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INSTITUTO DE RELAÇÕES INTERNACIONAIS

JOÃO PAULO HERNANDES TEODORO

The negotiation and implementation of intellectual property rights in preferential trade agreements: an analysis of the roles of the U.S. Congress and interest groups (1995 – 2012)

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The negotiation and implementation of intellectual property rights in preferential trade agreements: an analysis of the roles of the U.S. Congress and interest groups (1995 – 2012)

Tese apresentada ao Programa de Pós-Graduação em Relações Internacionais do Instituto de Relações Internacionais da Universidade de São Paulo para a obtenção do título de Doutor em Ciências.

Orientador: Prof. Dr. Yi Shin Tang

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ATA DE DEFESA

Ata de defesa de Tese do(a) Senhor(a) João Paulo Hernandes Teodoro no Programa: Relações Internacionais, do(a) Instituto de Relações Internacionais da Universidade de São Paulo.

Aos 23 dias do mês de junho de 2020, no(a) realizou-se a Defesa da Tese do(a) Senhor(a) João Paulo Hernandes Teodoro, apresentada para a obtenção do título de Doutor intitulada:

"A negociação e implementação de direitos de propriedade intelectual em acordos preferenciais de comércio: uma análise dos papeis do Congresso e de grupos de interesse dos Estados Unidos (1995 – 2012)"

Após declarada aberta a sessão, o(a) Sr(a) Presidente passa a palavra ao candidato para exposição e a seguir aos examinadores para as devidas arguições que se desenvolvem nos termos regimentais. Em seguida, a Comissão Julgadora proclama o resultado:

Nome dos Participantes da Banca	Função	Sigla da CPG	Resultado
Yi Shin Tang	Presidente	IRI - USP	Não Votante
Tullo Vigevani	Titular	UNESP - Externo	Aprovado
Felipe Pereira Loureiro	Titular	IRI - USP	Aprovado
Umberto Celli Junior	Suplente	FDRP - USP	Aprovado

Resultado Final: Aprovado

Parecer da Comissão Julgadora *

Eu, Yi Shin Tang, lavrei a presente ata, que assino juntamente com os(as) Senhores(as). São Paulo, aos 23 dias do mês de junho de 2020.

Tullo Vigevani

Felipe Pereira Loureiro

Umberto Celli Junior

Yi Shin Tang
Presidente da Comissão Julgadora

* Obs: Se o candidato for reprovado por algum dos membros, o preenchimento do parecer é obrigatório.

A defesa foi homologada pela Comissão de Pós-Graduação em _____ e, portanto, o(a) aluno(a) _____ jus ao título de Doutor em Ciências obtido no Programa Relações Internacionais.

_____
Presidente da Comissão de Pós-Graduação

A ata não foi fisicamente assinada pelos membros votantes da Comissão Julgadora porque a tese foi defendida remotamente, através da internet.

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To everything (turn, turn, turn, turn)
There is a season (turn, turn, turn, turn)
And a time to every purpose under heaven
[…]
Time get, time to lose
[…]
There's time to sow
Time to reap
Time for silence, time to speak
[…]
Time to cast away stones
And time to gather stones together
[…]
Time to break down
Time to build up
[…]
Time for war, time for peace
I swear it's not too late

(Selected lines from "Turn! Turn! Turn!" by Pete Seeger, as adapted by Nina Simone in her album "To Love Somebody", 1969).

ABSTRACT

The United States has a complex legal and institutional setting in place for the negotiation and implementation of international trade agreements. Such framework defines the roles of the president, Congress, and private advisory committees. This dissertation analyzes how such actors interacted to negotiate and implement the intellectual property rights included in preferential trade agreements from 1995 – 2000 and 2001 – 2012. The analysis of the first period relies on statements by members of the United States Congress and concludes that the intellectual property rights negotiated with trade partners influenced the overall U.S. trade policy and the domestic patent legislation. As regards the second period, we focus on the intellectual property rights applied to the production and trade of pharmaceuticals because since 2001 health-related concerns had become key trade-related issues. The analysis of the 2001 – 2012 period also relies on official reports produced by industry advisory committees. We identified patterns in views expressed by members of Congress and concluded that the influence of the committees was limited in scope and in time. Since both domestic and international factors influenced the U.S. trade policy at that time, throughout this dissertation we rely on theories about the two-level interactions.

Keywords: United States. Congress. Interest Groups. Intellectual Property Rights. Pharmaceuticals.

RESUMO

Os Estados Unidos têm um complexo sistema legal e institucional para a negociação e implementação de acordos internacionais de comércio. Tal sistema define os papeis do presidente, do congresso e de comitês de assessoramento privados. Esta tese analisa como tais atores interagiram para negociar e implementar os direitos de propriedade intelectual incluídos em acordos preferenciais de comércio entre 1995 – 2000 e 2001 – 2012. A análise do primeiro período se baseia em declarações de membros do Congresso dos Estados Unidos, e conclui que os direitos de propriedade intelectual negociados com parceiros comerciais influenciaram a política comercial estadunidense em geral e a legislação doméstica sobre patentes. Quanto ao segundo período, nos focamos nos direitos de propriedade intelectual aplicados à produção e comércio de medicamentos porque desde 2001 preocupações relacionadas à saúde haviam se tornado centrais ao comércio. A análise do período 2001 – 2012 também considera relatórios oficiais produzidos por comitês industriais de assessoramento. Nós identificamos padrões nas visões manifestadas no Congresso e concluímos que a influência dos comitês foi limitada ao longo do tempo e em escopo. Como tanto fatores domésticos quanto internacionais influenciaram a política comercial estadunidense no período, ao longo desta tese nos baseamos em teorias sobre as interações de dois níveis.

Palavras-chave: Estados Unidos. Congresso. Grupos de Interesse. Direitos de Propriedade Intelectual. Farmacêuticos.

LIST OF ACRONYMS

CAFTA-DR	Dominican Republic – Central America Free Trade Agreement
GATT	General Agreement on Tariffs and Trade
IFAC	Industry Functional Advisory Committee
ITAC	International Trade Advisory Committee
NAFTA	North American Free Trade Agreement
NGO	Nongovernmental Organization
TPA	Trade Promotion Authority
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
USMCA	Agreement between the United States of America, the United Mexican States, and Canada
USTR	Office of The United States Trade Representative
WTO	World Trade Organization

CONTENTS

LIST OF TABLES 10

1 INTRODUCTION 11

2 IMPLEMENTING TRADE AGREEMENTS: THEORY AND THE UNITED STATES PRACTICE 22

2.1 National and international politics: intertwined levels 22
2.2 Negotiating and implementing trade agreements in two-level scenarios 29
2.3 U.S. domestic laws and institutions for the negotiation and implementation of trade agreements 32
2.4 Conclusion: Congress and intellectual property advisory committees on intellectual property: relevant actors at the U.S. domestic level 38

3 CONGRESSIONAL VIEWS ON INTELLECTUAL PROPERTY RIGHTS RELATED TO PHARMACEUTICALS INCLUDED IN PREFERENTIAL TRADE AGREEMENTS 40

3.1 Importation of pharmaceuticals 44
3.2 Doha Declaration 52
3.3 Criticism of the Industry Advisory Committee on Intellectual Property Rights 59
3.4 Impacts on access to medicines in developing countries and in the preferential trade partners 62
3.5 The 10 May Agreement and its impacts on the trade agreements with Peru, Colombia and Panama 71
3.6 Conclusion: unstable party divisions 79

4 IFAC-3 AND ITAC-15 REPORTS ON PHARMACEUTICALS 81

4.1 Partial approval of trade agreements: the main reports 84
4.2 Reversing views due to Congressional demands: the addenda to the original reports 96
4.3 Conclusion: the industry advisory committees' role in the U.S. trade policymaking . 100

5 CONCLUSIONS 103

REFERENCES 110

ANNEX 1: PRIMARY DATA 127

ANNEX 2: PAPER BASED ON DATA FROM YEARS 1995 – 2000 129

LIST OF TABLES

Table 1: Summary of views of members of the U.S. Congress on provisions related to importation of pharmaceuticals included in preferential trade agreements (2001 – 2012).....50
Table 2: Summary of views of members of the U.S. Congress on provisions related to the "Doha Declaration on the TRIPS Agreement and Public Health" included in preferential trade agreements (2001 – 2012)...58
Table 3: Summary of views of members of the U.S. Congress on the industry advisory committees on intellectual property rights (2001 – 2012).....61
Table 4: Summary of views of members of the U.S. Congress on the impacts of preferential trade agreements on access to medicines in preferential trade partners (2001 – 2012).....69
Table 5: Summary of views of members of the U.S. Congress on reasons for the renegotiation of trade agreements and on results of the May 10 Agreement between Congress and the federal administration, 2001 – 2012.....77
Table 6: Pharmaceutical company and trade association members of the USTR industry advisory committees (2001 – 2012).....83

1 INTRODUCTION

The Institute of International Relations at the University of São Paulo (IRI – USP) requires PhD candidates to write an in-depth dissertation and to submit at least one article based on its findings to a peer-reviewed journal. We submitted an article containing the findings regarding years 1995 to 2000 to *The Journal of World Intellectual Property* (see Annex 2). The article was eventually published, including adjustments suggested by the Journal's reviewer (for the final version see Teodoro (2020)).

This dissertation analyses the roles of the U.S. Congress and private actors in negotiating and implementing the intellectual property provisions related to pharmaceuticals included in the preferential trade agreements ratified by the U.S. from 1995 to 2012. We do so by analyzing the statements made by members of the U.S. Congress and the reports produced by official private advisory committees on intellectual property. To the best of our knowledge, these sources had never been analyzed in depth and in tandem, as we did, whereby we expect to provide original contributions to the academic production on the topic.

Data from years 1995 – 2000 are analyzed separately from the ones from 2001 – 2012 for many reasons. For one, the Congressional instructions that guided the negotiation and ratification of trade agreements are different for each period. Also, the trade opportunities and constraints each president faced are different, since our time frame encompasses the administrations of Bill Clinton, George Bush, and Barack Obama. Finally, the issues that mobilized Congress – or at least a significant, vocal subset of it – also changed over time.

The sources available for each period are also different. The statements by members of the U.S. Congress are available for both, but the official private advisory committee reports only became available from 2002 on, when Congress approved a new trade law establishing the creation of industry advisory committees[1]. Therefore, we rely on those official inputs provided by domestic industries to U.S. negotiators to estimate

[1] The trade advisory committee system was established for the first time in the trade act of 1974. Mirroring the original law, the Trade Act of 2002 requests sectoral committees to produce reports to the president, the USTR, and Congress regarding both tariff and non-tariff measures included in trade agreements, which applies to intellectual property rights (Section 2104 (e)). The Act also requested the committees to comment on extensions to the trade promotion authority (Section 2103 (c)(3)(A)) (INTERNATIONAL TRADE ADMINISTRATION, 2019; UNITED STATES SENATE; THE HOUSE OF REPRESENTATIVES OF THE UNITED STATES OF AMERICA, 2002). We explain the creation and evolution of the advisory committee system in greater detail in chapter two.

the extent of the private influence on the negotiation and implementation of trade agreements.

From 1995 to 2000 the main issues regarding intellectual property in trade agreements were their impacts on the U.S. patent system and on the extension of preferential trade preferences granted to developing countries. On the other hand, from 2001 to 2012 the connection between intellectual property rights and public health became a pressing issue at the international level and generated abundant domestic responses in the U.S. We focus this dissertation on such reactions by analyzing the views of the members of the U.S. Congress and of the private advisory committees on the provisions related to pharmaceuticals included in preferential trade agreements[2].

The United States has implemented several preferential trade agreements despite the fact that the World Trade Organization (WTO) has been in force since 1995. Its creation is an important landmark because the WTO set an unprecedented legal and institutional framework to deal with tariff and nontariff issues at the multilateral level. One of its founding agreements, the "TRIPS" (Agreement on Trade-related Aspects of Intellectual Property Rights), determines minimum standards of intellectual property rights that all WTO members must meet. It encompasses copyright and related rights, trademarks, geographical indications, industrial designs, patents, topographies of integrated circuits and protection of undisclosed information. Moreover, the TRIPS is supported by a dispute settlement body that addresses violations of the WTO agreements upon request.

Despite the benefits the TRIPS grants to intellectual property holders, it contains no specific rules as to certain technologies that have become very significant – such as the internet, which facilitates the diffusion, storage and exchange of digital works

[2] Preferential trade agreements set exclusive trade-related rules, valid for contracting parties only. This concept is more precise than others, such as "regional trade agreement" (often used indiscreetly to refer to trade agreements between countries not belonging to a same region) and "bilateral trade agreement", since it does not encompass trade agreements signed between more than two nations. In fact, among the trade agreements in force for the U.S., only the "Agreement between the United States of America, the United Mexican States, and Canada" (hereinafter "USMCA") is strictly regional, since it is composed of the three North American countries. All other U.S. trade partners in preferential agreements are quite far from the U.S. territory. The WTO describes these agreements as "regional" (for the WTO terminology see https://www.wto.org/english/tratop_e/region_e/region_e.htm (accessed Apr. 25, 2017)). Freund (2010) refers to U.S. preferential trade agreements as "regional trade agreements"; Calabrese and Briziarelli (2011) refer to U.S. preferential trade agreements as "bilateral trade agreements". Bhagwati (1995) and Mavroidis (2011), on the other hand, prefer to highlight the preferential nature of trade agreements notified to the WTO, rather than calling "regional" agreements that are not region-wide; we find this approach more precise.

protected by copyright or related rights –, effective technological measures[3] and encrypted satellite signals.

