on how certain interest groups behaved during the negotiations of a notable trade agreement. In the same vein, this case study will provide readers a clear understanding of interest group theories and how interest groups operate under these frameworks. With more and more interest groups getting involved in political activities in contemporary times, it is essential to have publications that demonstrate how these theories are not only valid in domestic political settings but also on the international level.

In a world that is not only seeing its economy become globalized, but also its politics as well, interest group theory is still very much in play when analyzing how certain treaties, supranational organizations, and international policy decisions come about. All in all, this study hopes to illustrate how the study of interest groups is now more relevant than ever when it comes to the analysis of international agreements and similar arrangements.

Theoretical Framework for Interest Group Analysis

Introduction

Interest groups undoubtedly played a role during the negotiation and ratification process of the trade agreement. Groups from both sides of the aisle made their opinions heard and made efforts to shape the IPR provisions included in the trade agreement. This section will seek to give this case study a deeper understanding of how interest groups work in the political process and if the pluralistic interest group hypothesis put forward was actually in effect during these negotiations. For the purposes of this case study, interest group theory analysis and an overview of interest groups involved will be touched upon in order to understand what impact, if any, they actually had on the modifications of the trade agreement.

The original hypothesis maintained that pluralist interest group theory was at work throughout the ratification process. Therefore, this theory explains how

the modifications to the trade agreement came about. What started out as an agreement that seemingly favored pharmaceutical interests, turned into a more balanced agreement that was favorable towards public health advocates. This all came into fruition through interest group pressure in tandem with a Democratic majority that was more willing to reform these types of IPR provisions.

Pluralist Theory

The original hypothesis put forward in this case study contends that pluralistic interest group theory was present throughout the negotiation process. Given the assumptions of the pluralist interest group theory, interest groups were the principal actors in helping usher in these modifications to the trade agreement. Although compelling, this hypothesis will still be put to test.

To start off, one must understand the very basics of pluralistic theory. In a rudimentary sense, pluralism can trace its origins all the way back to the publishing of *Federalist No. 10* by American statesmen James Madison. Madison believed that competing interest groups served as a means to prevent a “tyranny of the majority”.¹³ Diverse interest groups and factions were key to the success of the system. If trouble arose, these groups could rise together behind a common cause to prevent a potential tyranny of the majority.

¹³ Madison, James. 1787, *The Federalist: The Federalist No. 10* [online] The Library of Congress <http://thomas.loc.gov/home/histdox/fed_10.html> [Accessed October 6, 2015.]

Despite not being labeled as pluralism, this theory would be further developed for years to come. Eventually, the theory of pluralism would officially enter into the academic lexicon in the early 1950s with the publication of David B. Truman's seminal work *The Governmental Process*.¹⁴ In this book, Truman held that interest groups arose when certain economic or social developments had negative impacts on people or institutions. This would lead to the formation of certain civil action groups that would band together to correct these dilemmas. It was this ability for groups to organize and compete that allowed for supposedly "fair" political outcomes that would be healthy for the growth of democracy and functional governance.

The basis of pluralistic theory lies in the assumption of competition among interest groups. As opposed to previous political analysis that placed more of an emphasis on the "absolute sovereignty of the state" and the political designs of certain states, pluralism focused more on particular groups that were involved in the policymaking process.¹⁵ A healthy democracy was one that featured a diverse array of groups competing against each other to produce optimal outcomes.

¹⁴ Truman, David B. (1951), *The Governmental Process: Political Interests and Public Opinion*, New York: Alfred A. Knopf.

¹⁵ Baumgartner, Frank R. & Leech, Beth L. (1998), *Basic Interests: The Importance of Groups in Politics and in Political Science*, Princeton: Princeton Press. 46p.

The state in this context would be an arbiter or referee of sorts that would not directly interfere in this process or pick certain winners or losers. Under this framework, the optimal democracy would not necessarily be the one with a particular constitutional design, but instead would be one that allows for a dynamic and vibrant group system.¹⁶ Competition and independence from the state are key in pluralistic interest group analysis. In sum, groups that genuinely represented their members' interests would be more effective in safeguarding the democratic stability and decision-making of a country than a particular institutional framework.

Competition is paramount in the pluralistic model. In essence, in a pluralistic system there is not one group or a small set of groups that wields a disproportionate amount of power. For every powerful actor, there would be another actor that is capable of countering it and keep it from completely dominating the political arena.¹⁷ To some extent, the pluralistic model operates similar to a model of perfect completion among interest groups. Constant competition among interest groups effectively promotes a dispersion of power in a political system.

At first glance, pluralism can be assumed in the case of the PTPA. Both sides of the political aisle saw advocacy organizations confront one another during the ratification process. From the early stages of the agreement it looked

¹⁶ Ibid

¹⁷ Ibid.

like the more powerful pharmaceutical interests had the edge on their rivals. However, changes in the U.S Congress in 2006 propelled changes to the PTPA that in many respects went against the interests of the pharmaceutical industry.

The Olsonian and Neopluralist Alternatives

To understand why these changes to the PTPA occurred, Mancur Olson's group mobilization theory serves as an alternative theory to explain these developments. In contrast to the popular pluralist theory of the day, Olson posed the argument that smaller, more established groups will win out in the public policy process. This stood in sharp contrast to the traditional pluralistic vision that contends that the "best political outcomes would arise as a result of group conflict" and that free and active group activity is crucial for the maintenance of democracy.¹⁸

On the other hand, Olson had a much bleaker vision of special interest groups in his magnum opus *The Logic of Collective Action*. In a democracy in which multitudes of interest groups may exist, those that are able to provide greater selective incentives to their group members will organize and mobilize

¹⁸ Baumgartner, Frank R. & Leech, Beth L. (1998), *Basic Interests: The Importance of Groups in Politics and in Political Science*, Princeton: Princeton Press. 46p.

more effectively.¹⁹ Thus, producer groups will generally trump consumer groups in the public policy arena. Ultimately, the select few cases of citizen action groups that impact public policy are those that are able to provide select benefits that exceed the costs of group membership.²⁰

In the same vein, E.E Schattschneider noted that the flaw in the “pluralist heaven is that heavenly chorus sings with a strong upper-class accent.”²¹ Interest group organization would ultimately spiral into a battle of small, cohesive groups representing the elite strata of society. This would result in unfavorable policy outcomes for the general public.

Despite some of its flaws, the pluralist school of thought has evolved over the years to take into account certain aspects of Olson’s collective action problem. In line with this evolutionary trend, the neopluralist school sought to integrate aspects of Olsonian analysis with pluralism to get a stronger understanding of how policy outcomes are determined. Neopluralism describes interest group interactions as a tug-of-war between competing groups.²² In the

¹⁹ Olson, Mancur. (1965), *The Logic of Collective Action*. Cambridge: Harvard University Press. 133p.

²⁰ Chubb, John. (1983), *Interest Groups and the Bureaucracy: The Politics of Energy*. Stanford: Stanford University Press. 32p.

²¹ Schattschneider, E.E. (1975), *The Semisovereign People: A Realist's View of Democracy in America*. Boston: Wadsworth Publishing. 35p.

²² Godwin, R. Kenneth, Ainsworth, Scott, Godwin, Erik (2012), *Lobbying and Policymaking: The Public Pursuit of Private Interests*, Washington, DC: CQ Press. p. 37-38

lobbying process certain groups have more leverage and control, but in other stages the tide can shift in favor of their rivals.

The neopluralist theory, in fact, vindicates the Olsonian analysis of interest groups. It concedes that interest group competition is not enough to account for explaining certain political outcomes. Based on certain aspects of neopluralism and Olson's beliefs, there exists a propensity for power to be concentrated in interest groups whose interests generally go against the majority of the general public. There is not always a positive policymaking outcome, as opposed to what traditional pluralist theory assumes.

What the PTPA case demonstrates is that policy change on certain public policy matters is the consequence of certain changes in political power (the rise of the Democrat party in the U.S Congress in this case). Direct interest group pressure does not always result in policy change, especially "positive" change that favors the majority of the populace or that is healthy for democracy. The neopluralist theory takes this into account and believes that interest groups may have indirect impacts on policymaking. This indirect pressure can be channeled through certain mediums such as political parties and large-scale political developments. Events such as elections, can play decisive roles in policy outcomes and at times can constrain the impact that interest groups have on determining political outcomes.²³ Although neopluralism still maintains a positive

²³ Ibid.

outlook on the interest group process, it does concede that interest groups sometimes need help from external factors such as elections to mold policymaking decisions.

1. The Development of the PTPA

Introduction

The passage of the PTPA was no isolated incident. It was part of a political era in which the U.S. was dedicated to expanding its free trade regime. Having sealed the North American Free Trade Agreement (NAFTA) in 1994, the U.S. wanted to continue this trend of trade liberalization and sought to create a free trade sphere in the Western Hemisphere through bilateral trade agreements.

The U.S. had its sights set on Andean countries, Peru in particular, as the next set of countries to come into its free trade fold. This process of integrating Andean countries into the trade fold began in 1991 through the enactment of the

Andean Trade Preference Act (ATPA). This was implemented in efforts to economically develop the region's white market industries in order to curb drug trafficking. Peru would be added to this agreement in 1993 after complying with certain standards.²⁴

Later in 2002, this act would be converted into the Andean Trade Promotion and Drug Eradication Act (ATPDEA). This renewed version of the act contained tariff exemptions for an increased amount of Andean products, changing the amount of exempt products from 5,600 to 6,300.²⁵ Peru was able to achieve this renewal despite a very close vote in the U.S. Congress. If it were not able to gain these trade and tariff preferences, Peru could have potentially faced an upswing in illegal coca cultivation at the time.²⁶

This was all a part of a free trade agenda where the U.S. saw free trade as an avenue to fight drug trafficking and promote national security. Although an Andean free trade zone never came into fruition, the U.S. continued to push on with its efforts to negotiate trade agreements individually with countries such as Colombia and Peru. With the previous experience of barely surviving a narrow vote on the ATPDEA, it became clear to Peru that it could not rely on provisional or non-binding trade arrangements.²⁷ At this point, Peru had to pursue a lasting,

²⁴ Ferrero, Alfredo (2010), *Historia de un Desafío*. Lima: Planeta. 65p.

²⁵ The White House. 2002. *Andean Trade Promotion and Drug Eradication Act: By the President of the United States of America*. [online] <<http://georgewbush-whitehouse.archives.gov/news/releases/2002/10/20021031-9.html>> [Accessed October 19, 2015.]

²⁶ Ferrero, Alfredo (2010), *Historia de un Desafío*. Lima: Planeta. 69p.

²⁷ Ferrero, Alfredo (2010), *Historia de un Desafío*. Lima: Planeta. 76p.

bilateral trade agreement with the U.S. in order to insure investor confidence and have a stable environment for its exports.

During this same time period, the inclusion of Intellectual Property Rights (IPRs) protections in trade agreements started to become a controversial norm. The establishment of The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) set important precedents in international IPR standards, especially in bilateral trade agreements between countries. Pro-IPR interest groups, such as the film, music, and pharmaceutical industry became very comfortable with this new framework and now could enjoy protection of their IPRs on a global scale.