Furthermore, the TRIPS agreement is filled with generalist, imprecise language, which may give room to temporary or permanent exceptions to granted intellectual property rights. One example of such vague language is TRIPS article 31; it states that in certain circumstances WTO members can authorize the use of the subject matter of a patent without the authorization of the right holder. It goes on to specify that:

> […] such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public noncommercial use. (WORLD TRADE ORGANIZATION, 2017b, p. 14).

No definitions of "reasonable commercial terms and conditions" or "reasonable period of time" are included in the agreement. Rules and procedures for determining "national emergency or other circumstances of extreme urgency" are not specified, either. This provision has led to fierce disagreements between developed and developing countries over how and when this waiver could be used to issue compulsory licenses for patented pharmaceuticals[4].

Disputes on the interpretation of this and other obscure TRIPS articles arose during the contentious negotiations that resulted in the creation of the "Declaration on the TRIPS Agreement and Public Health" in 2001 (DEERE, 2009). Prompted by a group of twenty developing countries, the initial objective of the Declaration was to ensure that the WTO would not prevent the production or distribution of pharmaceuticals used to address

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[3] The United States – Korea Free Trade Agreement provides a good definition of "effective technological measures" in article 18.4.7(f): "[it means] any technology, device, or component that, in the normal course of its operation, controls access to a protected work, performance, phonogram, or other protected subject matter, or protects any copyright or any rights related to copyright." (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2007a, p. 12). According to Díaz (2008), effective technological measures are usually applied to protect the contents of DVDs, electronic books, videogames, on-line streaming, and webpages. They can also refer to hardware devices designed to avoid illegal replications of protected works.

[4] A compulsory license may be defined as "[...] the authorization given by a judicial or administrative authority to a third party for the use of a patented invention, without the consent of the patentee, on various grounds of general interest (e.g., absence of working, public health, anticompetitive practices, emergency, national defense)." (CORREA, 2005, p. 27).

the HIV/AIDS epidemic that ravaged several developing and least-developed countries at that time, most notably in Sub-Saharan Africa[5].

The Doha Declaration gives WTO members discretion to determine what situations can be described as "emergencies in public health or other circumstances of extreme urgency", whereby issuing compulsory licenses for patents on pharmaceuticals would be allowed, according to TRIPS article 31. The Declaration also emphasizes that least developed countries[6] could request postponements to the initial 10-year term they had been granted for TRIPS implementation and that each member country is free to establish its own intellectual property rights exhaustion regime[7] (WORLD TRADE ORGANIZATION, 2017b; 2001b). Furthermore, the Declaration established that until January 01, 2016, least-developed WTO members were not required to implement the TRIPS Agreement as regards patents for pharmaceuticals[8].

The Declaration also set a deadline for WTO members to define a practical solution whereby countries with insufficient or no manufacturing capacities in the

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[5] For the complete text of the Declaration see World Trade Organization (2001b). Sell and Odell (2006) comprehensively analyze the content of the Declaration and the negotiations that resulted in its creation.

[6] The WTO relies on the United Nations Economic and Social Council list of "least developed countries". It takes into account the GDP per capita; data on nutrition, health, literacy and school enrollment; indicators of natural and trade-related shocks, physical and economic vulnerability to shocks, and geographical position (minding whether a country is too small or too remote) (UNITED NATIONS CONFERENCE ON TRADE AND DEVELOPMENT, 2013). According to these criteria, currently there are 48 least developed countries; 36 of them are WTO members (WORLD TRADE ORGANIZATION, 2017a).

[7] The exhaustion of patents refers to the right patent holders may have to prevent the importation of products manufactured abroad with their consent. International regimes establish that patent holders cannot prevent importations of protected products, unless they are counterfeit. National exhaustion regimes, on the other hand, allow patent holders to control importations of protected products (WORLD INTELLECTUAL PROPERTY ORGANIZATION, 2019a). The TRIPS article 28 establishes that patent holders shall be able to prevent third parties from importing patented products or products produced through patented processes. Nevertheless, its article 6 establishes that the agreement's provisions on dispute settlement should not be used to address the exhaustion of intellectual property rights (WORLD TRADE ORGANIZATION, 2017b).

[8] In 2002, following negotiations at the Council for TRIPS, WTO members also decided to suspend the validity for least developed countries of paragraph 9 of TRIPS Article 70 until January 01, 2016. Such paragraph establishes that countries that did not provide patent protection for pharmaceuticals before their implementation of the TRIPS should file pharmaceutical patent requests, creating what came to be known as "mailboxes", and protect those products when patent legislation for pharmaceuticals became effective. It also determined that they should provide five-year exclusive terms of protection for pharmaceutical products that had been patented and granted marketing approval in another member country (WORLD TRADE ORGANIZATION, 2017b; 2002). In November 2015, the waiver on mailbox and exclusive marketing rights with respect to pharmaceutical products was extended until January 2033 (WORLD TRADE ORGANIZATION, 2015b). In that same month, WTO members also decided that least developed country members are not required to implement the TRIPS provisions on patents and undisclosed information related to pharmaceuticals until January 01, 2033 (WORLD TRADE ORGANIZATION, 2015a). Any waivers to the validity of any provision included in the agreements establishing the WTO must be reviewed by the Ministerial Conference every year. Such reviews may determine extensions or changes to waivers or even terminate them (WORLD TRADE ORGANIZATION, 1994b, arts. IX(3) and IX(4)).

pharmaceutical sector could benefit from compulsory licenses. Such solution was reached in August 2003, when the "Decision on the Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health" was finalized at the WTO. It sets several legal and technical requirements for the exportation of pharmaceuticals produced under compulsory licenses to countries with insufficient pharmaceutical production that have declared public health emergency (WORLD TRADE ORGANIZATION, 2003). In 2005 the WTO members also decided that such rules should be included in the main text of the TRIPS Agreement, thereby making them permanent. The TRIPS could only be amended if at least two thirds of the WTO members formally accepted it, which eventually happened in January 2017 (WORLD TRADE ORGANIZATION, 2019).

The Declaration and subsequent related decisions at the WTO largely address the developing countries' demands, thereby not including the restrictions supported by the United States throughout the negotiations (SELL; ODELL, 2006; ABBOTT, 2002).

Therefore, the multilateral intellectual property standards are dynamic, since they have evolved over time to clarify certain provisions and address concerns raised by the majority of the WTO members. Despite these updates, the General Agreement on Tariffs and Trade (hereinafter "GATT") still provides the basis for the WTO. It was established in 1947 as a temporary alternative to a multilateral trade organization, and it bequeathed to the WTO its rules for the creation of preferential trade agreements. As established in its article XXIV, WTO members can create and join customs unions and free-trade areas, as long as they do not impose higher barriers to trade between contracting parties, do not impose higher barriers to trade with non-members, and eliminate duties and other restrictive regulations on substantially all the trade between member countries; a specific definition of "substantial" is not provided, though (GENERAL AGREEMENT ON TARIFFS AND TRADE, 1947). In case third parties are negatively affected by preferential trade agreements, they can proportionally withdraw previous concessions. When creating such preferential trade areas, WTO members must notify all other WTO members (GENERAL AGREEMENT ON TARIFFS AND TRADE, 1947).

TRIPS article XXIV states that WTO members may, by a two-thirds majority, approve proposals which do not fully comply with these basic requirements. Nevertheless, WTO members later agreed that free-trade areas and customs unions shall not deviate from these core principles (WORLD TRADE ORGANIZATION, 1994a). They also decided that the formation of free-trade areas and customs unions should not

exceed ten years (except in "exceptional cases"), and clarified that compensations to affected third parties may take the form of reductions of duties on other tariff lines (i.e. not on the ones originally affected by the preferential agreement) (OLIVEIRA, 2013; WORLD TRADE ORGANIZATION, 1994a).

The WTO's Committee on Regional Trade Agreements is responsible for assessing whether preferential trade agreements notified by WTO members fully comply with their commitments under the WTO framework. Nevertheless, due to lack of political will from WTO members and to the vertiginous speed at which preferential trade agreements have proliferated, the Committee has not been able to ensure that preferential trade agreements are GATT-consistent; neither have WTO members systematically litigated against preferential trade agreements (CELLI JUNIOR, 2012; MAVROIDIS, 2011).

Therefore, though WTO-members willing to create preferential trade agreements should consider the multilateral system's rules for doing so, the application of the GATT/WTO's article XXIV has been very permissive since 1947. In this sense, Tang (2009) asserts that "[…] the debate on the actual scope of this provision has gained increased attention as several WTO members decided to continuously rely on Article XXIV in order to indiscriminately conclude numerous PTAs [preferential trade agreements]." (TANG, 2009, p. 147).

In fact, from 1949 on the GATT/WTO has regularly been notified about the creation and expansion of preferential trade areas. The number of notifications received in every single year since 1999 is greater than the equivalent number for any year from 1949 to 1998, as shown by data gathered by the GATT/WTO[9].

This proliferation of trade agreements has led to a complex trade-related legal framework, with several overlapping tariff schemes, complex rules of origin and provisions on nontariff barriers. This situation led the economist Jagdish Bhagwati to refer to the current trade system as a "spaghetti bowl" (BHAGWATI, 2008; 1995). Such metaphor has spread through the literature; Menon (2009) and Baldwin (2006), for

[9] The WTO's Regional Trade Agreement Information System provides data on notifications of preferential trade agreements to the GATT/WTO from 1948 on. It includes agreements setting free trade areas, customs unions, agreements liberalizing trade in services, and agreements covering "only certain products" (the so-called "partial scope agreements"). Data also includes enlargements of existing arrangements, such as the accession of new members to the European Union. When members of a trade agreement covering only trade in goods notify its expansion to trade in services – and vice-versa –, this new notification is counted – i.e. a single trade agreement covering both goods and services may appear twice on the list. Data and definitions are available at: <https://rtais.wto.org/ui/PublicMaintainRTAHome.aspx> (accessed Sep. 25, 2019).

example, mention the "spaghetti bowl", though not sharing Bhagwati's despise for the phenomenon. Preferential trade agreements concluded by important traders, such as the European Union, Switzerland, the European Free Trade Association – composed of Iceland, Liechtenstein, Norway and Switzerland –, China, South Korea, India, Japan, and the United States include chapters on intellectual property rights (DEERE, 2009).

The U.S. is one of the key actors driving this process; since 1995 the country has ratified thirteen trade agreements[10]. Negotiations were launched with the Philippines, Malaysia, the United Arab Emirates, Thailand, the members of the South African Customs Union (Botswana, Lesotho, Namibia, South Africa and Swaziland), Bolivia and Ecuador, but they were not concluded due to divergences with trade partners (DENT, July 2013; DEERE, 2009; BENTES et. al., 2008; CHOREV, 2007). In fact, most trade agreements currently in force for the U.S. were signed after the WTO became effective, since the trade agreement with Israel is the only preferential trade agreement ratified by the U.S. before 1995 (U.S. CUSTOMS AND BORDER PATROL, 2017; THE EMBASSY OF ISRAEL TO THE UNITED STATES, 2013).

Most parties of preferential trade agreements ratified by the U.S. are Latin American developing countries. Among the countries that have signed preferential trade agreements with the U.S. so far, only five – Israel, Canada, Singapore, Australia, and South Korea – can be classified as "developed"[11].

Therefore, the preferential trade agreements negotiated by the U.S. have impacted the intellectual property rights of developing and developed partners. Most notably, the technical provisions on pharmaceuticals restrict the trade partners' ability to issue compulsory licenses for patented pharmaceuticals and to expedite the introduction of generic products in their national markets following the end of patent terms.

On the other hand, the trade agreements – especially the most recent ones negotiated with Latin American countries – include caveats and exceptions that reinforce

[10] The parties are Jordan, Chile, Singapore, Australia, Bahrain, Morocco, Oman, Peru, Colombia, Korea, and Panama. Costa Rica, the Dominican Republic, Nicaragua, Honduras, El Salvador, and Guatemala are members of a same trade agreement with the U.S., the Dominican Republic – Central America Free Trade Agreement (hereinafter "CAFTA-DR"). In the same vein, the USMCA is in force for Canada, Mexico, and the United States. For general information regarding the U.S. trade agreements see: https://ustr.gov/trade-agreements/free-trade-agreements (accessed July 02, 2020). All of these trade agreements contain chapters on intellectual property rights.

[11] The World Bank describes these countries as "high-income economies" because their annual gross national income per capita is equal or greater than US$12,376 (see <https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups>, accessed on Jan. 21, 2020). Their human development indexes are also greater than 0.9 (see <http://hdr.undp.org/en/content/2019-human-development-index-ranking>, accessed on Jan. 21, 2020).

the trade partners' multilateral commitments aimed at facilitating the production and international distribution of pharmaceuticals during epidemics and other public health emergencies.

While objections to stricter intellectual property rights could be expected from the U.S. partners, the inclusion of exceptions related to pharmaceuticals also suggest that there was no consensus about it in the United States, whereby the implementation of the trade agreements would have required domestic negotiations.

The new U.S. approach to intellectual property rights may also impact the multilateral trade system in the long run. Since the country has consistently negotiated international provisions that differ from the TRIPS Agreement, it is unlikely that the United States would support multilateral agreements that reproduce the WTO standard. The U.S. has been a member of the WTO since its creation, is the second largest exporter and the larger importer in the world[12]. Therefore, any substantive changes to multilateral trade standards can only become effective if the United States participates.

Due to this interesting dichotomy in the provisions related to pharmaceuticals and to the prospects of broader impacts by the U.S. approach to intellectual property rights in trade agreements, this dissertation investigates how relevant domestic actors in the United States interacted to shape and implement the intellectual property rights related to pharmaceuticals included in preferential trade agreements. We consider data from 2001 to 2012.