These interest groups still were not satisfied with the TRIPS framework; they believed that this framework could be expanded upon in trade agreements. Taking advantage of this dynamic, pro-IPR forces were heavily involved in the lobbying process of the PTPA. U.S. pharmaceutical companies heavily rely upon patent protections and other IPR restrictions to protect their works from foreign off-shoots and pirated versions of their products. The PTPA not only was a great opportunity for the pharmaceutical industry to secure its market share in Peru, but it also presented an opportunity to rein in Peru—a country that the pharmaceutical industry has seen as a weak defender of IPRs.

This following section outlines the political and economic contexts and the original ratification process that took place during the negotiation of the PTPA.

Political Context

The PTPA was crafted during the middle of the Bush administration, a time when the U.S. was entering a very polarizing political climate. Issues from national security to economic policy generated much controversy on both sides of the political aisle. An era dominated by conservative policies –economic liberalization and heavy interventionism in foreign policy– was now seeing heavy attacks coming from left-leaning Democrats. The 2006 elections, in which the Democrats came out victorious, marked the beginning of a leftward shift in American politics.

Since the Reagan Revolution of the 1980s, American politics has been characterized by an economic paradigm that favors high degrees of economic liberalization domestically and abroad. There have been various notable exceptions, such as the increase in steel tariffs and farm subsidies during the Bush administration, but the overall trend of American economic policy has been

geared towards opening up its markets to international trade.²⁸ From the Clinton Administration up to the Bush Administration, free trade has been the norm in matters concerning the U.S.'s international economic policy.

The Democrat's arrival to power in the 2006 Congressional elections presented a promising opportunity for left-leaning ideas to enter into the political arena. These opportunities were not just confined to Democrats, even independent left-leaning politicians and organizations joined in the fray. Bernie Sanders, one of the United States Senate's most famous independents and champions of left-leaning causes, saw the PTPA as a "continuation of failed agreements such as the North American Free Trade Agreement, the Central American Free Trade Agreement, and permanent normal trade relations with China."²⁹ Numerous other political figures and NGOs voiced their disapproval and started to mount campaigns against free trade measures.

Traditionally fringe issues such as intellectual property were now entering the public policy debate. From a first glance, it seemed that the PTPA could have possibly met its death with the Democrats taking over the House and the

²⁸ The Economist. 2002. George Bush, Protectionist. [online] The Economist: Six Months On < <http://www.economist.com/node/1021395>> [Accessed August 3, 2015.]

²⁹ Sanders, Bernie. 2007. Sanders Statement on the U.S.- Peru Trade Agreement. [online] <<http://www.sanders.senate.gov/newsroom/press-releases/sanders-statement-on-the-us-peru-trade-agreement>> [Accessed August 10, 2015.]

Senate in 2006. However, certain political realities were already in place that proponents of separating IPRs from FTA had to accept:

1. Free Trade policies have received substantial support from both sides of the political aisle. Despite Democrats not casting a majority of votes in favor of FTAs such as the North American Free Trade Agreement (NAFTA), the opposition to FTAs on the part of the Democrats has not been strong enough to change the tide of key FTA votes. There is definitely potential in the future for the Democrats to have a monolithic Anti-FTA presence, but at the time of their Congressional victories in 2006, that dynamic was not firmly set in place.
2. Democrats' implicit duty to govern in a bipartisan fashion. The Bush Administration and the Republican Party's brand fell out of favor with the American public given the rising unpopularity of the Iraq and Afghanistan wars, alongside economic policies that many believed to have favored the rich. Above all, Congress's reputation of being able to competently govern in a bipartisan fashion was also put in doubt by many voters. Totally dismantling certain political projects that did not have widespread public opposition would not be a good start for incoming Democrats that want to establish their credibility with the American people. At times, political groups must make certain compromises and at least work with the opposition to successfully pass certain bills to establish a minimum

standard of of political competence. In the case of the PTPA, the Democrats used this opportunity to leave their footprint on a piece of legislation that was originally a prized possession of the Bush administration.

From the outset, Democrats knew that they were restrained in certain ways from what they could do politically once they took over Congress. A relatively fringe issue such as IPRs in matters of pharmaceuticals would obviously not be an issue at the forefront of political discussion. Democrats and sympathizers of less stringent IPRs had to take what they could get. At the same time, public health interest groups had a much stronger interest in this than the average Democrat Congressmen. Given that this issue was already fringe, these Congressmen would be more willing to compromise on certain parts of IPR measures since it was not a high priority. A compromise would show that Congressional Democrats “got something done”, while at the same time, placating some of their anti-IPR constituents with a compromise that appears to be a step in the right direction in the campaign to remove IPRs from trade agreements altogether.

The political context of Peru at the time is also worth highlighting. From the 1990s up until the 2000s, Peru had gone through a profound set of economic reforms set by then controversial president, Alberto Fujimori. Fujimori’s set of policy prescriptions were part of the “Washington Consensus” package of

economic liberalization measures that included opening up international trade, privatization, government spending cuts, and the encouragement of increased private investment.³⁰

Despite coming to prominence by campaigning against Fujimori, Fujimori's successor, Alejandro Toledo, continued many of the trade liberalization policies that were part of the same neoliberal, Washington Consensus paradigm. At the time, it was clear that the Peruvian state's economic policy was oriented towards open trade. This policy had top priority and was not subject to change regardless of the changes in government and electoral pressures that took place during this time period.³¹ Under Toledo's administration, talks between the U.S. and Peru commenced with regards to the formation of the PTPA. Among the Peruvian political elites, the bilateral agreement was viewed favorably and seen as a vital undertaking for Peru's economic development. Toledo wanted to make the PTPA a part of his presidential legacy and declared that the PTPA will be signed no matter what (sí o sí).³² From the outset, it was clear that there was a strong motivation among the executive branch and higher levels of government to push

³⁰ Williamson, John. 2004. A Short History of the Washington Consensus. [online] Institute for International Economics <<http://www.iie.com/publications/papers/williamson0904-2.pdf>> [Accessed August 17, 2015.]

³¹ Perales, José Raúl. 2010. "La política comercial del Perú en el contexto regional". In Perales, José and Eduardo Morón (eds.), La Economía Política del Tratado de Libre Comercio entre Perú y Estados Unidos. Washington: Woodrow Wilson International Center for Scholars, 17-24 p.

³² Ferrero, Alfredo (2010), Historia de un Desafío. Lima: Planeta. 159p.

the PTPA through. Peruvian business interests were also strongly onboard with the agreement. These factors proved to be key throughout the negotiations.

Even Alan Garcia, a political figure commonly known for his left-leaning views, helped push the PTPA through during his presidency despite his ambiguous campaign rhetoric regarding the PTPA. During Garcia's term, Law 29316 was implemented on January 14th, 2009, which effectively created the opportunity for U.S. corporations to patent genes extracted from Peruvian flora while loosening the requirements for attaining a patent. This was a notable break from the Andean Community of Nations' (CAN) intellectual property standards, which normally offer stronger protection of indigenous and local resources.³³

Naturally, there was strong opposition from people on the ground given the trade agreement's neoliberal characteristics. Numerous civil society organizations mounted protests against measures that they believed would hurt the working class and the poor while benefiting the upper class and multinational corporations. For purposes of this study, the IPR provisions contained in this agreement are the most relevant points of disagreement.

³³Council on Hemispheric Affairs. 2009. Ramming the Matter Home: Peru-U.S. FTA Rushed, Diluted and Finagled. [online] <<http://www.coha.org/ramming-the-matter-home-peru-us-fta-rushed-diluted-and-finagled/>> [Accessed August 17, 2015.]

For a developing country such as Peru, such measures evoke a large degree of controversy given the country's economic status and the competitive disadvantages it faces in the international market. Such measures are relatively new in matters of international trade agreements and are seen as potential hazards towards the public health sectors of developing countries.

Even amongst the Peruvian proponents of the PTPA, the IPR measures were seen as measures that went too far. Such opposition grew to the point that nationalist leader and presidential candidate, Ollanta Humala lent his support to protests and mobilizations in the street against the trade agreement.

Through a clever political sleight of hand, Alejandro Toledo made sure that the PTPA would be signed after the First Round of elections in order to avoid politicization of the topic and ensure that the PTPA's ratification would have no effect on the First Round of elections.³⁴

On the Peruvian front, any efforts to separate IPRs from the PTPA were effectively dead in the water. Ultimately, it would take political action from the U.S. Congress to modify some of the concerns mentioned.

³³ Palomino, Maria Luisa. 2006. TLC con EEUU enfrenta a candidatos a presidencia de Perú. [online] Invertia online April 5, 2006 <<http://www.invertia.com/noticias/articulo-final.asp?idNoticia=1505766>> [Accessed August 24, 2015.]

Patent Context

Patent grants in of themselves have evoked strong degrees of controversy in the realm of development economics. Statistics concerning the granting and filing of patents paint a First World centric picture. Figures from the OECD from 2000 to 2011, show that over 80% of the world's patent applications under the Patent Cooperation Treaty (PCT) came from the U.S, E.U., and Japan.³⁵ Patents belonging to the Triadic Patent Families, which is a sub-set of patents that were all filed at the European Patent Office (EPO), the Japanese Patent Office (JPO), and the US Patent and Trademark Office (USPTO), also shared the same characteristics. Approximately 85% of these patents came from the aforementioned developed economies.

On the other hand, Peru has registered much smaller figures throughout the years. In total, it accumulated a measly 5 pharmaceutical patents filed during this same timeframe. In some of those years, Peru even had zero patents filed. The Triadic Patent Families painted a similar a bleak picture, as Peru managed to get only 1.4 patents filed in total during this period. It should be noted that the

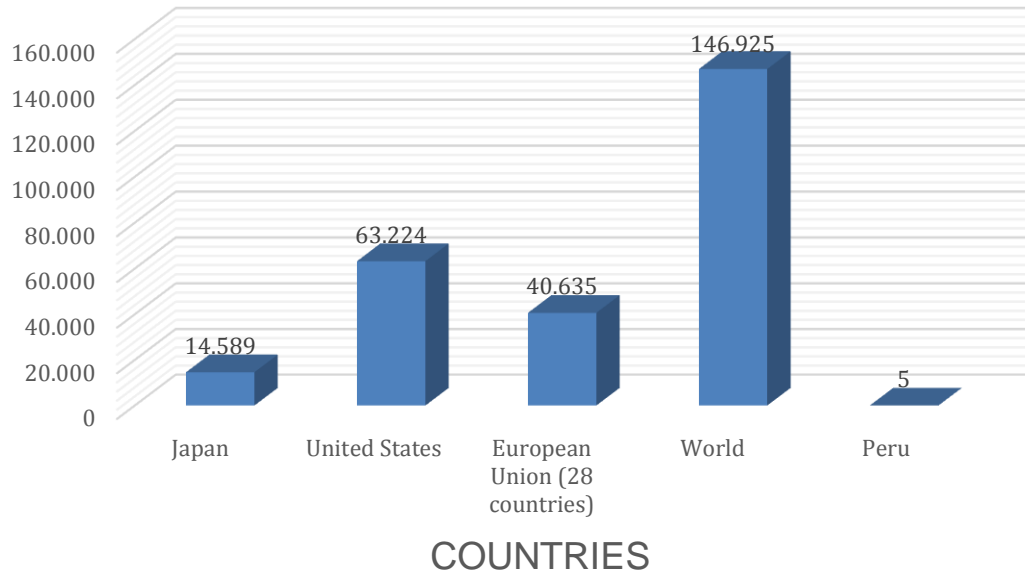
³⁵ OECD. OECD.Stat. [online] <http://stats.oecd.org/Index.aspx?DatasetCode=PATS_IPC#> [Accessed: September 3, 2015]

OECD will assign fractions if the application in question had inventors from different countries.