As we will explain in greater detail in the next chapter, other analyses on the topic regard the international circumstances that provided incentives for the U.S. federal government to change the course of its trade policy toward preferential agreements with very specific tariff and nontariff provisions that are different from the multilateral standards. They also assess the likely impacts of the preferential trade agreements on the U.S. partners' laws and policies related to intellectual property rights. Nevertheless, such studies either fail to account for the role of U.S. domestic actors in consolidating these trade agreements or only superficially acknowledge their influence.

[12] Information on the U.S. membership in the WTO is available at <https://www.wto.org/english/thewto_e/countries_e/usa_e.htm> (accessed Jan. 21, 2019). Information on the relative participation of the U.S. in international trade is available at <https://www.cia.gov/library/publications/the-world-factbook/rankorder/2078rank.html> and at <https://www.cia.gov/library/publications/the-world-factbook/fields/242rank.html> (accessed Jan. 21, 2019).

Therefore, in this dissertation we address these shortcomings by analyzing the views of members of the U.S. Congress and of private advisory committees on intellectual property as regards TRIPS-Plus protections for pharmaceuticals included in preferential trade agreements. Such protections are usually more rigorous than the ones established by the TRIPS Agreement, both in terms of scope and enforcement (SELL, 2007).

Though the U.S. federal administration negotiates treaties and eventually signs them into law, the U.S. Congress has to approve these agreements to secure implementation. If most Congress members disapprove of a trade agreement, they may either reject it altogether or request the president to submit a revised version of the agreement. That requires more time and effort because the federal administration would need to renegotiate with trade partners.

The private advisory committees on intellectual property are formally required to make recommendations to the U.S. negotiators. No other domestic actors have such direct and stable channel of communication with federal negotiators. Moreover, their reports are public, whereby they may influence the views of the president, members of Congress, and societal actors. Nevertheless, they cannot vote on or otherwise prevent the implementation of trade agreements.

Therefore, in the next chapter we also explain in greater detail the legal and institutional framework setting the rules for the participation of public and private actors in trade policymaking in the U.S. We emphasize that no branch of government alone can craft viable international agreements, whereby reaching domestic deals is often necessary to carry out foreign policies. We also explain the evolution of mechanisms devised to overcome deadlocks in implementing trade agreements in the United States and emphasize that the proliferation of preferential trade agreements signed by the U.S. in the period covered by this dissertation depended on specific instructions provided by the Congress to the federal administration.

Since preferential trade agreements can be regarded as examples of international cooperation, they are important from an International Relations theoretical standpoint. In the next chapter we summarize how some of these theories have dealt with the achievement of international agreements. We explain their intellectual foundations, emphasize how they differ from previous International Relations approaches, show how they have evolved, and discuss how useful they can be for studies on trade politics. Their main point is that the formulation and implementation of international policies are driven

by complex social relations within states and by their interactions at the international level.

In this sense, in chapter three we analyze the views of members of the U.S. Congress on intellectual property rights related to pharmaceuticals included in U.S. preferential trade agreements. We rely on the transcriptions of their statements delivered on the floor from January 01, 2001 to December 31, 2012.

They encompass the debates about most trade agreements ratified by the U.S. and regard what Congress members thought would be the impacts of the trade agreements' patent and related provisions on access to pharmaceuticals in the U.S. and abroad. They also reveal the emphasis a group of members of Congress placed on ensuring that the preferential agreements did not render void agreements aiming to improve access to medicines negotiated by the WTO members. The most concrete result of that was the renegotiation of the trade agreements with Peru, Colombia, and Panama, which we also explain in chapter three.

During the debates, members of Congress relied on views expressed by several domestic actors. In this sense, the private advisory committees were often criticized for unduly influencing the intellectual property rights included in the trade agreements, and for providing advice that harmed American consumers and low-income citizens in developing countries.

In chapter four we explain that, even though these private committees supported most trade agreements negotiated by the United States, they also criticized several provisions related to pharmaceuticals throughout the period. Furthermore, we show that specific members of the advisory committees withdrew their approval of the trade agreements negotiated with three Latin American countries because of new provisions related to pharmaceuticals that were renegotiated due to the insistence of the majority in Congress.

In the conclusion we highlight that the U.S. Congress prevailed over the advisory committees. We also emphasize that the approval of intellectual property provisions related to pharmaceuticals by members of Congress – or lack thereof – was counterintuitive to a certain extent because it could not be perfectly described by party affiliation. Also, the very fact that the Congress created a mechanism to boost the implementation of trade agreements – instead of insisting on protectionist approaches to please local interests – is an interesting finding.

We conclude by suggesting topics for further research. Our view is that the framework we employ throughout this dissertation can be replicated to analyze other periods or aspects of the U.S. trade policy, or even to guide research on trade policies carried out by other countries that also provide access to necessary documents.

2 IMPLEMENTING TRADE AGREEMENTS: THEORY AND THE UNITED STATES PRACTICE

International agreements are usually the outcome of very complex negotiations. While systemic approaches focus on the interactions between states, emphasizing the role of power asymmetries and alliances, others regard situations where negotiations between interested stakeholders at the domestic level are also crucial in achieving international cooperation.

Since the United States has a legal and institutional setting that requires the participation of different domestic actors in the negotiation and ratification of trade agreements, the second group of theories is more appropriate to guide research on the U.S. trade policy and to provide a connection between case studies on trade and International Relations theory.

In other words, an adequate theoretical foundation for this dissertation must account for the complex interactions between the national and the international levels. Therefore, in section 2.1 we present an overview of such theories, emphasizing how they apply to the negotiation and implementation of international agreements. In section 2.2 we explain how such theoretical framework relates specifically to the definition and implementation of trade policies. Since each domestic system is peculiar, in section 2.3 we provide an overview of the United States laws and institutions that guide the negotiation and implementation of trade agreements. We conclude in section 2.4 by highlighting how these theoretical, legal and institutional frameworks are useful in explaining the inclusion of intellectual property rights related to pharmaceuticals in trade agreements.

2.1 National and international politics: intertwined levels

The theories developed by Putnam (1988), Mo (1994), Epstein and O'Halloran (1995), Milner (1997), and Bueno de Mesquita (2010) are among the ones that emphasize the importance of the interactions between the national and the international levels for the implementation of international policies.

Since the late 1980s these theories have been refined. Putnam's seminal article (1988) was important for defying the validity of International Relations theoretical

approaches that overemphasize the role of state power, thereby disregarding the importance of the domestic political game.

Subsequent academic works have formalized Putnam's model, varied its assumptions, and debated the consequences of these changes, such as Mo (1994) did. Milner (1997) also discusses some of Putnam's assumptions and results, and develops a formal model to explain international cooperation. In the same vein, Epstein and O'Halloran (1995) built a model to explain the interactions between legislatures, administrative agencies, and interest groups. Some of Bueno de Mesquita's (2010) core assumptions and conclusions also relate to this group of theoretical developments.

Despite the differences between these approaches, they essentially pose that the formulation of foreign policies in each state at the domestic level is limited and stimulated by the international scenario. When implemented, these policies impact other international actors, thereby constituting the international level.

While the international system influences state policies, the latter shape the international system, through iterated interactions between states. Therefore, domestic politics matter for international politics and vice-versa; the two levels are co-constitutive. Though the international level poses opportunities, challenges and limitations to states, the way they respond to such externally induced stimuli depends on the interactions between public powers and interest groups[13], which eventually consolidate in foreign policies.

The ratification of treaties in democracies is one of the situations where the dynamic interactions between the national and international levels take place. Their diplomats must mind the probability of ratification at home when negotiating agreements, since there is a range of possibilities, determined at the domestic level, within which they can effectively act. An agreement is feasible when it is within the range of possibilities of all negotiators (PUTNAM, 1988; MILNER, 1997; GOLDSMITH; POSNER, 2005).

In this sense, the ratification process is interpreted as more than just a set of strict voting procedures for the approval of international agreements by legislatures:

> If a political leader needs to change a domestic law, norm, or practice because of the cooperative agreement, then even if a formal vote on the agreement is not required, the domestic change itself becomes a vote on

[13] We refer to "interest groups" as those societal groups that interact with state powers to influence foreign policies, or at least try to do so. Therefore, our definition is behavioral, since it encompasses only mobilized actors. Epstein and O'Halloran (1995) draw on a similar definition. For other definitions see Dür and Mateo (2014) and Baroni et. al. (2014).

> the agreement. This is also the case if the agreement requires any budgetary changes. (MILNER, 1997, p. 73).

The very requirement of approval by domestic legislatures suggests that domestic politics matter for international relations.

In the same vein, Milner (1997) identifies five crucial powers to foreign policy-making: the definition of proposals to be negotiated with foreign countries, the ability to amend any proposed policy, the ratification or vetoing of international agreements, the proposition of referenda on international issues, and the ability to change domestic institutions[14]. The greater the control a domestic actor has over these, the greater is his influence on foreign policy.

The importance of the interactions between domestic actors in foreign policy making holds true even for dictatorships, since power holders in such regimes can only remain in office if they make concessions to domestic groups – such as the military, landed oligarchies, big businesses, or political parties (BUENO DE MESQUITA, 2010; MILNER, 1997)[15].

Since the costs and benefits related to international cooperation bear unevenly on domestic constituents, interest groups with opposing views may compete to capture the attention of public actors to influence the formulation, negotiation and implementation of foreign policies (EPSTEIN; O'HALLORAN, 1995; MILNER, 1997; GOLDSMITH; POSNER, 2005; BUENO DE MESQUITA, 2010). "Those who stand to lose should block or try to alter any international agreement, whereas those who may profit from it should push for its ratification." (MILNER, 1997, p. 63).

Interest groups can both contribute campaign funds and mobilize voters, whereby ensuring their support may be decisive for politicians seeking reelection or trying to maintain their political party in office (BUENO DE MESQUITA, 2010). Shifts in public opinion – caused by campaigns promoted by interest groups or other factors – can also have electoral consequences (PUTNAM, 1988; MILNER, 1997). In this sense, when politicians seek reelection, they will prefer policies that enhance the economy – i.e. those that positively impact economic growth, employment, and inflation – and those that bring

[14] Since the institutions in place matter for foreign policymaking, politicians may try to arrange them to benefit themselves or their political parties. This also holds true when politicians can choose which procedures will be implemented to deal with international agreements.

[15] Bueno de Mesquita (2010) highlights that autocratic leaders usually remain in office by providing private benefits to those social groups whose support is vital for political survival. They tend to care less for public welfare than for satisfying their cronies, since they do not rely on elections to maintain power.

gains to their interest group supporters (MILNER, 1997; BUENO DE MESQUITA, 2010). When interest groups preferences are at odds with the general economic welfare, politicians must weigh up the options at hand. Furthermore, when competing groups try to influence policies, politicians have to choose which side they will take.

When negotiators at the international level fear that agreements will not be ratified – either at home or at counterparts' domestic level – they may abort negotiations altogether (PUTNAM, 1988). To facilitate negotiations and avoid stalemates, diplomats may also demand counterparts to have a defined set of domestically acceptable proposals before coming to the negotiating table. This demand can take the form of a previous agreement between domestic decision-makers, whereby amenders or ratifiers relinquish control to the executive (MILNER, 1997).

Domestic decision-makers can also negotiate with foreign partners that favor their positions to try to force (or avoid) changes at the domestic level. They can also do so to consolidate their own conception of the national interest, implement their party program or enhance national security (PUTNAM, 1988; MILNER, 1997; BUENO DE MESQUITA, 2010). In this sense, Putnam (1988) asserts that "Politicians may be willing to risk a few of their normal supporters in the cause of ratifying an international agreement, but the greater the potential loss, the greater their reluctance." (PUTNAM, 1988, p. 458).

In the same vein, international negotiators can try to convince their constituents that an international agreement is desirable, make concessions at home and use side-payments to secure the implementation of international trade agreements (MILNER, 1997; GOLDSMITH; POSNER, 2005; LANTIS, 2005)[16]. They can also try to coopt domestic constituents from the nations they negotiate with (MO, 1994).

The effectiveness of such strategies depends on the quality of information held by each counterpart in an international negotiation. In this regard, Putnam (1988) asserts that

[16] Side-payments may refer to corruption, but the concept also encompasses other kinds of bargains concerning public decision-makers and interest groups: "[they] include such practices as log-rolling, vote trading, compromise, concessions, reciprocity, bribes, and issue linkage. […] an actor gives up value on one issue of lesser importance in order to gain value from others on an issue of greater importance." (MILNER, 1997, p. 109). They can also consist of promises of not to carry out threats, such as when politicians promise to maintain party discipline in exchange for something else. Milner (1997) offers an example of how side-payments can affect international agreements: "[…] in the NAFTA agreement President Clinton was able to secure legislative votes in the final days of negotiations by offering exemptions from the agreement to various producers in important congressional districts." (MILNER, 1997, p. 112). Moreover, Clinton also negotiated supplemental agreements on environmental and labor issues with Canada and Mexico to overcome domestic opposition (LANTIS, 2005).

“Uncertainty about the size of a win-set [the range of acceptable outcomes] can be both a bargaining device and a stumbling block in two-level negotiations [i.e. in negotiations simultaneously regarding the national and international levels].” (PUTNAM, 1988, p. 452). Negotiators can use win-sets to obtain better deals by stating that an agreement will not be accepted at home, no matter how accurate this assertion might be. They can also push foreign negotiators when they estimate that more favorable concessions can be made.