Many contend that this skewed distribution of patent applications overwhelmingly favors developed countries, especially multinational corporations coming from these very countries. As a result, many developing countries such as Peru struggle to innovate and must heavily depend on multinational corporations and other corporate entities to get basic medical supplies. According to many anti-IPR advocates, the development of local pharmaceutical industries and other forms of domestic competition have arguably been stifled in many cases due to the current patent regime.

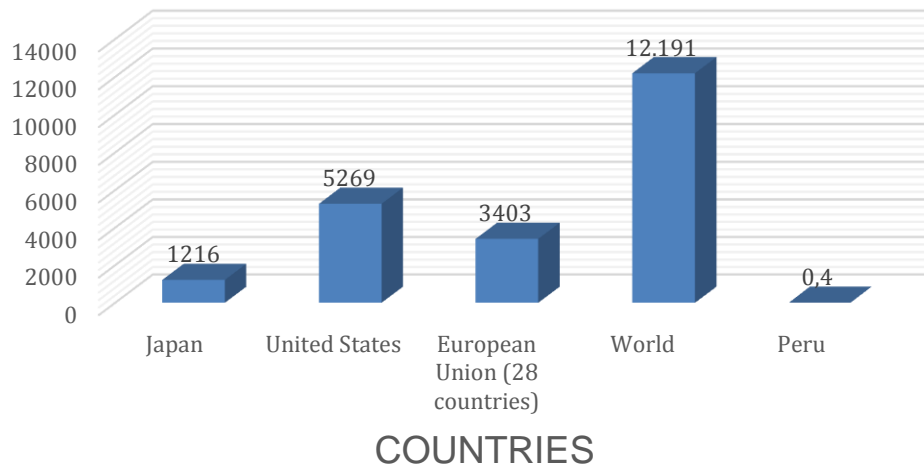
Irrespective of whether patent policies harm developing countries such as Peru or not, it is clear that the US pharmaceutical industry has a major interest in dominating the patent sphere. Without a doubt, they are the number one player in the filing and granting of pharmaceutical patents. It is no surprise that the pharmaceutical industry would employ lobbies such as PhRMA to maintain this status quo and consolidate their foothold on an international scale.

Total PCT Pharmaceutical Patents Filed (2000-2011)

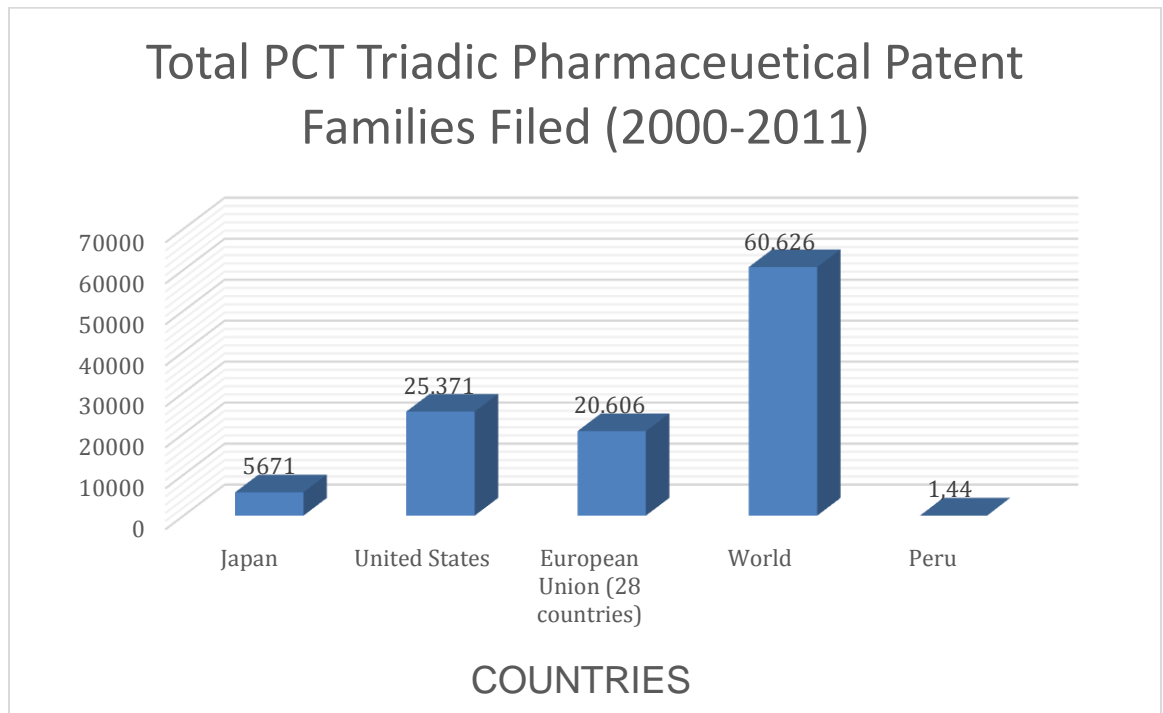


Source: OECD.STAT 2012.

Average PCT Pharmaceutical Patents Filed (2000-2011)



Source: OECD.STAT 2012.



Source: OECD.STAT 2012

Ratification Process

1. First Phase

Trade agreement talks began with the U.S. and Peru during the mid-2000s. A meeting was held in Miami in 2003 to discuss potential projects with the 34 nations that comprised the Free Trade Area of the Americas (FTAA). Peru was among these countries and it made its case during these negotiations for a trade agreement with the U.S. Its main focus was on the need to incentivize the development of formal economic sectors in the country in order to help curb the incentive for farmers to turn towards illegal coca production. The FTAA reunion ended up facing numerous roadblocks and the negotiations eventually died down. Even though the FTAA negotiations fell apart, this reunion proved to be historical as it marked the beginning of FTA negotiations with the ATPDEA states (Bolivia, Colombia, Ecuador, and Peru).³⁶

Eager to continue expanding its trade agenda, the U.S. originally brought together Bolivia (in observer status), Colombia, Ecuador, and Peru for the US-Andean FTAs on May 18, 2004 in Cartagena de las Indias, Colombia. These countries were a part of the Andean Trade Promotion and Drug Eradication Act (ATPDEA). Enacted in 2002, this trade preference system provided tariff free access on products that came from the aforementioned countries as a way to impede drug trafficking.

³⁶ Ferrero, Alfredo (2010), *Historia de un Desafío*. Lima: Planeta.142p.

When negotiations started in the first rounds of discussions, IPR issues were among the most controversial points of discussion during these talks. Once the U.S. submitted its IPR proposals during the 1st round, each of the Andean countries manifested certain doubts about the TRIPS-Plus measures proposed by the U.S. For Peru, controversies also arose when discussing the agricultural impact of the FTA given that this agreement would allow for its market to receive subsidized American foods and crops.³⁷ Under these conditions, Peru would have much trouble competing against the American agricultural sector.

More fuel to the fire was added when the UN Special Rapporteur on the Right to Health, Paul Hunt, visited Lima, Peru on June 2004. Hunt expressed concerns about how the current trade agreement that the U.S. was proposing would “water-down internationally agreed health safeguards, leading to higher prices for essential drugs that millions of Peruvians will find unaffordable”.³⁸ He also added that the trade agreement in its current form did not respect the spirit of the Doha Declaration, which provided for certain safeguards for public health. Despite the growing list of concerns, negotiations proceeded smoothly for Peru.

³⁷ Ferrero, Alfredo (2010), *Historia de un Desafío*. Lima: Planeta. 161p.

³⁸ United Nations Human Rights Office of the High Commissioner. 2004. US-Peru Trade Negotiations: Special Rapporteur On Right To Health Reminds Parties Of Human Rights Obligations. [online]<<http://www.ohchr.org/en/NewsEvents/Pages/DisplayNews.aspx?NewsID=1906&LangID=E>> [Accessed: October 27 , 2015.]

By the Third Round in the negotiations, the Andean nations would then submit a counter proposal to the U.S set of IPR provisions.³⁹ This proposal demanded lower levels of IPR protection and a reference to the Doha Declaration in the trade agreement. The U.S. maintained its ground and rejected this proposal, but it still continued with the negotiations.

Despite this refusal by the U.S., the Andean team was still able to get certain IPR points as a part of its negotiation with the U.S. team. The Peruvian Ministry of Foreign Commerce and Tourism (Henceforth it will be referred to as the Ministry of Commerce) assured in a statement on March 2005 that current negotiations were part of a plan to craft an agreement that upheld Peru's interests and that would also not be a carbon copy of CAFTA and previous trade agreements.⁴⁰ It also added that the PTPA would not restrict access to medicines or raise their prices.

At this point it was becoming clear that the commerce team was seeing eye to eye with U.S. more so than the public health team was on matters concerning IPRs. Most pushback that came from Peruvian government was from Dr. Pilar Mazzetti, the Minister of Health at the time.⁴¹ She believed that the

³⁹ Braun, Johanna von (2012), *The Domestic Politics of Negotiating International Trade: Intellectual Property Rights in US-Colombia and US-Peru Free Trade Agreements*, London: Routledge. 193-194 p.

⁴⁰ Ibid.

⁴¹ Murillo, Guillermo. 2004. *Latin American Activist Denounce the Policies and Practices Used in the Negotiation of Free Trade Agreements Between the United*

PTPA as it was originally proposed was in clear violation of the Doha Declaration. However, Mazzetti and her ministry's skepticism did not impede any type of progress with the trade agreement.

Peru would hold its ground trying to use data exclusivity as a bargaining chip during the 4th, 5th, and 6th rounds.⁴² It was becoming clear throughout the second phase of the PTPA negotiations that the IPR issues were not making much progress for Peru and its Andean counterparts.

The 8th Round in Washington DC during March 14th to 18th of 2005 was not without its fair share of controversy. The president of Peru's intellectual property authority (INDECOPI), Santiago Roca, openly clashed with INDECOPI's negotiator and representative during the negotiations, Luis Alonso García.⁴³ Roca believed that García was compromising INDECOPI and Peruvian domestic interests by not being sufficiently hardline on the IPR items in the negotiation agenda. García would eventually resign and work with the Ministry of Commerce to help facilitate the IPR negotiations, while Roca would eventually resign from his position in INDECOPI.⁴⁴ INDECOPI would continue providing

States and Latin American Countries. [online] World Campaign Against the Trading Away of Health and Life
<<http://www.cptech.org/ip/health/trade/cafta/ngos11302004.html>> [Accessed October 29, 2015.]

⁴² Braun, Johanna von (2012), *The Domestic Politics of Negotiating International Trade: Intellectual Property Rights in US-Colombia and US-Peru Free Trade Agreements*, London: Routledge. 198p.

⁴³ Ferrero, Alfredo (2010), *Historia de un Desafío*. Lima: Planeta. 174p.

⁴⁴ Ibid.

technical know-how during the negotiations, but its institutional role was largely diminished due to the outbursts made by Roca.

During a session in the 8th round, Peru drew a sharp line in the sand by stating that it would not sign any trade agreement that demanded stricter IPR standards than what the World Health Organization (WHO) required or IPR standards that went beyond those that Central American countries agreed to during the approval of the Central American Free Trade Agreement (CAFTA).⁴⁵ This round marked a turning point in that the U.S. was ready to move on from technical aspects and start discussing more political matters. It became clear that the U.S. would not concede much ground on IPR concerns.

Before a mini-round dealing with agricultural matters that was scheduled for June 20th to June 23rd, then vice-president of Peru, David Waisman, stated that the representatives from the Peruvian Ministry of Commerce were on a mission to beg the U.S. it to loosen its positions and sign the agreement out of charity.⁴⁶ This caused quite a stir amongst the Peruvian press and created a tense environment for the negotiators once they arrived in the U.S. Despite this gaffe committed by the Peruvian vice-president, the negotiations proceeded as planned.

⁴⁵ Ibid.

⁴⁶ Ibid.

In the 12th round on September 19th, 2005, the U.S. featured a completely different IPR negotiations team. This negotiations team paid no real heed to the points of concern put forward by the Peruvian health team and was ready to move forward. The Peruvian Ministry of Commerce had already made significant advances in the negotiations and was prepared to move onto to more political negotiations. Coupled with Peruvian President Alejandro Toledo's desire to finalize the PTPA by the end of 2005, the Peruvian health team had no choice but to give up in their efforts and eventually resign from their duties.⁴⁷

This same course of events took place with the Colombian team during their negotiations. As a result, President Toledo was compelled to abandon the Andean agreement and seek a bilateral avenue exclusively with the U.S. By the 13th and 14th rounds of the negotiations, the Andean cooperation project was no more.

To strengthen ties between the Andean countries and the U.S, the USTR urged President George Bush to negotiate bilateral trade agreements separately with each country. In time, Ecuador would also pull out of the original agreement during the discussions due to political reasons. The U.S. would then open discussions with Colombia and Peru separately.

⁴⁷ Braun, Johanna von (2012), *The Domestic Politics of Negotiating International Trade: Intellectual Property Rights in US-Colombia and US-Peru Free Trade Agreements*, London: Routledge. 202p.

Negotiations with Peru and the U.S. were finished on December 7th, 2005. In the final round of negotiations, high ranking officials from the Ministries of Commerce, Economy, and Health were present. There was a consensus, more or less, established on matters concerning IPRs, though conflicts on patents, data exclusivity, and genetic resources were not completely resolved. Health Minister Mazzetti was also present and endorsed the agreement under the condition that health authorities be compensated for any price increases that resulted from the data protection.⁴⁸ Despite NGOs calling Mazzetti to withdraw her endorsement for the agreement, the negotiations were closed on December 7th, 2005 in Washington, DC.

2. Second Phase

With the agreement signed in Washington, DC, the PTPA was then sent to Peru in 2006 to initiate the principal ratification phase. Controversy erupted with the passage of the PTPA in the Peruvian Congress with only a few weeks left before the new Peruvian Congressmen came into office. Many Peruvian Congressmen raised complaints about the approval of the PTPA for the rapid manner in which it was passed and how there was very little debate before its passage. Some of the incoming Congressmen of the 2006 Peruvian elections even threatened to subject the PTPA's approval to a popular referendum. In response, the Peruvian Ministry of Commerce made a firm announcement that the PTPA would be approved or rejected by the current Congress, and not the

⁴⁸ Ibid.

incoming Congress that was not present in the negotiations and was not fully informed about the agreement's details and provisions.⁴⁹

Despite grievances from the opposition, the agreement was overwhelmingly approved on June 28th, 2006 by 79 to 14 votes in Peru's 120-member legislative chamber. It was of the utmost importance for Toledo's administration to ratify this agreement before the arrival of the incoming Congress. This new Congress had members who were adamantly opposed to the trade agreement and could have posed as a potential threat to the agreement's passage.

The USTR under the Bush Administration originally crafted the trade agreement, but when the Democrats gained control of Congress in 2006, the game completely changed. Many of these newly elected Democrats that came into office assumed new roles in the USTR and wanted to immediately leave a mark on certain trade policies. The Peru agreement represented an interesting opportunity for them to accomplish this.

As a part of the Democrat's *New Trade Policy for America*, the main focus in the modification of this agreement was centered on environmental and labor standards. Democrats also snuck in certain IPR related concerns to this new

⁴⁹ Ibid.

trade agenda.⁵⁰ Various Congressmen such as Ted Kennedy spearheaded efforts to include IPR reform in certain trade agreements in the past and now saw this new agreement with Peru as another opportunity to finally achieve their IPR reform goals.

Naturally, the Bush administration did not want to see many changes, if any, to the provisions included in the trade agreement. Given the scenario of a Democrat dominated Congress, the Bush administration was faced with the staunch reality of having to compromise with Democrats, especially on matters concerning free trade.

The Democrat newcomers made it clear that for the Peru agreement to pass, changes must be made to the finalized agreement with Peru. As a result, Democrats and Republicans came together to work in a bipartisan manner in crafting the “New Trade Agenda for America”. In this document, new norms were put in place in the IPR chapters.

These norms included the addition of the Doha Declaration to the actual text of the agreement, modifications in the terms of data exclusivity, and limits in patent term extensions. In effect, the U.S. acknowledged that the previous IPR

⁵⁰ Villarreal, M. Angeles. 2007. U.S.-Peru Economic Relations and the U.S.-Peru Trade Promotion Agreement. [online] CRS Report for Congress <<https://www.fas.org/sgp/crs/row/RL34108.pdf> > [Accessed June November 16th, 2015.]

template in the trade agreement with Peru could have had deleterious effects on access to public health if the agreement was passed in its original form.

Ultimately, the change in government that led Democrats to attain majorities in both chambers of Congress allowed for these modifications to come into play.

The New Trade Agenda was announced on May 10, 2007 and was well received by then Peruvian Minister of Commerce Mercedes Araoz. Araoz signaled that there would not be much debate needed for these new amendments to the treaty. U.S. Trade Representative Susan Schwab announced that, in tandem with Minister Araoz, the changes made in the New Trade Agenda were already translated and were added to the already ratified agreement.⁵¹ On June 24 and June 25, the U.S. and Peru would then sign a Protocol of Amendment, which contained certain modifications to the PTPA that were agreed upon during the formation of the May 10 Agreement. These amendments came before the Peruvian Congress on June 27, 2007 and were approved by a 70-38 majority.⁵²

This agreement would finally pass in the U.S. House of Representatives on November 8, 2007 by a vote of 285-132. It would be subsequently passed in

⁵¹ Ibid.

⁵² House of Representatives. House Report 110-42. U.S. Government Publishing Office. [online] <<https://www.gpo.gov/fdsys/pkg/CRPT-110hrpt421/html/CRPT-110hrpt421.htm>> [Accessed: June 20, 2015].

the Senate on December 4, 2007 by a vote of 77-18. To top it off, President Bush signed the Implementation Act for the trade agreement on December 14, 2007.

PTPA Timeline



Andean Trade Promotion and Drug Eradication Act (ATPDEA) enacted.

First Round of PTPA discussions begins in Cartagena, Colombia on May 18.

- PTPA signed in Washington DC on April 12th.
- Peruvian legislature approves PTPA on June 28th.

- New Trade Agenda announced on May 10 by Congressional Democrats.
- Peruvian Congress votes 70-38 in favor of the modifications to the PTPA on June 27.
- U.S. House of Representatives votes 285-132 in favor of PTPA on November 8.
- Senate votes 77-18 in favor of PTPA on December 4.
- President George W. Bush signs the Implementation Act for PTPA on December 14.

PTPA is implemented by the Bush Administration via proclamation on February 1, 2009.

Understanding the Changes Made to the PTPA

To understand why modifications were made to the PTPA, one must observe the political context that the U.S. was in. The Bush administration at the time was dedicated in its efforts to expand U.S. trade agreements with countries all over the globe. This also meant promoting trade agreements containing provisions that would expand the reach of the TRIPs-Plus framework.

The Bush Administration was starting to experience declines in popularity due to its aggressive foreign policy and the economic liberalization policies it pursued during its first term. Not long after Bush's reelection in 2004, did his unpopularity begin to rise.

The rising unpopularity of the Bush administration allowed for Democrats to attack Bush on different fronts. With Bush's economic policies coming into question, Democrats saw this as an opportunity to hack away at the the trade agreements crafted by the administration.

In this type of environment, Senator Ted Kennedy finally had the chance to see some progress in his efforts to promote IPR reform in trade agreements. Kennedy, alongside fellow Senator Diane Feinstein, would introduce an amendment in 2005 that sought to have the Doha Declaration enforced more

tightly in future trade agreements. Despite not being passed, Kennedy continued to be one of the key figures in pushing for the inclusion of the Doha Declaration in future agreements.

Once the Democrats assumed control of Congress in 2006, this was the opportune moment for Kennedy to push for this measure. Naturally, Democrats took control of the USTR Trade Board and put the Republicans in a position where they had no choice but to compromise and allow for provisions such as the one that Kennedy pushed for to be implemented.

In the same token, questions concerning patent term extensions and compulsory licensing were also brought up. For an issue that historically has been relatively on the margin of political discussion, patent term extensions have drawn broader attention from public health advocates and other mainstream sectors of public advocacy in recent times.

Using public health arguments, anti-IPR advocates finally saw some of their grievances resonate with Congressmen on Capitol Hill. This culminated in the following reforms:

Patent Extension Term Limits

The original trade agreement with Peru featured various provisions on patent term extensions. These provisions allowed for American

pharmaceutical companies to shield themselves from generic pharmaceutical competition, as these extensions would effectively delay the entry of cheaper generic drugs. This was a major concern during the ratification process in Peru, in which the Association of Pharmaceutical Industries of Peru (ADIFAN) and Foro de la Sociedad Civil en Salud (ForoSalud) feared that cheaper, generic medicines would not be readily accessible to the Peruvian populace due to the higher prices caused by patent term extensions.⁵³ ADIFAN and ForoSalud were both adamantly opposed to any trade mechanism that extended patent terms beyond 20 years and delayed the entry of generic drugs into the market.⁵⁴

To rectify these concerns, the modified agreement makes extension of patents due to delays in the patent or marketing approval process voluntary. On its end, Peru would process applications in a reasonable and timely manner, with the U.S.'s aid and oversight. In addition, patent extensions to compensate for delays in the patent-or marketing-approval process were no longer obligatory. This was traditionally an obligation since the NAFTA negotiations and its modification illustrated a significant shift towards IPR liberalization. In the

⁵³ Weissman, R. (2006), Public Health and TRIPs Plus Provisions in FTAs. [online] World Health Organization <<http://applications.emro.who.int/dsaf/dsa1081.pdf>> [Accessed November 10, 2015.]

⁵⁴ Garcia, Luis Alonso. 2008. Intellectual Property in the US-Peru Trade Promotion Agreement. Intellectual Property. [online] Bilateral Agreements and Sustainable Development Series: 3. <http://www.ciel.org/Publications/IP_USPeruFTA_Jun08.pdf> [Accessed: May 2, 2015.]

Peruvian context, domestic companies and the generic industry could now play on a more level playing field in the pharmaceutical market.