As for the stumbling-block effect, Milner (1997) asserts that domestic actors such as legislatures will often veto policies they lack information about, i.e. uncertainty may negatively affect cooperation. In this sense, Epstein and O’Halloran (1995) consider that federal agencies, including those responsible for negotiating with foreign countries, are usually better informed about the details of their policy areas, which may make it difficult for legislators to effectively oversee their actions.

Interest groups may mitigate these asymmetries by providing information to public powers. In this sense, interest groups will only be able to influence policies if their interests do not conflict with public powers’ preferences, and if these powers both trust and find it useful to rely on information provided by these groups (EPSTEIN; O’HALLORAN, 1995; MILNER, 1997). If competing interest groups support different views, public powers’ agents need to weigh them up and choose the ones they will rely on (EPSTEIN; O’HALLORAN, 1995). “In this role they [interest groups] do not directly shape the political actors’ preferences but rather act as signalers, alerting political actors to the consequences of various policies, in this case international cooperative ones.” (MILNER, 1997, p. 60).

On the other hand, if all domestic actors are fully informed about others’ stable preferences, the executive will know beforehand if the legislature is prone to accept international agreements, and what terms are acceptable. Since information provided by interest groups can affect the acceptability of agreements by public powers or influence their very content, it is useful for negotiators to know these groups’ preferences beforehand (MILNER, 1997). In case negotiators misinterpret domestic preferences, they may create bad, non-ratifiable agreements (LANTIS, 2005).

Therefore, the level of information held by each actor may affect negotiations both at the national and at the international level (PUTNAM, 1988; EPSTEIN, O’HALLORAN, 1995; MILNER, 1997).

Also, if government is divided – i.e. different branches of government do not agree on the desirability of international cooperation or on the terms of such cooperation –, it will be harder to achieve international agreements (LANTIS, 2005). The more divergent these preferences are, the more divided government is (MILNER, 1997). Milner (1997) offers an explanation for divided governments, based on the nature of constituencies:

> Executives and legislators represent different constituencies. Both the type and importance of special interests in their constituencies may differ. In presidential systems, where the two are elected in separate elections this point is fairly obvious[17]. Executives must worry about a national constituency, whereas legislators are concerned with their local district. Depending on the electoral laws, their district may represent a small or large part of the nation. Moreover, in multimember districts legislators may represent only part of their district, further narrowing their constituency and differentiating it from the executive's. (MILNER, 1997, p. 36)[18].

Legislators may vote against proposals supported by the majority of their party to please their constituents. On the other hand, if legislators are loyal to their party, they may ignore pressures from constituents or interest groups. Moreover, if the level of party discipline is high, international negotiators can better estimate whether an international agreement is acceptable domestically, since party affiliation is very likely to determine a legislator's vote (MILNER, 1997).

Moreover, if a government is divided and yet the executive wants to secure the implementation of an international agreement, it may need to renegotiate with foreign governments, minding other domestic decision-makers' views (MILNER, 1997; LANTIS, 2005).

When there is no domestic consensus between public powers and/or interest groups regarding international projects, they can only be implemented if alliances are made (LANTIS, 2005). In this sense,

> The internal struggle between these groups shapes the possibility and nature of international cooperative agreements. International negotiations to realize cooperation often fail because of domestic

[17] Milner (1997) also specifies that bicameral legislatures are more likely to cause divided government, since there is a greater chance that at least one house is controlled by parties not aligned with the executive at any given time.

[18] Bueno de Mesquita (2010) makes a similar point by asserting that the larger the constituency, the greater the incentives for policymakers to pursue policies that benefit the public instead of those that primarily satisfy special interests.

> politics, and such negotiations are often initiated because of domestic politics. (MILNER, 1997, p. 10).

On the other hand, when domestic decision-makers agree on a given international issue, it will be easier to consolidate the country's position; in these circumstances, the unitary actor assumption may be useful in explaining states' behavior[19].

Though domestic negotiations are important in explaining foreign policies, interactions between states are also crucially relevant. International agreements can only be achieved when countries' win-sets overlap (PUTNAM, 1988; BUENO DE MESQUITA, 2000; GOLDSMITH; POSNER, 2005). Usually, the more states take part in an international negotiation, the harder it is to achieve an agreement, and the more complex negotiations are (MORROW, 1999).

In this sense,

> […] political leaders are constantly playing in the domestic and international arenas simultaneously. They are trying to achieve their various goals using these two arenas, and they face different – and sometimes contradictory – pressures and constraints from each. Their behavior can only be understood when both internal and external factors are considered. (MILNER, 1997, p. 4).

In sum, international politics take place at the interface between these two arenas – or "levels", as Putnam (1988) calls them. Therefore, policy makers cannot disregard the domestic or the international level when analyzing foreign policies, since the two are intertwined. Neither can researchers, for the very same reason.

An important aspect of these theories is that they do not regard states as unitary actors – i.e. rational, coherent political entities – because their policy choices depend on the international context and on power relations between their domestic constituents, which includes interest groups. These relations are mediated by states' laws and institutions. Since domestic actors may have divergent preferences, it follows that the "national interest" is not given a priori; its determination depends on which views on foreign policy prevail domestically (PUTNAM, 1988; MILNER, 1997). Moreover, the actions carried out by states at the international level are not necessarily those that maximize the public good at home (GOLDSMITH; POSNER, 2005).

[19] As it is already clear from this discussion, the theoretical approaches we have been referring to do not interpret states as coherent, rational political entities. We will make this point clearer as follows, where we also explain the unitary actor assumption in more detail.

Therefore, these theoretical approaches emphasize that domestic negotiations between state powers – as well as their relations with constituents and interest groups – are also crucial. In this sense, "state strength" is not necessarily regarded by International Relations theories as a key variable of interest, since its measurement provides little, if any, indication of which foreign policies states will prefer (PUTNAM, 1988).

This does not amount to disregarding the importance of state power (or "strength"); it means that power calculation is not enough in itself to indicate the courses of action states will take. The deployment of power is dependent on the interactions between different branches of government within states, and on states' international interactions. "It also means that the terms of an international agreement will reflect each country's domestic situation in addition to its international influence." (MILNER, 1997, p. 98).

2.2 Negotiating and implementing trade agreements in two-level scenarios

The review we presented in section 2.1 is general, related to the interpretation of international relations as a whole. We stressed that these theories' core features are useful in explaining how several domestic and international factors influence political choices regarding international affairs. In this section we explain how this theoretical framework is also useful for studies on trade.

Researchers that acknowledge that national and international politics are co-constitutive can more easily explain the usually nuanced and complex interactions between domestic and international actors that drive the negotiation and ratification of international trade agreements.

Open national economies may be impacted by economic actions from other countries – such as the imposition of tariffs or non-tariff barriers. Therefore, these states have reasons to cooperate with foreign countries on trade issues to either foster certain actions by others or to prevent them from adopting undesired, harmful policies (GOLDSMITH; POSNER, 2005).

International trade agreements stabilize trade relations because they specify and delimit tariffs and nontariff barriers. When they establish reliable dispute settlement procedures, these agreements also provide means for smoothly solving conflicts between member states. Otherwise settling disputes could jeopardize the overall relations between trade partners, reach politically biased outcomes or create domestic political costs. In

addition, trade-related institutions can lower the communication and related transaction costs of continuous cooperation (GOLDSMITH; POSNER, 2005, p.13; 86).

In this sense, "[…] national leaders may want to advantage groups desiring freer trade and avoid sectoral pressures for protectionism by forging international agreements that lock free trade policy into place." (MILNER, 1997, p. 45). Therefore, though trade agreements may hurt some domestic actors, the choice to cooperate will typically prevail when policy makers are convinced that they can enhance the economy or please specific interest groups. Moreover, policymakers may prefer trade agreements aligned with their conception of the national interest and with their party program.

On the other hand, interest groups hurt by freer trade will usually advocate for protectionist measures. Depending on the political benefits accruing from such influence, such as campaign funds and potential votes, politicians may refuse to negotiate or ratify trade agreements, thereby maintaining trade restrictions in place or setting new such restrictions. The tradeoff between potential benefits to the economy as a whole and the obtainment of side-payments may also influence politicians' decisions (MILNER, 1997; BUENO DE MESQUITA, 2010)[20].

When international agreements are preferred by national policymakers and are eventually implemented, they result in less unilateral control over trade barriers by domestic powers, though. Therefore, when negotiating trade agreements, policymakers must weigh the benefits of cooperation against losses in economic policy autonomy (MILNER, 1997).

States can simply cheat and do not abide by the rules agreed with trade partners when doing so pays off. Trade barriers can bring about benefits in the short term, but they hinder cooperation in the long run because foreign partners may retaliate. Furthermore, these deviations may hurt states' international reputation, which may hinder their ability to cooperate in the future, since other countries may doubt that states that have cheated can consistently abide by agreed rules (GOLDSMITH; POSNER, 2005, p. 101)[21]. In this sense,

[20] Despite these simplifications, there are in-between situations, such as when trade agreements are implemented with exceptions tailored to please specific interest groups. Clinton's strategy to have NAFTA approved is an example of such tactic, as we explained in footnote sixteen.

[21] For an extensive discussion on the role of coercion, reputation and retaliation in international law compliance, including trade-related treaties, see Goldsmith and Posner (2005, p. 90; 102-103; 153-162) and Hathaway and Lavinbuk (2005-2006, p. 1442).

> In those areas where the net home benefits from a policy instrument are high, there will be resistance to cooperation. As a policy instrument's negative externalities grow, interest in coordinating policies will rise. The higher the probability of foreign retaliation that offsets a policy change, the more likely countries are to seek cooperative outcomes since their home benefits decline with the likelihood of retaliation. (MILNER, 1997, p. 59).

In this sense, politicians can be either pro or against the signature of more preferential trade agreements, and either support or reject the inclusion of intellectual property rights in them. Since even positions expressed by members of a same political party may vary over time, trade policies cannot be explained by simplistic, static generalizations based on party "tradition"[22].

In the same vein, competitive exporters are the typical supporters of trade agreements (MILNER, 1997; GOLDSMITH; POSNER, 2005; BUENO DE MESQUITA, 2010). Some of these supporters emphatically advocate for intellectual property rights that are more specific and strict than the ones present in the TRIPS Agreement (DRAHOS et. al., 2004)[23]. On the other hand, less internationally competitive economic sectors, trade unions, professional associations, social welfare organizations, epistemic communities, and supporters of flexible intellectual property rights, i.a., may also try to influence trade agreements through social mobilization and lobby (BUENO DE MESQUITA, 2010; DENT, Aug. 2013; DÜR AND MATEO, 2014)[24].

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[22] Donald Trump's trade priorities provide relatively recent examples of that. He was elected in 2016 relying on a rather protectionist platform, threatening to either renegotiate or denounce NAFTA and strongly criticizing the Trans-Pacific Partnership and other U.S. trade agreements. Nevertheless, the U.S. signed most of its trade agreements during the Republican administration of George Bush, the junior. NAFTA itself was largely negotiated during the presidency of George Bush, the senior. Moreover, the Trump administration has started a tariff battle against China that has caused intense domestic reactions, triggered retaliatory measures, and strained the international trade system. Therefore, Trump's trade policies deviate from what his party had been supporting for decades. For the debates where Trump made clear his protectionist views see The First (2016), Everything That (2016), and The Final (2016). On NAFTA's history see North American Free Trade Agreement (2009) and Lantis (2005). On the tariff battles with China see The Associated Press (Sep. 24, 2019; Sep. 25, 2019).

[23] On the multilateral intellectual property rights standard, as compared to a sample of recent preferential trade agreements, see Tang and Teodoro (2016). On the definition of strict versus flexible intellectual property rights see Sell (2003). Usually, "stricter" intellectual property rights last longer, set more rigorous enforcement mechanisms, and give right holders more discretion.

[24] Governments can address protectionist pressures by providing subsidies and safeguards (BUENO DE MESQUITA, 2010). Examples of such cop-outs are the subsidies that have been granted by some developed countries for decades to farmers to protect their national agriculture. Since some agricultural producing countries are adversely affected by these measures, agriculture has been one of the most controversial issues at the WTO. Disagreements over the topic, most notably those opposing developed to developing members, contributed to the long stall in the Doha Round negotiations (BECKER; BLAAS, 2007; NANDA, 2008; GANTZ, 2012).

The interactions between domestic actors are important for any state when it comes to formulating, negotiating and implementing trade agreements. Nevertheless, the level of participation of each branch of government in defining and carrying out trade policies varies from one country to another, even across democracies. In each political system the executive and the legislature play different roles, as determined by either law or customs – or a combination of both (LANTIS, 2005; GOLDSMITH; POSNER, 2005).

The way interest groups participate in foreign policymaking also varies across states. In some countries representatives of societal groups are regularly consulted during trade negotiations and can legally lobby. In other countries their participation is less direct, and lobby is legally interpreted as a form of corruption. In some cases, only representatives of certain economic groups are allowed to directly express their views to public powers.

In a similar vein, the procedures for ratification, such as the minimum number of legislative votes required to approve a treaty and the level of discretion of the executive power, vary across countries as well[25]. Power sharing over foreign policy also varies over time and across issues (MILNER, 1997).

2.3 U.S. domestic laws and institutions for the negotiation and implementation of trade agreements

As we explained in the previous section, each country has laws, institutions and customs in place that guide the negotiation and implementation of trade agreements. In this section we focus on the United States by explaining the main features of the conventional procedures that preceded its accession to international trade agreements during the time frame covered by this dissertation. We specify how agreements between the U.S. public powers meant to facilitate the conclusion of trade agreements were created, and how they have evolved. Finally, we also explain how specific groups of private domestic actors were given the chance to advise federal negotiators and produce reports that were made available to the general public.

[25] Though in some countries presidents can choose not to engage the legislature in international negotiations by signing "executive agreements", this choice can result in political costs, such as legislative retaliations (GOLDSMITH; POSNER, 2005). When legislatures do not agree with an executive agreement it is unlikely that it will approve legal or budgetary changes necessary to implement the international commitment negotiated by the head of the executive branch. Therefore, when legislatures are given the chance to debate, modify, and vote on international agreements, they eventually approve the viable, acceptable ones.

The negotiation of international agreements for the United States is a presidential power, as determined by the U.S. Constitution in article II, section 2: "He [the president] shall have the Power, by and with the advice and Consent of the Senate, to make Treaties, provided two thirds of the Senators present concur […]" (UNITED STATES SENATE, 2017, p. 20).

Since 1962, the government agency responsible for negotiating trade agreements is the "Office of the Special Representative for Trade Negotiations", later renamed "The Office of the United States Trade Representative", whose chief is appointed by the president (SHAPIRO, 2006, p. 11-12). Also known as "USTR", the office provides trade-related advice to the president and to Congress, and monitors – along with the Department of Commerce – trade partners' compliance with their agreements with the United States (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2017).

Article I, section 8 of the U.S. Constitution refers to Congress as a whole by stating that it shall have power to "[…] regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes […]." (UNITED STATES SENATE, 2017, p. 10). Therefore, the House of Representatives also participates in the approval of trade agreements. Even though the U.S. Constitution grants the president the power to reach international "executive agreements" with trade partners on his authority alone, Congress approval is essential because international agreements often require changes to domestic budget or to legislation that can only be enacted if the House and the Senate concur (GOLDSMITH; POSNER, 2005). In this sense, trade agreements can only be effectively implemented by the U.S. if both houses of Congress approve them (FERGUSSON, 2015; MASTEL, 2012; HATHAWAY, 2008).

Following approval by Congress, the president can implement international agreements by proclamation. As regards trade agreements,

> This typically occurs after the USTR has assured the President that the partner country(ies) has made the legislative and regulatory changes necessary to meet all obligations under the trade agreement, and the President exchanges notes with the trading partner government providing for the agreement's entry into force on or after a specific date. (FERGUSSON, 2015, p. 24).

As Congress oversight may be lengthy and even result in requests for changes to trade measures proposed by the executive – further delaying the implementation of the U.S. trade policy –, since the early twentieth century Congress has occasionally granted

significant greater authority to the president. The Reciprocal Trade Agreements Act of 1934 mainly provided leeway for the president to reduce tariffs in place within certain limits; it was reenacted eleven times until 1962 (ANDERSON, 2012, p. 587-590, p. 618, p. 620; SHAPIRO, 2006, p.10-11).

The Trade Act of 1962, valid until 1967, further expanded presidential authority by allowing him to not only reduce tariffs, but also to eliminate them in some circumstances. It also increased Congressional oversight of multilateral trade negotiations by requiring that Senators and Representatives became part of the U.S. negotiating delegations (SHAPIRO, 2006, p. 12).

The range of powers Congress delegated to the U.S. president was substantially enlarged in 1974, when the "fast track" was inserted for the first time in trade law to address the increasingly complex and contentious nontariff barriers (ANDERSON, 2012, p. 618; p. 620; SHAPIRO, 2006, p. 12-14). The fast track is meant to facilitate and accelerate the achievement of trade agreements by the Congressional provision of formal instructions to negotiators. When a fast track is in place, both the executive and trade partners know beforehand what Congress expects from negotiations, including its protectionist sentiments, thereby increasing the chances of negotiation of ratifiable trade agreements (ANDERSON, 2012, p. 583, p. 595, p. 620; SHAPIRO, 2006, p.3).

The specific requirements trade agreements must meet are set in fast track renewals that are periodically enacted by the U.S. Congress. Such reauthorizations are valid for a specific term, set a ninety-day legislative timetable to bring agreements to a vote, and establish that trade agreements must be approved by a simple majority in each house of Congress, thereby specifying the role of the House of Representatives (FERGUSSON, 2015; ANDERSON, 2012; HATHAWAY, 2008; SHAPIRO, 2006; GOLDSMITH; POSNER, 2005; LANTIS, 2005; UNITED STATES SENATE; THE HOUSE OF REPRESENTATIVES OF THE UNITED STATES OF AMERICA, 2002; 1974). Congress also commits to vote on trade agreements straightaway, without amending the original text (SHAPIRO, 2006). Furthermore, the fast track mandates in-depth consultations between the White House and Congress, and requires the participation of Congress members in trade negotiating delegations (ANDERSON, 2012; SHAPIRO, 2006). Therefore, "[…] fast track prevents Congress from amending an agreement, from filibustering it, from bottling it up in a committee, or from otherwise engaging in delaying or other tactics to frustrate an up-or-down vote." (SHAPIRO, 2006, p. 5).

The USTR must consider the instructions contained in fast tracks; otherwise Congress may either refuse to approve trade agreements or demand substantive modifications to them to do so (FERGUSSON, 2015; ANDERSON, 2012; HATHAWAY, 2008; GOLDSMITH; POSNER, 2005; LANTIS, 2005).

In this sense,

> Fast track can be viewed as a political device with both domestic and international functionality. Domestically, it represents a vehicle over which diffuse constitutional power and divergent policy preferences on international trade are arbitraged between Congress and the executive branch. Internationally, fast track sends important signals to potential trading partners about how far, where, and on which issues, the United States is prepared to advance in trade negotiations. (ANDERSON, 2012, p. 611).

Since its creation, the fast track has been renewed six times (1979, 1984, 1988, 1993, 2002, and 2015) (SHAPIRO, 2006; LEWIS, 2015). In 2002, the fast track was rechristened "Trade Promotion Authority" – or simply "TPA" (ANDERSON, 2012). It specified that the submission of bills implementing trade agreements should be accompanied by an explanation from the president about how he deemed the agreement complied with the objectives defined by Congress in the trade law, which included the protection of domestic health and consumer interests. The president also had to submit a report to Congress about the changes to existing laws that would be required to bring the United States into compliance with the agreement (Section 2105(a)) (UNITED STATES SENATE; HOUSE OF REPRESENTATIVES OF THE UNITED STATES OF AMERICA, 2002).

The trade law of 1974 required for the first time the creation of private sector advisory committees (ANDERSON, 2012, p. 590; p. 621). The fast track of 2002 mirrors it by establishing the creation of an advisory trade system encompassing a wide variety of issues (e.g. electronic commerce, chemicals, aerospace equipment, labor, and pharmaceuticals). They produce reports to the president, the USTR, and Congress evaluating trade agreements and making suggestions for future negotiations.

As defined by the fast track of 2002, the committees were required to provide their reports to the president, the Congress and the USTR no more than 30 days after the president notified the Congress of his intention to enter into a trade agreement (Section 2104(e)) (UNITED STATES SENATE; HOUSE OF REPRESENTATIVES OF THE UNITED STATES OF AMERICA, 2002).

One such committee concerns specifically intellectual property rights. It was originally called "Industry Functional Advisory Committee 3" (IFAC-3). In 2004 its name was changed to "Industry Trade Advisory Committee 15" (ITAC-15) (INTERNATIONAL TRADE ADMINISTRATION, 2019). The committees are composed of representatives of companies that either produce goods which are usually protected by intellectual property rights – e.g. pharmaceuticals, audiovisuals, software, hardware, electronic equipment, wines, spirits, and published materials – or represent them in court for intellectual property cases[26].

Most preferential trade agreements currently in force for the U.S. were negotiated and ratified under TPA instructions. Congress granted a TPA to the Bush administration in January 2002, valid until June 01, 2005, including tighter than ever limitations to the presidential discretion (ANDERSON, 2012, p. 620).

The term of the TPA would be automatically extended until July 01, 2007 if the president requested so and Congress did not disapprove it, which happened in June 2005 (UNITED STATES SENATE; THE HOUSE OF REPRESENTATIVES OF THE UNITED STATES, 2002; OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2005a, 2005b, SHAPIRO, 2006). Under this specific set of Congressional instructions, the Bush administration negotiated twelve preferential trade agreements. Simultaneously, the WTO Doha Round negotiations stalled and U.S. efforts to create regional free trade areas in Latin America and the Asia-Pacific gradually failed (DENT, July 2013; CHOREV, 2007).

Though the 2002 fast track and its renewal made the approval of trade agreements more likely, in 2007 Congress required the inclusion of additional provisions on labor, the environment, and intellectual property in trade agreements. The USTR had to renegotiate some parts of the agreements with Peru and Colombia to adjust them to the new legislative instructions, so that they could be eventually ratified. The USTR also had to mind these instructions to conclude the negotiations with Panama. These new requirements were made by Democratic members of Congress, as they became the majority in both the House of Representatives and the Senate as a result of the 2006 mid-term elections[27]. Up to that point Bush had governed with Republican majorities in Congress (BENTES et. al., 2008).

[26] Information about the IFAC-3 and the ITAC-15 is available on the USTR's website (https://ustr.gov/trade-agreements/free-trade-agreements , accessed June 10, 2016).

[27] We will explain these requirements in greater detail in chapter three.

Such new requirements demonstrate that even though TPAs provide a greater degree of predictability to the U.S. trade policy, shifts in party control or opinion in Congress can still lead to demands for adjustments to trade agreements (ANDERSON, 2012). Also, both houses of Congress can alter or revoke fast tracks at any time and for any reason (SHAPIRO, 2006).

The formation of this significant group of Democrats who were opposed to several aspects of trade agreements under debate for approval is worth academic attention because its requirements resulted in the negotiation of intellectual property standards that are in many regards different from those included in previous U.S. trade agreements, which includes several provisions on pharmaceuticals. Nevertheless, the academic literature about this and other aspects of the U.S. trade policy over the period covered by this dissertation does not properly address the role of the U.S. domestic actors.

In fact, most previous academic approaches to the subject focus on the international level. Evenett and Meier (2008), Weatherall (2011), Manger and Shadlen (2014), and Menezes (2015) explain how failed multilateral and regional trade negotiations impacted on the U.S. decision to pursue trade agreements with fewer partners. Cox (2008) and Braun (2012) take the domestic side into account when analyzing specific trade agreements, but they do not focus on pharmaceuticals. Drahos et al. (2004) discuss how the Australian public system of pharmaceutical procurement could be disrupted by the intellectual property rights chapter included in the preferential trade agreement between Australia and the U.S., but they do not investigate in depth the role of the U.S. Congress and the private advisory committee on intellectual property rights.

Deere (2009) asserts that interest groups in the U.S. influence the formulation and enforcement of trade policies, including those related to intellectual property rights. Nevertheless, she provides a general appraisal of such interferences and does not focus on the complex interactions between those actors, Congress and the federal administration. The main objective of her book is to explain how developing countries have reformed their domestic intellectual property rights systems due to the TRIPS and to TRIPS-Plus trade and investment agreements.

Since these authors do not analyze in depth the domestic side of the creation of trade agreements, there is room for research about the role of the U.S. domestic actors in negotiating and implementing trade-related intellectual property provisions, particularly regarding pharmaceuticals. This dissertation aims to address this shortcoming.

2.4 Conclusion: Congress and intellectual property advisory committees on intellectual property: relevant actors at the U.S. domestic level

As we explained in section 2.1, domestic politics matter for international relations. The definition of policies that will be carried out at the international level, the negotiation of international agreements, the implementation of commitments with foreign partners, and the adjustment of international agreements all depend on the political preferences that prevail at the domestic level.

As regards trade agreements, each country has specific laws, institutions, and customs in place to define which actors have deciding powers and which ones can advise decision-makers, as we explained in section 2.2. Trade agreements can be very controversial because though they usually benefit competitive economic sectors, they can result in economic losses to import-competing sectors, at least in the short term. In the same vein, manufactures of products that usually rely on intellectual property rights – such as pharmaceuticals – will approve of the diffusion of strict intellectual property rights, while domestic actors that advocate for open access to knowledge – such as NGOs – will voice support for flexible rights.

In the United States, the president, Congress and specific private advisory committees have their roles defined by the Constitution and the trade law. The president directs the USTR, a specialized agency that deals with the negotiation and enforcement of trade agreements.

Both the president and Congress have veto power over trade agreements. When government is divided, the implementation of trade agreements depends on negotiations between the executive and the legislature. Foreign partners must agree with any changes to trade agreements, which makes expanding trade liberalization an even more complicated task for the United States.

Moreover, through fast tracks Congress defines the trade-related goals the president must pursue. Members of Congress may become part of trade negotiating delegations. Congress also may request adjustments to trade agreements whose negotiations have already been concluded to approve them. Therefore, the Congress is a vital domestic actor for the implementation of trade agreements by the United States. Research on U.S. trade policies must mind its behavior.

Preferences regarding the intellectual property rights protection for pharmaceuticals included in preferential trade agreements may vary across domestic

interest groups in the U.S. Nevertheless, only a small subset of them advises the USTR and produces reports that are made available to the public by the federal government. This group makes up the official industry advisory committees on intellectual property rights. Therefore, their views are exceptionally important because they are privileged as compared to other domestic societal actors. They also represent innovative pharmaceutical companies that rely on patents and other kinds of protections for intellectual property rights.

As we explained in section 2.3, research on U.S. trade policies have disregarded the importance of the interactions between these domestic actors, despite their theoretical and factual importance. In other words, previous academic approaches did not pay enough attention to the views expressed by members of Congress and by the official advisory committees. This dissertation contributes to filling this gap by analyzing the reports produced by the latter and the statements delivered by the former on the floor. Annex 1, on pages 127 and 128 summarizes the primary data we rely on, how we use them in this dissertation, and their main sources.