Limit Data Exclusivity Terms

Data exclusivity has been one of the more controversial points in the realm of IPRs in U.S. FTAs. The majority of countries have an independent national agency that regulates the use and sets standards for drugs that are to be sold in the market. Ultimately, these agencies are concerned about the safety of medicines and if they comply with certain regulatory standards before they enter the market. Most of these agencies tend to have different roles from national patent agencies.⁵⁵

In essence, data exclusivity is a practice in which a national drug agency prevents and blocks the registration files originating from a generic pharmaceutical company that intends to produce and release a generic version of the original medicine. The original producer is given a set period of time, after the marketing approval of the drug, where no other generic competitor can use the original manufacturer's data to get a marketing authorization for a certain product.⁵⁶ The generic producer of the medicine must first obtain consent from

⁵⁵ Weissman, R. (2006), Public Health and TRIPs Plus Provisions in FTAs. [online] World Health Organization <<http://applications.emro.who.int/dsaf/dsa1081.pdf>> [Accessed November 10, 2015.]

⁵⁶ Data Exclusivity: Encouraging Development of New Medicines. [online] International Federation of Pharmaceutical Manufacturers & Associations.

the patent holder of the original medicine. If consent is not obtained, the generic manufacturer must repeat the clinical trials.

Many proponents of IPR contend that data exclusivity is a completely different form of protection and is not patent related. The reasoning used to justify data exclusivity is that pharmaceutical companies need compensation for their costly efforts in compiling test data and the investments they undertake in running clinical and experimental trials.

On the other side of the aisle, opponents of data exclusivity argue that these type of data should be available in the public domain because in many cases the data may contain vital information that is not readily available elsewhere. Such protection may have negative effects on society through its restriction of information that could potentially be reanalyzed and used to combat side-effects and other illnesses.

In addition, data exclusivity can effectively serve as a barrier to entry for generic drugs due to the lengthy tests that generic companies must undertake. This arguably represents a waste of resources and effort for generic companies that could otherwise just prove the biopharmaceutical equivalence of their drugs without having to go through a costly testing process. For certain anti-IPR groups

<<http://www.ifpma.org/innovation/ip-rights/data-exclusivity.html>> [Accessed: November 17, 2015].

such as Oxfam International, data exclusivity is a part of the TRIPS-Plus package that extends monopoly privileges for pharmaceutical companies.⁵⁷ Oxfam contends that it acts separately from the patent system, but that it still restricts access to medical products just like patent extensions.

Similarly, ForoSalud believed that the protection and exclusivity of test data for a period of 5 years would essentially function as a “pseudo patent” for drugs.⁵⁸ According to ForoSalud, these types of delays would hinder the entrance of generic drugs into the Peruvian market and maintain multinational pharmaceutical companies’ monopoly hold in the market. As a result, patients with limited resources that suffered illnesses such as cancer, diabetes, and HIV would be negatively affected due to the high monopoly prices of these drugs.

The original agreement stipulated that the data exclusivity period of 5 years would begin when the pharmaceutical product entered the market, with a potential grace period of 5 years. The new arrangement changed the language of “at least 5 years” to just 5 years. If said product was approved within 6 months of an application for marketing approval, the 5-year period begins at the time that

⁵⁷ Oxfam International. 2007. All costs, no benefits: How TRIPS-plus intellectual property rules in the US-Jordan FTA affect access to medicines. [online] Oxfam Briefing Paper.

<<https://www.oxfam.org/sites/www.oxfam.org/files/all%20costs,%20no%20benefits.pdf>> [Accessed November 28, 2015.]

⁵⁸ Garcia, Luis Alonso. 2008. Intellectual Property in the US-Peru Trade Promotion Agreement. Intellectual Property. [online] Bilateral Agreements and Sustainable Development Series: 3. <http://www.ciel.org/Publications/IP_USPeruFTA_Jun08.pdf> [Accessed: May 2, 2015.]

the product was approved in the U.S. This represented a notable shift from the traditional data exclusivity framework that favored established pharmaceutical corporations.

Inclusion of the Doha Declaration in FTA Text

The Doha Declaration on the TRIPS Agreement and Public Health made in 2001 at the WTO Ministerial Conference was a promising event for advocates of IPR reform in trade agreements. It acknowledged that TRIPS member states, especially those in developing regions, have the right to circumvent certain patent rights in order for these countries to have better access to medicines and promote public health.⁵⁹

Oxfam International was one organization that publicly criticized developed countries for pursuing trade agreements that violated the spirit of the Doha Declaration. Oxfam contended that 5 years since the passage of Doha Declaration countries like the U.S. have willingly ignored their commitment to the declaration and have imposed even more stringent IPR norms on developing countries.⁶⁰ This concern was raised during the negotiation phase of the PTPA,

⁵⁹ Abbott, Frederick M. 2004. The Doha Declaration on the TRIPS Agreement and Public Health and the Contradictory Trend in Bilateral and Regional Free Trade Agreements. [online] Quaker United Nations Office. <<http://www.geneva.quno.info/pdf/OP14Abbottfinal.pdf>> [Accessed November 22, 2015.]

⁶⁰ Oxfam International. 2006. Patents vs Patients: 5 years after the Doha Declaration. [online] Oxfam Briefing Paper.

where Oxfam noticed the U.S. embarking on a trend of pushing for TRIPS-Plus provisions in trade agreements with countries all over the world, not just Latin American ones.

The most energetic efforts and statements in favor of including the Doha Declaration in the PTPA came from U.S. Senator Ted Kennedy. In 2005, right when the Peruvian negotiations were underway, Senator Ted Kennedy made a statement in the U.S. Senate criticizing the Bush administration and the Trade Promotion Act of 2002 for violating the spirit of the Doha Declaration. Kennedy accused the Bush administration of using trade agreements to “promote the interests of the pharmaceutical industry”, while curtailing access to drugs in developing countries.⁶¹ Kennedy, alongside Senator Diane Feinstein, proposed an amendment that reinforces the Doha Declaration and puts the records of any violations of the Doha Declaration in print for future trade agreements, including the PTPA.

In the original trade agreement, the Doha Declaration was not included in the text. Under the modified agreement, the Doha Declaration was included so as to serve as a reference for resolving conflicts that could potentially compromise public health standards. It requires that both parties commit to the

<<https://www.oxfam.org/sites/www.oxfam.org/files/Patents%20vs.%20Patients.pdf> >
[Accessed December 7, 2015.]

⁶¹ Congressional Record Online. 2005. The Doha Declaration and the Trade Promotion Authority Act. [online] Government Publishing Office.
<<https://www.gpo.gov/fdsys/pkg/CREC-2005-02-16/html/CREC-2005-02-16-pt1-PgS1498-2.htm>>[Accessed December 9, 2015.]

principles laid out by the Doha Declaration and allow Peru to take necessary measures to protect public health.

All in all, these modifications marked a loosening of the enforcement of the IPR provisions in the PTPA. What was traditionally an obligation to comply with in the past, patent term extensions and similar measures became slightly more voluntary and flexible.

Interest groups voiced opinions on certain reforms for the PTPA, but their lobbying impact in general was not very noticeable in the creation of these reforms. With the exception of OxFam, groups like ADIFAN and Forosalud merely voiced opinions and issued statements on the issues concerning medical access. It should be noted that these two groups were not involved in heavy lobbying and intimate aspects of the negotiation process. There was a general perception that these two actors had political agendas and interests, thus they were generally shut out of the negotiations and had very little impact on making policy changes.⁶² Senator Ted Kennedy's efforts were the most energetic and would yield noticeable results once Democrats won a majority in the U.S. Congress.

⁶² Garcia, Luis Alonso. 2008. Intellectual Property in the US-Peru Trade Promotion Agreement. Intellectual Property. [online] Bilateral Agreements and Sustainable Development Series: 3. <http://www.ciel.org/Publications/IP_USPeruFTA_Jun08.pdf> [Accessed: May 2, 2015.]

Interest Groups Involved

1. Anti-IPR Groups

Various interest groups on both sides of the aisle were involved in the negotiation process. As mentioned before, the public generally accepted the PTPA, but there were some provisions with regards to IPRs that raised some doubts from various civil society organizations and generic industry interests based in Peru. Most of these groups positioned themselves during the 1st phase of negotiations from 2004 to 2006. This section will serve as a brief summary of the various interest groups involved.

The Association of Pharmaceutical Industries of Peru (ADIFAN), in principle, was not against the PTPA. In many respects, ADIFAN largely benefited from the increased market access that this agreement would bring about. Nevertheless, ADIFAN believed that the IPR provisions in the PTPA should have no link to trade; therefore they must be removed from the agreement.⁶³ In many ways these IPR provisions would hurt them against American competition and affect their overall market share. Despite using mostly market-based arguments, ADIFAN also adopted public health arguments when it went up against patent

⁶³ Garcia, Luis Alonso. 2008. Intellectual Property in the US-Peru Trade Promotion Agreement. Intellectual Property. [online] Bilateral Agreements and Sustainable Development Series: 3. <http://www.ciel.org/Publications/IP_USPeruFTA_Jun08.pdf> [Accessed: May 2, 2015.]

term extensions and the granting of patents for sensitive surgical procedures. However, these arguments were mostly used to generate good public relations and hid an otherwise strong profit motive for ADIFAN's opposition to the IPR provisions.

Foro de la Sociedad Civil en Salud (ForoSalud) was arguably the most active anti-IPR interest group involved in the first phase of the negotiations. ForoSalud is a Peruvian NGO that handles matters concerning public health. They were one of the most active civil society groups in Peru that rallied against IPR provisions. Unlike ADIFAN, there was no profit motive behind their arguments against the provisions. ForoSalud was adamantly opposed to any trade mechanism that extended patent terms beyond 20 years and delayed the entry of generic drugs into the market. Above all, they called for the respect of Peru's national sovereignty and public health policies.⁶⁴ This group frequently pressured Peruvian Health Minister Mazzetti to not endorse the PTPA in its current form in late 2005, but their pressure ultimately had no effect on the PTPA's original passage.

Acción Internacional para la Salud (AIS) is a Latin American branch, based in Peru, of the international NGO Health Action International. Similar to ForoSalud, AIS based its arguments against the PTPA using public health concerns. Its director at the time, Roberto Sanchez, argued that the IPR

⁶⁴ Ibid

provisions would make medicine prices *increase dramatically* and keep about 700,000 Peruvians from gaining access to vital medicines.⁶⁵

Oxfam was another group that played a role during the negotiation process, especially in the second phase of the negotiations whenever the Democrat Party took control of the U.S. Congress in 2006. Unlike other anti-IPR groups during the process, they had some degree of lobbying power and ability to organize in the political arena. Oxfam is also a non-Peruvian interest group.

OxFam is a confederation of organizations with operations in 94 countries that seeks to fight poverty and injustice across the globe. In recent times they broadened the scope of their activism by tackling issues concerning fair trade and access to medicines for people living in developing countries. The PTPA's original form was worrisome for Oxfam due to its IPR provisions that tended to favor pharmaceutical interests.

In a letter to members of the U.S. Congress, OxFam president Raymond C. Offenheiser claimed that the IPR provisions in the PTPA would greatly limit competition from generic manufacturers and lead to higher prices for newly

⁶⁵ Oxfam. 2006. The US-Peru Trade Deal a Step Back for Development. [online] Oxfam America. <<http://www.oxfamamerica.org/press/us-peru-trade-deal-a-step-back-for-development/>>[Accessed May 2, 2015.]

arriving medicines in the Peruvian market.⁶⁶ Offenheiser added that these IPR provisions effectively went beyond standards that were highlighted by the WTO, which stressed that public health has primacy over private patents and other measures that limit access to medicines.

Ultimately, the Peruvian interest groups had no real impact in the first phase of the negotiation process, as the PTPA was signed into Agreement in the U.S in 2005 and ratified by the Peruvian in Congress in 2006 without any changes made to the IPR provisions. It would take other factors, as will be discussed later, to ultimately bring about modifications to the PTPA's IPR provisions.

Arguments Against IPR Measures

Anti-IPR movements have been characterized by a diverse set of views on their justifications against IPR measures in trade agreements and in other areas of public policy. Some of the more radical sects of the anti-IPR movement question the legitimacy of intellectual property itself. On the other hand, the more mainstream anti-IPR movements see the legitimacy of intellectual property but believe there are certain lines that must be drawn in order to prevent abuse and

⁶⁶ Offenheiser, Raymond C. 2006. Oxfam America president to Congress: Vote 'No' on US-Peru FTA. [online]<<http://www.oxfamamerica.org/explore/stories/oxfam-america-president-to-congress-vote-no-on-us-peru-fta/>>[Accessed May 4, 2015.]

other unintended consequences. For the purposes of this study, the arguments analyzed are two-fold:

1. IPR provisions have no place in FTAs, thus must be completely separated from each other.
2. TRIPS-Plus goes too far and could potentially be costly for developing nations in terms of the access of medicines and the rising costs of trademarked items such as pharmaceuticals for consumers.⁶⁷ In effect, the original TRIPs framework needs no further expansion.

The Peruvian Ministry of Health was not completely against the PTPA, but it did voice various concerns of the IPR provisions in the agreement. In particular, they believed that these types of measures could raise the price of medicine by about 5% and could reduce access to certain medicines by about 10%.⁶⁸ In the same vein, various government officials conceded that IPRs were viewed as “important, but not essential” for attracting investment and encouraging economic

⁶⁷ Valle, Alvaro, 2015. Free Trade: Not Everyone Wins. [online] Harvard Political Review: The Americas <<http://harvardpolitics.com/world/free-trade-everyone-wins/>> Accessed September 16, 2015.]

⁶⁸ Valladares Alcalde, Gerardo, Cruzado Ubillús, Raul, Seclén Palacin, and Pichihua Serna, Zósimo Juan. 2005. Evaluación de los potenciales efectos sobre acceso a medicamentos del tratado de libre comercio que se negocia con los Estados Unidos de América. [online] Ministerio de Salud del Peru <http://www.minsa.gob.pe/portada/Especiales/TLC-MINSA/EstudioTLCSalud_ResumenEjecutivo.pdf> [Accessed September 16, 2015.]

development.⁶⁹ Javier Llamaza of Health Action International Latin America (AISLAC), also argued that “protecting test data on medications is a way of creating a monopoly, which violates people's basic right to health.”⁷⁰ It was very clear that arguments based on costs and access were the main issues that concerned Peruvian officials and civil society members during the negotiation process.

Though not as important, but still noteworthy, institutional arguments were also used against the PTPA and its provisions. Despite the modifications, numerous Peruvian Congressmen and figures from Peruvian civil society voiced concerns about how certain modifications in the agreement were carried out and implemented. Numerous individuals sustained that the Peruvian executive branch had exceeded the powers granted to it during the modification process of the agreement. In turn, they believed that this would set a bad precedent for increases in the executive power and the ability for future presidents to rapidly pass controversial foreign agreements without much debate or input from the opposition.

⁶⁹ Palmedo, Mike. 2012. The Economic Effect of the Intellectual Property Obligations in Free Trade Agreements [online] <<http://infojustice.org/wp-content/uploads/2012/05/Palmedo-Working-Paper-May-2012.pdf>> [Accessed September 22, 2015.]

⁷⁰ Salazar, Milagros. 2010. Free Trade Undermining Rights in Peru. [online] <<http://upsidedownworld.org/main/peru-archives-76/2418-free-trade-undermining-rights-in-per>> [Accessed September 25, 2015.]

2. The Pro-Pharmaceutical Side of the Aisle

The Pharmaceutical Research and Manufacturers of America (PhRMA) has been at the forefront of representing the interests of the pharmaceutical industry in the U.S. since its founding in 1958.⁷¹ PhRMA's mission and outreach scope has evolved throughout the years. With the emergence of free trade agreements with countries of all levels of economic development, PhRMA has made sure to have its interests served in matters concerning the protection of IPRs.

With the enshrinement of TRIPS as a standard for protecting IPRs on an international scale, it seemed that the American pharmaceutical industry would not have to worry about focusing more resources on the protection of IPRs internationally speaking. Despite the advances made on standardizing IPR norms internationally, interest groups like PhRMA still identify countries that do not fully comply with these norms.

These malfeasances in the protection of IPRs in select countries have propelled PhRMA to turn to Special 301 Report to voice complaints about the protection of the aforementioned rights. The Special 301 Report is annually prepared by the Office of the United States Trade Representative (USTR) which identifies trade barriers that U.S. companies and products face in the form of

⁷¹ Pharmaceutical Research and Manufacturers of America (PhRMA). About PhRMA [online] <<http://www.phrma.org/about>> [Accessed August 15, 2015.]

intellectual property laws present in other countries.⁷² PhRMA has voiced its concerns through annual submissions to this report. As a result of these submissions, Peru has remained on this watch list to this day.⁷³

PhRMA has voiced concerns about Peru's lax enforcement of intellectual property rights over the years, especially in matters concerning pharmaceutical products. According to PhRMA, Peru has implemented various regulatory requirements "that favor local producers" and leave the the protection of intellectual property rights in a state of uncertainty in Peru.⁷⁴ PhRMA saw the PTPA as the perfect opportunity to make an example out of Peru and initiate a trend in which FTAs would be used as vehicles to promote the strengthening of IPRs.

Even though the original Peru FTA maintained many of PhRMA's policies intact, the final edition, which was heavily shaped by Democratic politicians in the U.S., effectively hacked away at some of their desired standards. As a result, PhRMA released a statement voicing their displeasure with several of the

⁷² Biadgleng, Ermias Tekeste and Maur, Jean-Christophe. 2011. The Influence of Preferential Trade Agreements on the Implementation of Intellectual Property Rights in Developing Countries. [online] UNCTAD-ICTSD Project on IPRs and Sustainable Development < http://unctad.org/en/Docs/iteipc2011d01_en.pdf> [Accessed May 12, 2015.]

⁷³ Froman, Michael B.G. 2015. 2015 Special 301 Report. [online]< <https://ustr.gov/sites/default/files/2015-Special-301-Report-FINAL.pdf> > [Accessed August 12, 2015.]

⁷⁴ Pharmaceutical Research and Manufacturers of America (PhRMA). 2014. Special 301 Submission 2014 [online] <<http://www.phrma.org/sites/default/files/pdf/2014-special-301-submission.pdf>> [Accessed August 14, 2015.]

omissions enacted in the agreement. They claimed that the agreement seems to lay the groundwork for countries to “undermine U.S IP protections in the pharmaceutical sector”, thus limiting the funding for vital research and development projects.⁷⁵

Interestingly, PhRMA took a neutral stance towards the PTPA and just confined their criticism to the modifications made by the Democratic Congressmen. PhRMA knew that they lost a battle, but they had confidence in the long-term war ahead. It made sense to cut their losses and reassess their strategy in their long-term crusade to expand IPRs.

⁷⁵Ibid.

Effectiveness of Lobby

Were the reforms the product of effective lobbying by public health and other anti-IPR interest groups? The reality is that even with the arrival of the Democrats in Congress, IPR issues were still relatively fringe. In fact, most of the focus was placed on environmental and labor standards. IPR related concerns coincided with this reformist environment, but they were items at the bottom of the reformist agenda.

Anti-IPR extension lobbies and interest groups made some noise and generated attention, but it was mostly politicians like Ted Kennedy that did most of the leg work. Even then, only three points of reform were implemented. This was by no means a radical restructuring of the IPR provisions, nor did it represent a radical shift in the perception of IPR provisions that are included in trade agreements.

In fact, the anti-IPR lobby is relatively weak when compared to the pro-IPR lobby. Groups such as Coalition for Patent Fairness, Electronic Frontier Foundation (EFF), the Internet Association, and OxFam America are known to push for patent reforms and looser standards of IPR protections. Despite their common goals, they focus on IPR reform in different areas.

In the case of EFF and the Internet Association, these organizations are mostly concerned with IPR encroachments in Internet matters. Their main purpose is to promote the maintenance of a free internet and digital rights. At times these groups will stand against IPR measures that they perceive as threats to Internet freedom. There is not much evidence to show that they have led strong efforts against measures that aim to expand the protection of pharmaceutical patents.

Oxfam was clearly the strongest force against the expansion of IPRs in this time frame. Its presence was felt from 2006 to 2008 where it averaged roughly \$573,000 in lobbying spending per year.⁷⁶ Of the organizations observed, it was clearly the most organized and established of the anti-IPR provisions movement. According to its website, Oxfam relies on donations from members to finance its projects.⁷⁷ In return, Oxfam provides donors with the ability to have tax exemptions on these very donations. Many successful civil action organizations have this feature and it is generally one of the strongest incentives to motivate potential members to donate. Despite this type of presence, Oxfam is not an interest group that is solely dedicated to combatting IPR extensions. In fact, its

⁷⁶ OpenSecrets.org. 2008. Center for Responsive Politics. [online]<<http://www.opensecrets.org/lobby/firmsum.php?id=D000055126&year=2008>> [Accessed November 28, 2015.]

⁷⁷ Make a Grant to Oxfam America. [online]<<http://www.oxfamamerica.org/donate/make-grant/>>[Accessed December 7, 2015.]

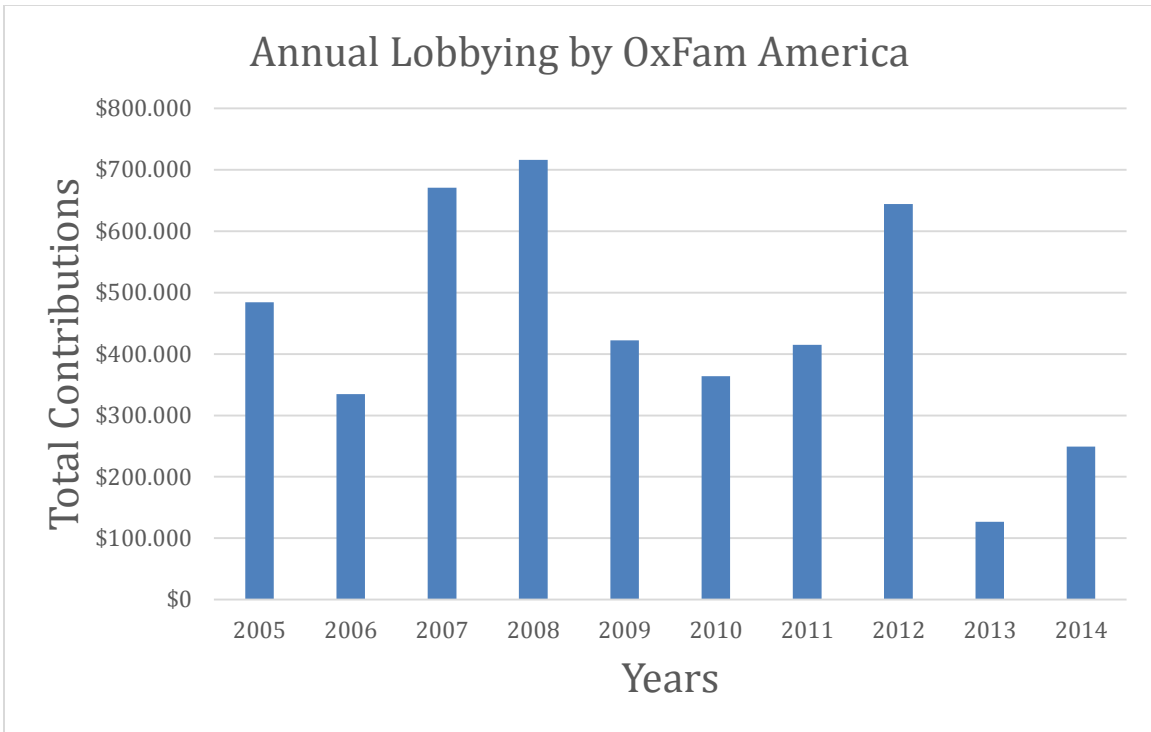
mission is rather diverse, thus making it have to prioritize certain political battles and issues at the expense of others.