We consider the 2001 – 2012 period because that was when the U.S. implemented most trade agreements currently in force. In fact, the last signature into law of a brand-new trade agreement by the United States took place in 2012. After that, the only comprehensive trade agreement reached by the United States has been the USMCA, which is the result of the renegotiation of NAFTA. Since 2001, the provisions on pharmaceuticals have also become increasingly important due to multilateral debates on access to medicines and to domestic demands in the U.S. for policies that reduce the price of pharmaceuticals.

We start that analysis in the next chapter, where we investigate the views on intellectual property rights related to pharmaceuticals of the U.S. Congress members. In each section we present the main topics debated by legislators. We also identify patterns in their statements and describe how they tapped into contributions by domestic societal actors. Finally, we explain how the party control of Congress following the 2006 mid-term elections led to adjustments to the provisions on pharmaceuticals included in the trade agreements with three Latin American countries.

3 CONGRESSIONAL VIEWS ON INTELLECTUAL PROPERTY RIGHTS RELATED TO PHARMACEUTICALS INCLUDED IN PREFERENTIAL TRADE AGREEMENTS

Several issues related to the intellectual property protection for pharmaceuticals drew the attention of members of the U.S. Congress and private advisory committee members from 2001 to 2012. We focus on data from these years for three reasons. The first is the emergence of access to medicines as the main topic of discussions related to intellectual property rights at the World Trade Organization. As we explained in the introduction, the TRIPS is one of the founding agreements of the WTO and has been effective since the Organization entered into force in 1995.

Even though it sets minimum standards for the protection of pharmaceuticals, it also includes flexibilities aimed at addressing emergencies. Since these flexibilities are very vague, two interpretations consolidated among the WTO members. One group of countries supported the TRIPS flexibilities, emphasizing that strict intellectual property rights could prevent low-income patients from accessing affordable medicines, most notably those in developing and least-developed countries with insufficient pharmaceutical production.

Another group of countries viewed the TRIPS Agreement as a necessary backstop for costly investments made by innovative companies, including the pharmaceutical sector. They supported the maintenance of or expansions to the TRIPS standards and emphasized that the intellectual property rights stimulate the development of new products and processes.

This schism came to the spotlight in 2001, when a group of developing countries demanded that the Council for TRIPS debated about which interpretation of the TRIPS Agreement should prevail. They also pushed for a technically viable and TRIPS-compliant mechanism to allow for the production and exportation of medicines under compulsory licenses for countries that were facing public health emergencies but had no or insufficient pharmaceutical production. Though their proposals aimed at addressing any emergencies in public health, the main issue driving the negotiations at the time was the HIV/AIDS epidemic and the legal challenges some developing countries had been facing to issue compulsory licenses for the production of patented antiretrovirals[28].

[28] On disagreements between the U.S. and the E.U. with Brazil, South Africa, and Thailand in the late 1990s and early 2000s see World Trade Organization (2001a); Gueniff; Mfuka (2003); Sell (2003); Sell; Prakash (2004); Sell; Odell (2006); Chorev (2007); Castro; Westerhaus (2007).

These negotiations resulted in the adoption of the Doha Declaration on the TRIPS Agreement and Public Health by the WTO members. Over time other legal developments related to the Declaration were reached at the WTO. Throughout these negotiations, the U.S. and other developed countries supported the maintenance of the TRIPS standard or the negotiation of solutions aimed at addressing specific epidemics. Therefore, they rejected the approach supported by developing and least-developed countries, that aimed at facilitating the production and international distribution of any pharmaceuticals under compulsory licenses to address public health emergencies.

The negotiations attracted public attention to the HIV/AIDS epidemic and to potential solutions, which strengthened the positions advanced by a coalition of developing and least-developed countries. The eventual solution largely addressed their demands. Therefore, the U.S. diplomacy had been finding it increasingly difficult to preserve the TRIPS standard at the multilateral level. Moreover, these contentious negotiations also suggested that the WTO would not be the ideal forum for pushing for stricter and more specific intellectual property rights, either.

In addition to these multilateral setbacks, the U.S. was unable to advance its trade agenda at the regional level. Most notably, the negotiations on the Free Trade Area of the Americas and the Free Trade Area of the Asia-Pacific failed. As a result of that, the Bush administration decided to reach preferential trade agreements with fewer partners instead (SCHOTT, 2004; CHOREV, 2007; KRIKORIAN; SZYMKOWIAK, 2007; CORREA, 2008; DÍAZ, 2008; DEERE, 2009; GILLMAN, 2009; MICARA, 2012; DENT, July 2013). That leads to the second reason for our focus: the unprecedented proliferation of U.S. preferential trade agreements from 2001 to 2012. During this period, the U.S. implemented trade agreements with seventeen nations. Until 2000, only Israel, Canada, and Mexico had comprehensive preferential trade agreements in force with the U.S.

The third reason for our focus is the fact that most of the trade agreements negotiated and implemented over the period covered by this dissertation were guided by the same set of standards. Such guidelines were defined by Congress in the trade law of 2002 and in subsequent amendments to it. They were valid even for the agreements signed into law by President Barack Obama.

Vote and opinion patterns in Congress are not determined a priori by party affiliation because its members vote individually and may state their own particular views

on the floor when debating trade agreements. In addition, some members of the private advisory committees were much more sensitive to the intellectual property rights applied to pharmaceuticals than their counterparts; their views also differed from those of some members of Congress. This context gives rise to some questions:

- Was there coincidence between the legislative determinations and the opinions expressed by interest groups to the USTR as regards intellectual property rights related to pharmaceuticals?

- In case of persistent disagreement between the advisory committees on intellectual property and the majority in Congress, which view prevailed in the final agreements?

- Did Congress members directly mention groups interested in intellectual property rights, other than the ones part of the USTR's intellectual property rights advisory committees? Which ones were more frequently mentioned?

- Were there clear party divisions when it comes to supporting the intellectual property rights chapters and requesting adjustments aimed at improving access to pharmaceuticals?

These questions are worth academic attention because they provide insights into the level of influence of each of these domestic actors on the U.S. trade treaty-making. The questions also relate to access to pharmaceuticals in developing countries, an important issue that has been receiving special attention by both scholars and policymakers that deal with trade (see e.g. ABBOTT, 2002; SELL, 2003, 2007; CORREA, 2005; NOEHRENBERG, 2006; SELL AND ODELL, 2006; DÍAZ, 2008; DEERE, 2009; THRASHER; GALLAGHER, 2010; TANG; TEODORO, 2016). Moreover, to the best of our knowledge, the primary sources we have analyzed had not yet been considered in tandem and in depth, whereby this dissertation provides contributions to the literature on the topic.

We collected the statements made by Congress members from the Congressional Record, which is run by the U.S. Library of Congress[29]. We searched for the keywords ["intellectual property rights" AND trade] on May 02, 2018, at 10:30. Then we narrowed the results down to the documents issued from 2001 to 2012 and screened those labeled as "Congressional Record", "Treaty Documents", "House Communications", and

[29] Available at: <https://www.congress.gov/congressional-record>.

"Senate Communications" to select the ones that relate to preferential trade agreements. It yielded 593 hits. Finally, we selected all statements where members of Congress state views on intellectual property rights protection for pharmaceuticals[30]. Such selection included the statements by members of both houses of Congress and from all political parties.

We also analyze two documents issued by the U.S. Congress that set guidelines the executive had to take into account when negotiating trade agreements: the Trade Promotion Authority Act of 2002 (UNITED STATES SENATE; THE HOUSE OF REPRESENTATIVES OF THE UNITED STATES OF AMERICA, 2002) and the bipartisan agreement between Congress and the presidency, reached in May 2007 (WAYS AND MEANS COMMITTEE, 2007; OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2007k).

In the subsections ahead (3.1 to 3.5) we categorize the mentions of intellectual property rights protection for pharmaceuticals in Congress, highlighting the main discussions and pointing out patterns and deviations. As we explained in section 2.3, the diffusion of U.S.-like intellectual property rights through trade agreements and the respect to the Doha Declaration were among the objectives defined by the trade law of 2002. Such law also required the president to mind domestic health and consumer interests.

Though aspects of the trade law of 2002 are very detailed – such as tariffs on specific products –, the objectives related to intellectual property rights are vague, imprecise. Therefore, different interpretations of the trade law were expressed in Congress during the debates that led to the eventual approval of trade agreements. Members of Congress directly referred to these objectives when debating about the prospects of parallel importation of pharmaceuticals into the U.S. and about the Doha Declaration, as we will explain in sections 3.1 and 3.2. The trade law also established the creation of industry advisory committees; in section 3.3 we summarize the views in Congress about them. Congress members also debated about the likely impacts of the trade agreements on access to pharmaceuticals in developing countries in general and in the trade partners. We turn to that in section 3.4.

In section 3.5 we explain how disagreements between the federal administration and the Congress over intellectual property protection for pharmaceuticals led to the renegotiation of trade agreements with three Latin American countries. We conclude in

[30] As we explained in the introduction, the statements delivered from 1995 to 2000 were also analyzed; the outcomes of such analysis are described in the article in "Annex 2".

section 3.6 by summarizing the main findings of this chapter. We also explain what they reveal about the importance of the Congress in trade policy making and about the significance of pharmaceuticals for the U.S. trade policy.

3.1 Importation of pharmaceuticals

Several trade agreements included provisions that could limit the ability of the United States and her preferential trade partners to import brand-name pharmaceuticals. The agreement with Australia, for example, determines in article 17.9.4 that:

> Each Party shall provide that the exclusive right of the patent owner to prevent importation of a patented product, or a product that results from a patented process, without the consent of the patent owner shall not be limited by the sale or distribution of that product outside its territory, at least where the patentee has placed restrictions on importation by contract or other means. (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2004a, p.15).

On the other hand, the TRIPS Agreement openly states in article six that each member country is free to decide whether patent holders should be allowed to prevent importations of protected products (WORLD TRADE ORGANIZATION, 2017b, p.4).

Even though at the time pharmaceutical patent holders could prevent importations of their products into the U.S., bills under consideration in Congress aimed at allowing importations of pharmaceuticals to reduce domestic prices. Therefore, several members of Congress considered that the provisions included in the preferential trade agreements might affect the ability of Congress to change legislation on the topic. In this sense, House member Henry Waxman (D-CA) considered that pharmaceutical companies were trying to affect health policies in both the U.S. and her trade partners by including importation provisions in trade agreements (U.S. GOVERNMENT PUBLISHING OFFICE, Sep. 08, 2004)[31].

House member Louise Slaughter (D-NY) considered that provisions included in the trade agreements with Jordan, Chile, Singapore, Australia, Morocco and the CAFTA-DR due to the influence of pharmaceutical industries could prevent the importation of generic medicines or low-cost brand-name drugs into the U.S. (U.S. GOVERNMENT

[31] Henceforth we identify the party and state of each member of Congress in parentheses following their names. Republicans are identified by "R", Democrats by "D", and Independents by "I". We rely on the state abbreviations used by the United States Postal Service (available at: https://pe.usps.com/text/pub28/28apb.htm, accessed on Oct. 03, 2019).

PUBLISHING OFFICE, July 22, 2004, p. H6570). Senator Edward Kennedy (D-MA) expressed a similar view as regards the trade agreements with Singapore and Australia (U.S. GOVERNMENT PUBLISHING OFFICE, July 15, 2004). House member Maxime Waters (D-CA) stated that the agreement with Singapore would prevent the South-East Asian country from practicing parallel importation and issuing compulsory licenses, which could increase the costs of medicines (U.S. GOVERNMENT PUBLISHING OFFICE, July 24, 2003)[32].

House members James McGovern (D-MA), Fortney Stark (D-CA), Sherrod Brown (D-OH), and Senators Charles Schumer (D-NY), Richard Durbin (D-IL), Herb Kohl (D-WI), and Barbara Mikulski (D-MD) considered that provisions related to pharmaceuticals were included in the agreement with Morocco due to the improper influence of pharmaceutical companies on the negotiations[33]. They asserted that setting the U.S. policy on importation of pharmaceuticals should be a Congressional prerogative instead (U.S. GOVERNMENT PUBLISHING OFFICE, July 14, 2004; July 15, 2004; July 22, 2004)[34].

In this sense, House member Sherrod Brown (D-OH) considered that the provisions had been included in the trade agreement because the Bush administration had "fronted for and assisted in drug industry abuses" due to money pharmaceutical industries had given to President Bush and to the Republican leadership (U.S. GOVERNMENT PUBLISHING OFFICE, July 22, 2004, p. H6641).

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[32] As we explained in footnote seven, countries that have in place international exhaustion regimes of intellectual property rights – also known as "first sale regimes" – do not allow right holders to prevent exports or imports of patented products that have already been legally sold. In this sense, parallel importation refers to legal international trade of patented products, even if patent holders oppose it (NOEHRENBERG, 2006, p. 171). Such regimes allow for the acquisition of patented medicines in the international market at the lowest prices (ABBOTT, 2002, p. 497). In the United States, a national exhaustion regime prevailed until very recently (SELL, 2007, p. 61). Nevertheless, Supreme Court decisions on importation of patented electronics (2017) and books protected by copyrights (2013) were based on the international principle, setting precedents for similar interpretations regarding other products (ABBOTT, 2017a, 2017b; BARRACLOUGH, 2017).

[33] Senator Kohl (D-WI) further considered that the benefits for the pharmaceutical industries had only been achieved because of tradeoffs that could negatively affect other industries, such as dairy (U.S. GOVERNMENT PUBLISHING OFFICE, July 15, 2004).