When looking at the Peruvian interest groups in action, similar dynamics were also in play. ADIFAN and ForoSalud were organizations that arguably represented a broad array interests and quite possibly represented the interests of the majority of Peruvians. In spite of this, mobilizing these people would be much more difficult due to the diverse nature of the audience. When conflicting interests arise, it becomes nearly impossible to organize a cohesive lobbying operation. These weaknesses also prevented ADIFAN from having much of a presence internationally, especially in the halls of Washington, DC. There was no documented evidence that pointed to them having much of a presence in trying to lobby U.S. Congressmen. This was also the case with ForoSalud. Unsurprisingly, despite their warnings and pressure on the Peruvian government in the preliminary stages of the PTPA negotiations, these Peruvian groups could not make any changes to the original version of the PTPA.

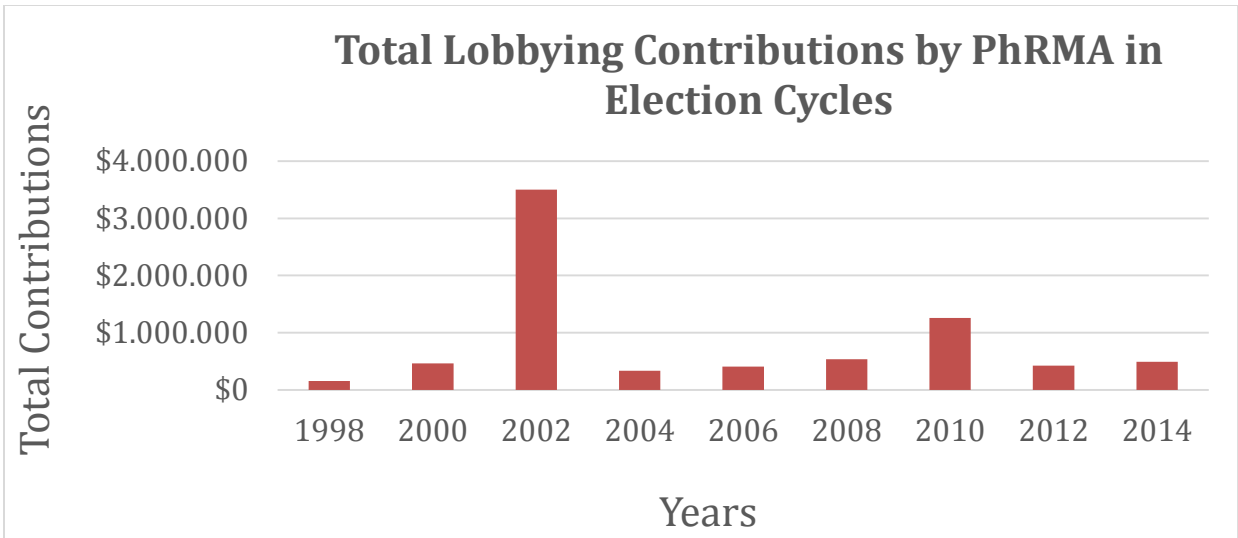
With groups such as PhRMA and the Intellectual Property Organization (IPO), the pro-IPR side has interest groups that despite their small size, wield a disproportionate amount of of power. This is due to the pharmaceutical industry's low costs in organizing which incentivizes it to continuously pursue concentrated benefits. The costs of organizing lobbying campaigns for these groups is very

low, and their opponents generally have low incentives to organize efforts against them.

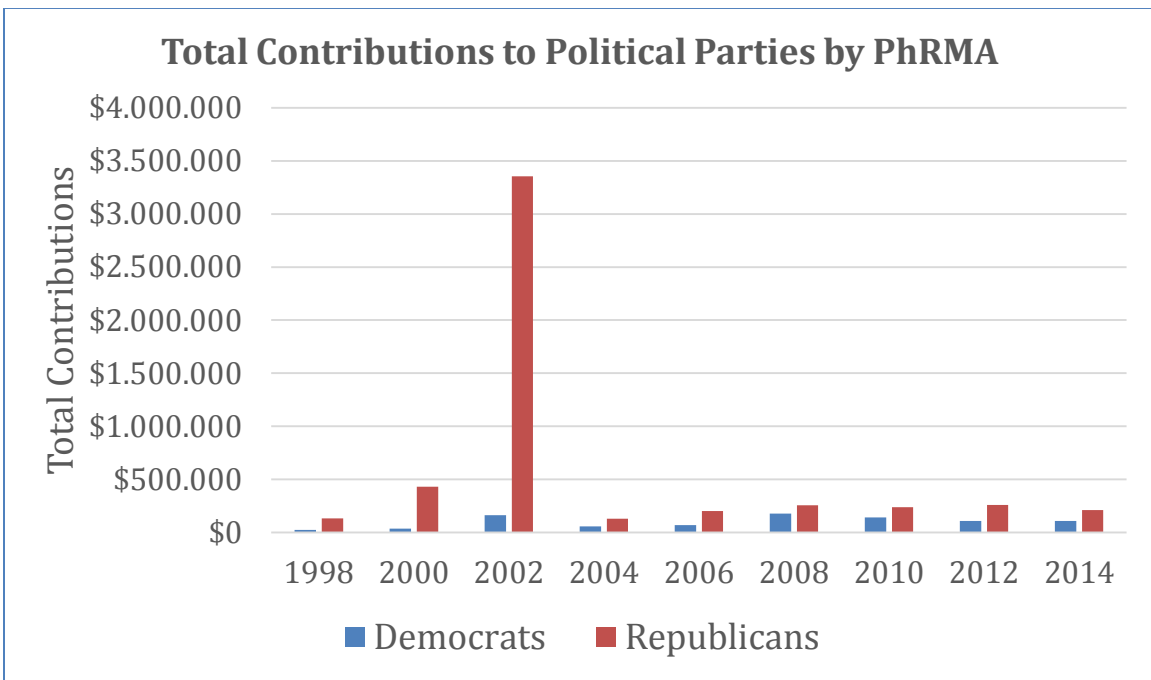
PhRMA has been one of the most influential players in the field of lobbying. Historically speaking, PhRMA has contributed more to Republicans in Congress. In the year of 2002, they dedicated 95% of their \$3.5 million total political contributions to the Republican Party alone. When the Democrats came to office in 2006, PhRMA started focusing its efforts on Democrat Congressmen. Consequently, their contributions to both parties became more equally distributed. PhRMA was confronted with a Democrat party that has traditionally been opposed to policies that favored the pharmaceutical industry, so they were compelled to interact and align themselves with Democrats in order to have a broader reach in Congress.



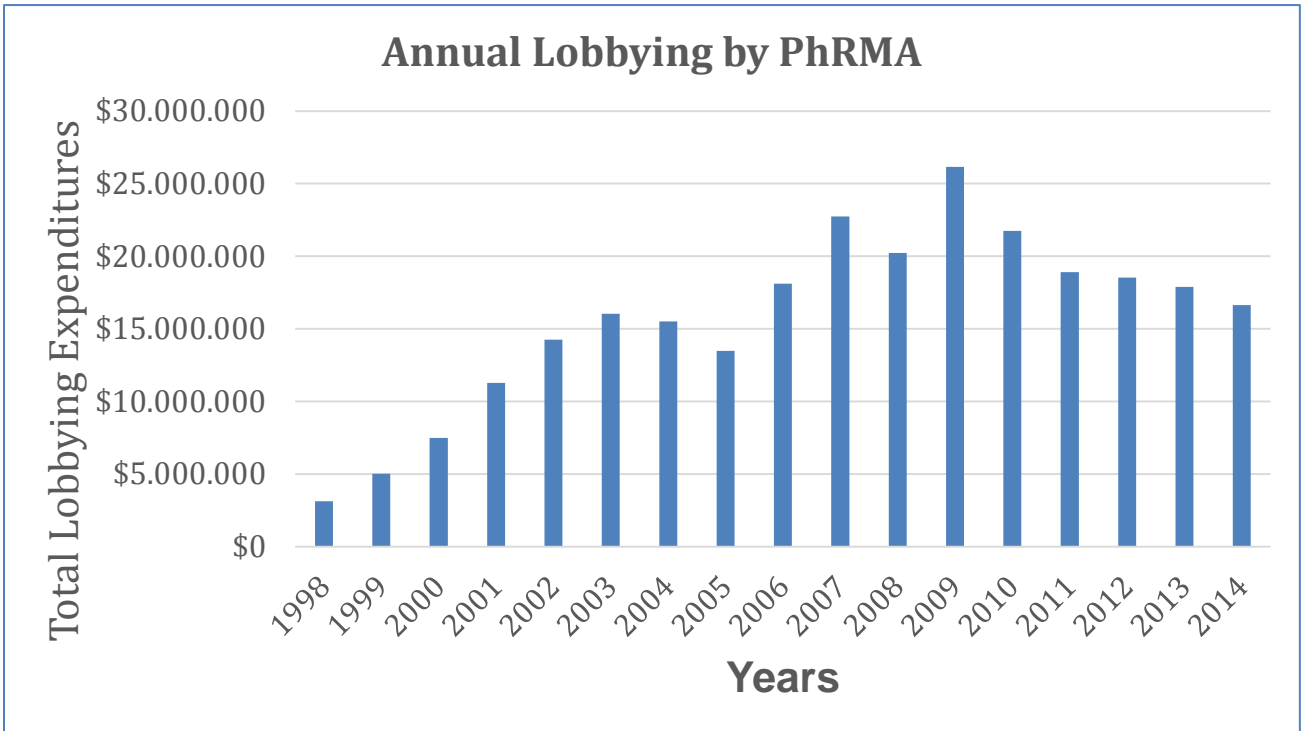
Source: Open Secrets. Annual Lobbying by OxFam America. 2005-2014.



Source: Open Secrets. 2012. Total Lobbying Contributions by PhRMA in Election Cycles



Source: Open Secrets. Total Contributions by Party Recipients 1998-2014.



Source: Open Secrets. Lobbying Totals, 1998-2014

2. Rethinking the Impact of Pluralism

Introduction

The PTPA case study sheds light on how interest groups operated during the ratification process. After careful research and analysis of the actions of interest groups during the negotiations, it has become clear that interest group pressure was not a direct factor in propelling changes to the IPR provisions in the PTPA. What really was at play was a change in governance (the arrival of the Democrat party as a majority in Congress in 2006) that ultimately determined this policy change.