[34] Representative Fortney Stark (D-CA) refers directly to PhRMA as a trade association that had been causing the USTR to prioritize the interests of the pharmaceutical industries over the health care of Americans (U.S. GOVERNMENT PUBLISHING OFFFICE, July 14, 2004, p. H5699; Dec. 07, 2005, p. H11169). Created in 1958, the Pharmaceutical Research and Manufacturers of America (PhRMA) is composed of 35 pharmaceutical and biotech companies (PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, 2019). It was a member of the advisory committee that analyzed the agreements with Chile, Singapore, Morocco, Australia, the CAFTA-DR members, and Bahrain (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2003b, 2003d, 2004c, 2004f, 2004i, 2004m).

In a similar vein, House member Dennis Kucinich (D-OH) considered that the agreement with Morocco would prohibit the importation of lower-cost pharmaceuticals, which – along with protections for test data – would maintain high prescription drug prices in the U.S. (U.S. GOVERNMENT PUBLISHING OFFICE, July 22, 2004)[35]. House member Fortney Stark (D-CA) was also concerned about the importation provisions included in the agreement, which could impact access to pharmaceuticals in both the U.S. and Morocco, especially during public health emergencies. He considered that such impact could also be caused by protections for test data, compulsory licensing, and other market exclusivity provisions[36]. He also stated that the inclusion of the provisions was due to the fact that the administration had been ignoring Congressional instructions and acting on behalf of pharmaceutical industries because of their large campaign donor status (U.S. GOVERNMENT PUBLISHING OFFICE, July 22, 2004, p. H6649).

The Democrats who criticized the importation provisions were joined by Republicans both from the House and the Senate. As for the former, Gilbert Gutknecht (R-MN) considered that Congress was still debating bills about importation of pharmaceuticals, whereby the USTR should not negotiate provisions about the issue with trade partners. He also stated that the importation provisions had been included in the agreement with Australia because the USTR advisory committee on intellectual property included representatives of the pharmaceutical industry, while senior, consumer, or market access advocates provided no inputs during the negotiations. He further considered that Australia would be allowed to pursue dispute settlement proceedings in case the bills about importation of pharmaceuticals eventually became effective in the United States (U.S. GOVERNMENT PUBLISHING OFFICE, July 14, 2004)[37].

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[35] "Test data" refers to data on safety and efficacy required by health authorities to grant marketing approval for pharmaceutical products, which may also apply to products that are not protected by patents. The preferential trade agreements with Peru, Colombia, and Panama require a term of protection of "usually" five years. The other agreements require a 5-year minimum term of protection (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2003a, 2003c, 2004a, 2004d, 2004g, 2004k, 2006a, 2006d, 2006g, 2007a, 2007g).

[36] See introduction for a definition of "compulsory license".

[37] The U.S. preferential trade agreements contain chapters on investment that allow private parties to pursue dispute settlement proceedings against member states in cases that could be described as expropriations. Nevertheless, the agreements specify that compulsory licenses that comply with the TRIPS and the preferential trade agreements' intellectual property rights chapters may not be challenged through such proceedings. Moreover, the investment chapters state that nondiscriminatory regulatory actions aimed at protecting public health cannot be regarded as expropriations. Examples of such provisions can be found e.g. in article 11.7 of the Australian agreement and in article 10.7 of the Panamanian agreement (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2004a, 2007g). The agreement with Bahrain does not include a chapter on investments. The bilateral investment

As regards the Senate, John McCain (R-AZ) was very vocal against the importation provisions included in the preferential trade agreements with Singapore, Australia, and Morocco. His remarks mirrored those of the Democrats in that he considered that the agreements could impair Congress' ability to pass legislation on the importation of pharmaceuticals. He stated that the provisions were included in the trade agreements to protect "powerful special interests", and that they could block American consumers from accessing lower-cost pharmaceuticals (U.S. GOVERNMENT PUBLISHING OFFICE, July 15, 2004, p.S8198). He also stated that the agreements contravened Congressional intent because Congress had recently enacted laws that facilitated the importation of medicines under certain circumstances. In addition, Senator McCain (R-AZ) considered that states, cities, and counties too had been trying to address the rise in costs of drugs.

McCain's remarks were also aligned with those of Democrats who stated that the provisions on importation had been created because the IFAC-3 was composed of representatives of pharmaceutical industries and other lobbyists, while no consumer or advocacy groups were included in the committee (U.S. GOVERNMENT PUBLISHING OFFICE, July 15, 2004; July 21, 2004). He mentioned specific domestic actors when debating the issue: "An overwhelming majority of Americans believe they have a right to import cheaper medicine. AARP, the leading advocacy group for senior citizens, recently joined the battle." (U.S. GOVERNMENT PUBLISHING OFFICE, July 15, 2004, p. S8199). He also considered that the Bush administration was not abiding by the Trade Act of 2002 because it had been protecting the special interests of pharmaceutical companies, and that no future trade agreements should include such provisions on importation (U.S. GOVERNMENT PUBLISHING OFFICE, July 15, 2004; July 21, 2004)[38].

treaty between the U.S. and Bahrain does not mention compulsory licenses or includes a similar exception related to public health (OFFICE OF THE U.S. TRADE REPRESENTATIVE, 2004k; U.S. DEPARTMENT OF STATE, 2001).

[38] The Trade Act of 2002 requires that trade agreements entered into by the United States reflect a standard of protection for intellectual property rights similar to that found in the U.S. law and ensure that American right holders are able to prevent unauthorized uses of their works (UNITED STATES SENATE; THE HOUSE OF REPRESENTATIVES OF THE UNITED STATES OF AMERICA, 2002, Sec. 2102 (b)(4)(A)). It also establishes that the president should mind the protection of domestic health and consumer interests when taking actions to address and maintain the U.S. economic competitiveness (UNITED STATES SENATE; THE HOUSE OF REPRESENTATIVES OF THE UNITED STATES OF AMERICA, 2002, Sec. 2102 (c)(6)). As we explain in greater detail in session 3.2, the Act also addressed the availability of pharmaceuticals in developing countries.

On the other hand, House member David Dreier (R-CA) approved of the importation provisions included in the agreements with Singapore and Australia (U.S. GOVERNMENT PUBLISHING OFFICE, July 14, 2004). According to him, the U.S. would not be prevented from importing low-cost medicines from Australia because Australian law itself prohibited exportation of medicines without the authorization of patent holders (U.S. GOVERNMENT PUBLISHING OFFICE, July 14, 2004). He further stated that the agreement with Australia could not prevent Congress from changing legislation – which would be a Constitutional prerogative – and that the agreement would not require changes to the U.S. patent law or to the Federal Food, Drug and Cosmetic Act. In addition, he dismissed concerns over lack of consideration for the will of Congress by pointing out that the USTR had consulted with a bipartisan group of members from both the House and the Senate during the negotiations of the trade agreement (U.S. GOVERNMENT PUBLISHING OFFICE, July 14, 2004, p. H5666)[39].

Two Democrat House members from Texas, Gene Green and Sheila Jackson-Lee, expressed a view similar to Dreier's when it comes to the impacts of the Australian agreement on the importation of pharmaceuticals into the U.S., while also emphasizing that the provisions should not be set as a precedent for future agreements (U.S. GOVERNMENT PUBLISHING OFFICE, July 14, 2004). House member Sander Levin (D-MI) and Senators Carl Levin (D-MI) and James Jeffords (I-VT) expressed similar views (U.S. GOVERNMENT PUBLISHING OFFICE, July 14, 2004; July 15, 2004)[40].

Senator Charles Schumer (D-NY) replied to Dreier's dismissals by stating that the importation provisions in the Australian agreement had been included because of the influence of the IFAC-3 and that:

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[39] In fact, section 2107 of the Trade Act of 2002 required the creation of a bipartisan Congressional Oversight Group to advise the USTR during the negotiation of trade agreements. It should be composed of five members of the House and five of the Senate. The chairman and ranking member of every committee that had jurisdiction over provisions negotiated with foreign countries should also be part of the Group. As for its activities, section 2107 established that "The Congressional Oversight Group shall consult with and provide advice to the Trade Representative regarding the formulation of specific objectives, negotiating strategies and positions, the development of the applicable trade agreement, and compliance and enforcement of the negotiated commitments under the trade agreement." (UNITED STATES SENATE; THE HOUSE OF REPRESENTATIVES OF THE UNITED STATES OF AMERICA, 2002, Section 2107 (a)(4)). It also establishes that the president should meet with the Group before initiating negotiations or during the negotiations if the Congressional Oversight Group so requested (UNITED STATES SENATE; THE HOUSE OF REPRESENTATIVES OF THE UNITED STATES OF AMERICA, 2002, Section 2107).

[40] Senator Jeffords (I-VT) also stated that he did not think the agreement with Australia would require any changes in U.S. pharmaceutical purchasing programs (U.S. GOVERNMENT PUBLISHING OFFICE, July 15, 2004, p.S8207).

> If this provision [on importation] has no practical effect in this trade agreement, then its only purpose must be to make it more difficult to pass a drug importation bill. It can and might become precedential—we have it in Australia; we should put it elsewhere. The provision was put in the Australia Free Trade Agreement to set a precedent, to lay the groundwork. (U.S. GOVERNMENT PUBLISHING OFFICE, July 15, 2004, p. S8197).

As regards the CAFTA-DR, House member Sherrod Brown (D-OH) considered that the administration – with the help of the USTR and Republican members of the House – had been including provisions on importation of medicines in trade agreements, which contributed to keeping prices of prescription drugs at high levels. Moreover, he considered that Congress should not have to monitor trade agreements so closely because the USTR should be acting in the best interests of American consumers in the first place:

> Congress should not have to scour every trade pact to make sure that some patent extension or importation barrier or other Big Government crutch designed specifically for the drug industry has not been inserted into the trade agreement by the U.S. trade representative or by the President or by my friends on the other side of the aisle. (U.S. GOVERNMENT PUBLISHING OFFICE, June 09, 2005, p. H4312).

Table 1, on the following pages, summarizes the views of members of Congress about the provisions on importation of pharmaceuticals included in the preferential trade agreements.

Table 1: Summary of views of members of the U.S. Congress on provisions related to importation of pharmaceuticals included in preferential trade agreements (2001 – 2012)

	Against influence of pharmaceutical companies	Against provisions that restrict importation of pharmaceuticals into the U.S.	Against provisions that restrict importation of pharmaceuticals into trade partners	Criticize campaign donations	Criticize federal government for ignoring Congressional instructions	Criticize the industry advisory committee	State that agreements will not impact the U.S. ability to import pharmaceuticals
Democrats	Barbara Mikulski (S – MD), Charles Schumer (S – NY), Edward Kennedy (S – MA), Fortney Stark (H – CA), Henry Waxman (H – CA), Herb Kohl (S – WI), James McGovern (H – MA), Louise Slaughter (H – NY), Richard	Dennis Kucinich (H – OH), Edward Kennedy (S – MA), Fortney Stark (H – CA), Henry Waxman (H – CA), Louise Slaughter (H – NY)	Fortney Stark (H – CA), Henry Waxman (H – CA), Maxime Waters (H – CA)	Fortney Stark (H – CA), Sherrod Brown (H – OH)	Fortney Stark (H – CA)	Charles Schumer (S – NY)	Carl Levin (S – MI), Gene Green (H – TX), Sander Levin (H – MI), Sheila Jackson-Lee (H – TX)

	Durbin (S – IL), Sherrod Brown (H - OH)						
Republicans	Gilbert Gutknecht (H – MN), John McCain (S – AZ)	John McCain (S – AZ)	-	-	Gilbert Gutknecht (H – MN), John McCain (S – AZ)	Gilbert Gutknecht (H – MN), John McCain (S – AZ)	David Dreier (H – CA)
Independents	-	-	-	-	-	-	James Jeffords (S – VT)

Based on statements delivered in Congress. Data from Congressional Record (2001 – 2012). Names of members of Congress are in alphabetical order and are followed by the house they are part of (H = House of Representatives; S = Senate) and by the abbreviation of the state they represent.

3.2 Doha Declaration

As we explained in the introduction, the Doha Declaration was adopted by consensus at the World Trade Organization due to negotiations requested by a group of developing countries. It clarifies the meaning of provisions in the TRIPS Agreement related to trade of pharmaceuticals produced under compulsory licenses. It is also meant to facilitate public strategies to address crises in public health and other urgent circumstances, especially by countries with insufficient pharmaceutical production.

The connections between the preferential trade agreements and the Doha Declaration were pointed out by several members of Congress. House member Maxime Waters (D-CA) considered that the trade agreement with Singapore would prevent Singaporeans from having access to medicines for HIV/AIDS and other diseases (U.S. GOVERNMENT PUBLISHING OFFICE, July 24, 2003). She blamed the Bush administration's disregard for Congressional instructions for the negative impacts of the trade agreement on the protection of public health:

> We cannot trust this administration to negotiate free trade agreements with developing countries when the administration ignores the explicit instructions of Congress in the Fast Track bill to respect the Doha Declaration and allow developing countries to take appropriate measures to protect public health. (U.S. GOVERNMENT PUBLISHING OFFICE, July 24, 2003, p. H7505)[41].

In the same sense, House member Henry Waxman (D-CA) stated that the large multinational pharmaceutical industries were advancing their financial interests by undermining the Declaration and promoting health policy changes through trade agreements such as CAFTA, the ones negotiated with Morocco and Bahrain, and the ones under negotiation with the Andean nations and Panama[42]. He mentions the provisions on

[41] The Trade Promotion Authority Act of 2002 includes the respect to the Doha Declaration among the United States' principal negotiating objectives regarding intellectual property rights (UNITED STATES SENATE; THE HOUSE OF REPRESENTATIVES OF THE UNITED STATES OF AMERICA, 2002, Sec. 2102 (b)(4)(C)). Senator Edward Kennedy (D-MA) stated that he and Senator Dianne Feinstein (D-CA) had requested the inclusion of such provision in the fast track, but that the administration had been refusing to fulfill it. In this sense, he complained that the administration was seeking standards for intellectual property protection and enforcement abroad as requested by the 2002 Act, while ignoring other aspects of it (U.S. GOVERNMENT PUBLISHING OFFICE, Feb. 16, 2005). On the Trade Act of 2002's provisions on intellectual property rights and other objectives related to pharmaceuticals, see footnote 38.