Analyzing the Impact and Power of Interest Groups Involved

For the purposes of this study, understanding the lobbying power and goals for the opposing sides of the PTPA is crucial to understanding how these groups acted and what impact, if any, they had on shaping the final outcome of the agreement. The goals and benefits that these groups were seeking are especially important, since these generally determine what incentives exist for interest groups to form and organize around a certain cause.

In the context of the PTPA, Peruvian consumers see lower pharmaceutical prices and access to medicines as their collective benefit. Under the optimistic theory of group pluralism, this conflict between the civil society organizations that represent them and pro-IP forces in the U.S. and Peru would ultimately lead to a positive result in the long-term. There is only one problem: Consumer groups have very diverse interests that at times clash with one another, therefore creating barriers to effective organization and group formation.

In the Peruvian case, the generic pharmaceutical industry was not only small, but it also largely benefited from other provisions of the PTPA. There would come a certain point that continuing to go up against the PTPA would be too costly, when considering that other non-IP related benefits of the agreement clearly outweighed the costs of the IP provisions.

In the same vein, consumers may stand to benefit from large aspects of the PTPA, despite some of the negative provisions of the IPR template in the agreement. Additionally, these public health civil society groups represent dispersed groups of consumers that are much harder to organize. Given Peru's economic development, it would be much harder for large numbers of group members to receive substantial benefits and also finance this type of lobby.

When observing the political clout of organizations such as Health Action International, ADIFAN, or Oxfam, the difference between them and PhRMA is

very noticeable. In 2006, PhRMA was reported to have 30 lobbyists at its disposal in Washington D.C, and in that same year it spent \$18 million in lobbying.

OxFam International and its subsidiary OxFam America were exceptions in the anti-IPR aisle due to them being present in the lobbying arena. Even then, the numbers indicate that their lobbying clout is not on the same level as PhRMA's during the same time frame. PhRMA nearly dedicated 60 times more money in lobbying expenses in 2006. Oxfam did ramp up its spending in the following two years, but PhRMA's spending figures still dwarfed Oxfam's.

These disparities in spending and lobbying presence are by no means mere coincidences. They are the maximum expression of the collective action problem and neopluralism. The tug-of-war between competing interest groups was on full display during the ratification process. Despite this "tug-of-war" present during the ratification process, there was not much evidence that Oxfam's lobbying played a pivotal role in modifying the IPR provisions in this agreement.

In sum, this environment leads to a situation where the costs of the IPR template for the consumer in terms of higher prices will be spread out amongst a large array of consumers, whereas the US pharmaceutical industry would enjoy significant concentrated benefits. These concentrated benefits amongst a small coalition of large pharmaceutical companies provide the adequate conditions for

effective group mobilization and a strong lobby for IPR provisions in the PTPA. Ultimately, these factors contributed greatly to the original ratification of the PTPA by the Peruvian Congress in 2006, which contained all of the TRIPS-Plus provisions.

Interest groups can only have so much of an impact on the policymaking process. In times of major political shifts, especially in the case of the 2006 U.S. Congressional elections, these types of changes can override and constrain any type of interest group pressure. Even the strongest and most influential of interest groups, is no match for a drastic political change. The ascendance of the Democrat Party in the U.S. Congress was the most decisive factor in contributing to the modifications in the IPR provisions in the PTPA. The Democrat's trade reform agenda would have no problem being implemented given its newly acquired power in Congress. No type of rival interest group could override this dynamic at that point in time, as PhRMA would learn when they saw their pet provisions get modified in ways that benefited their rivals.

To ultimately address the IPR expansion problem, political pressure from above would be used to rein in powerful interest groups such as PhRMA.

Why Did These Changes Occur?

The changes made in this treaty reflected more of an agenda on the part of the Democrats to chip away at certain political projects pushed by George W.

Bush during his presidency. These changes did not necessarily represent a genuine change in their ideas towards the inclusion of IPRs in trade agreements. This was part of a larger agenda where the Democrat Party wanted to leave its mark in certain pieces of legislation.

The Democratic party also had to prove its ability to govern on a bipartisan basis. Completely overturning a political project that was deemed as an essential part of the post-9/11 national security agenda was completely out of the question. Free trade was a popular aspect of this agenda, and completely overturning this agreement would put the Democrats on a bad start. As then Democratic Senate Majority Leader Harry declared, the “days of the do-nothing Congress are over” and it was time that the Democrat Party prove its competence in governance to the American people.⁷⁸

Going too strong on fringe issues such as IPRs carried the risk of stalling the approval of this agreement. Modifications could be made here and there, but a complete dismantling of an otherwise popularly accepted free trade agreement was out of the question. At this juncture, proving the ability to govern in a bipartisan fashion was the most important task for the Democrats in their quest to establish credibility with American voters.

⁷⁸NBC News. 2006. Democrats win control of Senate. [online] <<http://www.nbcnews.com/id/15620405/ns/politics/t/democrats-win-control-senate/#.Ve-8951Vikp>> [Accessed: September 8, 2015.]

Ultimately, anti-IPR positions have never been a mainstream issue of great discussion in American politics. With the pharmaceutical industry's organizing power, they should have no problem in convincing Democrat politicians in the near future despite some of the losses they incurred in the ratification of this FTA.

This case study demonstrates that governments at times must make decisions from above in order to keep powerful interest groups from accumulating even more power. However, these governments can't fully contain certain types of interest groups given the nature of these powerful groups' organizing efficiency and power.

The neopluralist school offers a more realistic perspective of how public policy is generated not just by interest group activity or pressure. The power of the neopluralistic framework lies not only in its acknowledgment of the inherent interest group struggle that is present in policymaking, but also its recognition that political ideologies, political parties, and elections are often "more important than organized interests in determining policy".⁷⁹ Interest groups played a role in

⁷⁹ Godwin, R. Kenneth, Ainsworth, Scott, Godwin, Erik (2012), *Lobbying and Policymaking: The Public Pursuit of Private Interests*, Washington, DC: CQ Press. p. 67

the PTPA process, but it was ultimately Democrat political actors in the U.S. that helped usher in these modifications.

3. Long-Term Perspective

Peruvian interest groups—ForoSalud, ADIFAN based in Peru—came out victorious largely due to the help of Democrat Congressmen in the U.S. The 2006 elections marked a significant political shift in the U.S. where more center-left forces took control of Congress. In turn, they shaped new policies like the Peruvian trade agreement in ways that nominally reflected their viewpoints—emphasizing environmental protection, labor rights, and intellectual property.

These changes were brought about through political actors that were willing to leave behind their political mark on certain policies. This did not necessarily represent a major philosophical shift in the ideas towards IPRs on the part of the U.S. Democratic Party. Political pragmatism was involved in this process, as the Democrats had to reach out to certain public health interest groups by giving them attractive concessions on certain policy projects. Groups such as these are a natural part of the Democrat's support base. Logically, Democrats would like to assuage their concerns from the start. That being said, this by no means guarantees that Democrats will readily represent their interests consistently in the near future.

On other hand, PhRMA lost to a large extent. Although most of the TRIPS framework stayed in place, the TRIPS-Plus standards that it pushed for—Data exclusivity and patent term extensions —were excluded in the final version of the agreement.

Despite the loss, PhRMA did not necessarily come out against the modified FTA. It expressed disappointment, but its neutrality was rather telling. This neutrality indicates that their loss in these negotiations was not as great as it originally appeared. PhRMA continues to push for TRIPS-Plus standards in other trade agreements despite the roadblocks it faced in Peru. Their organizing power is not to be questioned and most industry lobbies generally can organize more efficiently than their consumer group counterparts. When there are concentrated benefits and diffused costs, narrow economic interest groups such as the pharmaceutical industry have natural advantages in the realm of lobbying.

Despite these natural advantages, the pharmaceutical industry will now face much more opposition considering various factors:

- **The Climate of Ideas**: Despite being more of a political maneuver to undermine then President George Bush's agenda, the Democrat's willingness to tackle issues of IPRs in matters of public health has brought more public attention to this issue. Unintentionally, the Democrats have given grassroots organizations and other groups skeptical of IPRs a platform to attack these controversial

measures. Now that the ideas of the anti-IPR expansion movements are becoming more mainstream, a paradigm shift in the way that people view IPRs may be brewing. The power of ideas should never be underestimated, even when dealing with small or large victories against conventional public policies that have been in existence for extended periods of time. These changes in ideas will propel more civil society groups to join in the battle against IPR expansions.

- **Cooperation Between International Civil Society Groups:** Even though it did not have much impact in the short term, domestic group efforts in Peru have opened up collaboration efforts between civil society groups and political entities in both developing and developed countries to combat these measures. These developing nation groups effectively provide the data of why TRIPS-Plus provisions are dangerous to them, while developed nations have groups with more money and political clout to ensure that these trade agreements protect the developing nations' interests. Both the developed and developing nations need each other's support in these cases.

The arguments used against the IPR provisions were generally focused on cost-benefits analyses that demonstrated that these provisions would be deleterious to the public health of hundreds of thousands of Peruvians. This type of reasoning proved to be more powerful than the more economic, profit-driven arguments put forward by the Peruvian generic industry against the IPR provisions. When this matter was placed alongside human rights concerns in the

U.S, it became much easier for anti-IPR expansion advocates to gain support for reforms. This, along with a Democratic majority that controlled both branches of Congress, proved to be a potent combination in bringing about this unexpected change.

The modifications in the PTPA may have not fully overturned TRIPS policy, but they have given anti-IPR expansion groups the confidence and ammunition to go up against future trade agreements, like ACTA and the TPP. Lobbies such as PhRMA are very powerful and will not be easy to defeat in one blow. However, from the PTPA and going forward, they will face unprecedented amounts of resistance from the aforementioned groups. This is not just confined to the precedent set by the modifications in the PTPA, but a larger change in the overall views that citizens, policymakers, politicians, and civil society leaders hold towards IPRs. Even in recent times, Peruvian legislators have asked for greater transparency, and a “public, political, and technical debate on the proposals” with regards to the TPP.⁸⁰

What can be gleaned from this case study is that neopluralist interest group theory was very present throughout the PTPA negotiation process. In fact, the anti-IPR groups’ moderate success during this process demonstrates some of

⁸⁰ Kaminski, Margot E. 2014. The Capture of International Intellectual Property Law Through the U.S. Trade Regime. [online] Southern California Law Review <<http://lawreview.usc.edu/wp-content/uploads/Kaminski-Final-PDF.pdf>>[Accessed October q, 2015.]

the major roadblocks they will face in their quest to reform IPR provisions. The reality is that anti-IPR groups represent a very broad public that does not have much of a strong incentive to organize. In addition, this consumer public faced dispersed costs that were not very visible from the start.

In such cases, a third-party such as a government is needed to intervene in order to prevent powerful interest groups like the pharmaceutical industry from accumulating too much power.

Time will tell if the pharmaceutical industry's natural organizing advantages will prevail, or if the anti-IPR expansions movement will ultimately come out ahead. The current Trans-Pacific Partnership (TPP) agreement may shed light on the next stage of IPR trends in the 21st century. It could be that once again a government or a group of governments that purportedly holds the common interest must step in to contain powerful IPR lobbies.

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