[42] Four Andean countries, Colombia, Peru, Ecuador and Bolivia, started the negotiation of a single preferential trade agreement with the U.S., but Ecuador and Bolivia later decided to discontinue negotiations. Peru and Colombia negotiated separate, individual agreements with the United States (DEERE, 2009, p. 217; 223).

test data protection, compulsory licensing, and enforcement as examples of that. Such policies would make it harder for developing countries to respond to public health crises. He also stated that the administration was not abiding by the fast track of 2002 because it was contravening the Doha Declaration (U.S. GOVERNMENT PUBLISHING OFFICE, Sep. 08, 2004; July 27, 2005; Dec. 07, 2005).

To support his view, Representative Waxman (D-CA) endorsed a report produced by the minority staff on the Government Reform Committee about the performance of the administration as regards the Doha Declaration. It concluded that the agreements the U.S. trade negotiators had reached with Chile, Australia, Singapore, Morocco, the Central American nations, and Bahrain – as much as the one under negotiation with the Andean countries – restrict the ability of developing nations to acquire affordable medicines. The provisions that caused that would be the ones regarding market exclusivity, patent extensions due to delays in the regulatory approval process, linkage between patent status and market approval, enforcement of patents, compulsory licensing, and parallel importations[43]. It also emphasized that the agreement under negotiation with the Andean nations required member countries to issue patents for diagnostic, therapeutic, and surgical methods that were exempted from patentability up to that point (U.S. GOVERNMENT PUBLISHING OFFICE, July 27, 2005) [44].

In the same vein, House members Fortney Stark (D-CA) and Thomas Allen (D-ME) asserted that such interference of large pharmaceutical companies on the intellectual property rights included in the U.S. preferential trade agreements might undermine the Doha Declaration, impact the production of generic medicines, extend patent terms, raise drug prices, and prevent developing countries from addressing public health problems. Representative Allen (D-ME) also emphasized that the administration had been ignoring Congress will by prioritizing the views of pharmaceutical companies over the Doha Declaration. In the same vein, Representative Stark (D-CA) considered that the USTR

[43] For definitions of "parallel importation" and "test data" see footnotes 32 and 35. Article 14.8.6(a) of the trade agreement with Bahrain is an example of provision requiring the concession of additional terms of protection to patent holders to compensate for unreasonable delays that occur in patent granting (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2004k). Linkage refers to situations where drug regulatory authorities are mandated to determine the validity of patents as a condition of granting marketing approvals, which adds an additional bureaucratic requirement for the production of generic pharmaceuticals (U.S. GOVERNMENT PUBLISHING OFFICE, July 27, 2005; DÍAZ, 2008, p. 192). One example of such provision can be found in the preferential trade agreement with Singapore in article 16.8.4(c) (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2003c).

[44] The final agreements with Peru and Colombia do not include such provisions (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2006d, 2006g).

should no longer help pharmaceutical companies to obtain their preferred policies because, though their impacts on Bahrain's access to medicines could be limited, the same was not true for countries at lower levels of development (U.S. GOVERNMENT PUBLISHING OFFICE, July 24, 2003; Sep. 08, 2004; July 27, 2005; Dec. 07, 2005; Mar. 26, 2007).

House member Henry Waxman (D-CA) made a similar point by stating that though the agreement with Bahrain contravened the Doha Declaration, it would not diminish access to care because the middle-Eastern trade partner had a good public healthcare system, a relatively small population, and a low incidence of infectious diseases, unlike the Andean countries (U.S. GOVERNMENT PUBLISHING OFFICE, Dec. 07, 2005).

When debating the trade agreements already reached by the Bush administration at the time and the agreements under negotiation, Senator Edward Kennedy (D – MA) stated that the administration had been systematically blocking Congress from changing intellectual property rights because it was promoting the interests of brand-name drug companies instead[45]. He considered that the administration had been failing to abide by the Doha Declaration because it was including provisions on parallel importations, test data protection, and compulsory licensing in preferential trade agreements. Such inadequate clauses would negatively affect access to both patented and generic drugs in developing countries, including new treatments for HIV/AIDS. He also considered that the administration had not included provisions that reinstated the trade partners' ability to grant Bolar-type exceptions for patents, which would result in patent extensions that prevent timely access to medicines in developing countries (U.S. GOVERNMENT PUBLISHING OFFICE, Feb. 16, 2005)[46].

In this sense, Senator Kennedy (D-MA) considered that the administration should abide by the Doha Declaration in future trade negotiations. He also considered that developing trade partners should refuse proposals made by the USTR that could limit

[45] Senator Kennedy (D-MA) was also referring to the trade agreement with Jordan. Even though its negotiation and submission for congressional approval took place during Clinton's administration, President Bush signed the agreement into law in December 2001 (ORGANIZATION OF AMERICAN STATES, 2019a).

[46] "Bolar exceptions" allow generic pharmaceutical manufacturers to manipulate products protected by patents to produce data on their safety and efficacy in order to request marketing approvals before patent terms end. They are meant to make generic versions of pharmaceuticals available as soon as patents expire. Test data protection, on the other hand, prevents producers of generic medicines from relying on the efficacy and safety information submitted by the company that was first authorized to sell a pharmaceutical product (U.S. GOVERNMENT PUBLISHING OFFICE, Feb. 16, 2005; DÍAZ, 2008).

access to pharmaceuticals, and that Congress should do a better job in ensuring that trade agreements comply with the Doha Declaration (U.S. GOVERNMENT PUBLISHING OFFICE, Feb. 16, 2005).

House member Sander Levin (D-MI) had a different view from other Democrats as regards the Doha Declaration. He wrote a very detailed letter to the United States Trade Representative at the time, John Veroneau. The letter was also undersigned by House members Charles Rangel (D-NY), Jim McDermott (D-WA), and Henry Waxman (D-CA). They raised several concerns about the impact of the provisions related to pharmaceuticals included in the agreement with Morocco on her access to medicines and ability to respond to public health emergencies, including the HIV/AIDS epidemic. Among the provisions they mentioned as worrisome are those related to test data, protection for new uses of known products, compulsory licensing, and parallel importation[47]. They also feared that the agreement would contravene the Doha Declaration and the "Decision on the Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health". The USTR's response dismissed their concerns by stating that Morocco would still have room for maneuver to address public health problems. Representative Levin (D-MI) expressed satisfaction with the USTR's response and relied on it to explain his vote for the approval of the Moroccan trade agreement (U.S. GOVERNMENT PUBLISHING OFFICE, July 22, 2004).

In addition, Aziz Mekouar, Morocco's ambassador to the United States at the time, wrote a letter to Representative Sander Levin (D-MI) where he too dismissed the Congressman's concerns about the likely negative effects of the provisions related to pharmaceuticals included in the preferential trade agreement. In the letter, Mekouar stated that Morocco had a sufficient public health system, that the country did not allow parallel importations of pharmaceuticals even before the agreement was signed, and that compulsory licenses were still on the table when it comes to addressing public health crises. Moreover, he pointed out that Morocco supported the "Decision on the Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health". Such letter was also used by Representative Levin (D-MI) to justify his approval of the trade agreement, despite his initial concerns (U.S. GOVERNMENT

[47] The trade agreements with Australia, Morocco, Bahrain, Oman, and Korea require members to grant patent protection for any new uses or methods of using known products (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2004a, 2004d, 2004k, 2006a, 2007a). This provision may result in the concession of new patents to products or processes that would otherwise be in the public domain.

PUBLISHING OFFICE, July 22, 2004, p. H6647). Nevertheless, the congressman also stated that similar provisions should not be included in future trade agreements (U.S. GOVERNMENT PUBLISHING OFFICE, July 22, 2004, p. H6572).

House member Henry Waxman (D-CA) co-authored the letter transcribed by Representative Sander Levin (D-MI) but decided not to support the agreement with Morocco. He considered that Morocco had been facing an HIV/AIDS epidemic, and that the agreement would prevent the trade partner from aligning its laws with the Doha Declaration in case public health crises arose. Therefore, he did not trust the USTR's response as much as Representative Levin (D-MI) did.

Though Representative Charles Rangel (D-NY) disapproved of provisions that he considered harmful to access to medicines, he supported the agreement with Morocco (U.S. GOVERNMENT PUBLISHING OFFICE, July 22, 2004). Representative Jim McDermott (D-WA) did not mention the intellectual property protections for pharmaceuticals while debating the agreement, and voted for its approval (OFFICE OF THE CLERK – U.S. HOUSE OF REPRESENTATIVES, July 22, 2004).

Senator Ronald Wyden (D-OR) shared other Democrats' view that the federal administration had been ignoring the Doha Declaration for the benefit of drug manufacturers, which would prevent developing countries from protecting public health. Therefore, he introduced a bill prohibiting the USTR from negotiating test data provisions related to pharmaceutical products needed to address epidemics. The bill encompassed pharmaceuticals produced according to the "Decision on the Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health" (U.S. GOVERNMENT PUBLISHING OFFICE, Oct. 08, 2004). The bill was also meant to be applied to other USTR actions that could prevent foreign countries from accessing such pharmaceuticals.

He also pointed out that the bill was necessary due to its likely impacts on the United States:

> In today's world, it is shortsighted to think that infectious diseases cannot cross borders. By allowing developing countries access to generic drugs, we not only help improve health in those nations, we also help ourselves control these debilitating and often deadly diseases. (U.S. GOVERNMENT PUBLISHING OFFICE, Oct. 08, 2004, p. S10848).

The bill was referred to the Committee on Finance, but it was not enacted (CONGRESS.GOV, Aug. 10, 2004).

The statement from House member Thomas Allen (D-ME) summarizes the views expressed by most Democrats through the period about the connections between the Doha Declaration and provisions related to pharmaceuticals included in the preferential trade agreements:

> Every trade pact negotiated since 2002 has contained stringent intellectual property rules sought by the major drug companies. By keeping medicine prices high, these rules increase industry profits but restrict access to needed medicines for citizens in developing countries. Even in current free trade negotiations, USTR continues to ignore the will of Congress to respect the Doha Declaration[48]. That is why a new framework for trade must include a stronger role for Congress. The current model of nonbinding negotiating objectives permits the President to ignore the wishes of this Congress. It is no surprise that the administration has favored large corporate interests at the expense of American workers, the environment and global health. But it is wrong. (U.S. GOVERNMENT PUBLISHING OFFICE, Mar. 26, 2007, p. H3059).

Table 2 summarizes the views of members of Congress about the relations between the Doha Declaration and the provisions on pharmaceuticals included in preferential trade agreements.

[48] At the time, the agreements with Korea and Panama were under negotiation (ORGANIZATION OF AMERICAN STATES, 2019b; OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2007a, 2007c).

Table 2: Summary of views of members of the U.S. Congress on provisions related to the "Doha Declaration on the TRIPS Agreement and Public Health" included in preferential trade agreements (2001 – 2012)

	Agreement will prevent trade partner (s) from accessing medicines	The federal administration ignores Congressional instruction to respect the Doha Declaration	Pharmaceutical companies were undermining the Declaration	Agreements will prevent developing countries from accessing medicines	Trade partner would be able to address public health problems
Maxime Waters (H – D – CA) [Singapore]	X	X	-	-	-
Edward Kennedy (S – D – MA) [Preferential trade agreements in general]	-	X	X	X	-
Henry Waxman (H – D – CA) [Chile; Australia; Singapore; CAFTA-DR; Morocco; Bahrain; Andean nations, Panama (under negotiation)]	X	X	X	X	-
Fortney Stark (H – D – CA) [Preferential trade agreements in general]	-	-	X	-	-
Thomas Allen (H – D – ME) [Preferential trade	-	X	X	-	-

agreements in general]					
Sander Levin (H – D – MI) [Morocco]	-	-	-	-	X
Ronald Wyden (S – D – OR) [Preferential trade agreements in general]	-	X	X	X	-

Based on statements delivered in Congress. Data from Congressional Record (2001 – 2012). Names of members of Congress are followed by the house (H = House of Representatives; S = Senate), party (D = Democratic), and the abbreviation of the state they represent. In brackets are the parties to the trade agreements they refer to. Only Democratic representatives and senators expressed specific views on the Declaration over the period.

3.3 Criticism of the Industry Advisory Committee on Intellectual Property Rights

A group of members of Congress stated opposition to the influence of the pharmaceutical companies by directing their criticism specifically at the industry intellectual property rights advisory committees. They complained that the IFAC-3 did not include representatives of consumers, senior groups or advocates pro importation of pharmaceuticals (Fortney Stark (D-CA), July 14, 2004; Sherrod Brown (D-OH), July 14, 2004; July 22, 2004). House member Sherrod Brown (D-OH) stated that such lack of diversity was due to the campaign contributions made by pharmaceutical companies to Republican House members and to George Bush's reelection. Senator Charles Schumer (D-NY) complained that only representatives of PhRMA were at the negotiating table. He also supported the creation of a "neutral public health advisory committee" by asserting that "There must be someone at the table to protect access to affordable drugs and other health care in this country. The risks are too great to ignore." (U.S. GOVERNMENT PUBLISHING OFFICE, July 15, 2004, p. S8197). Representative Sherrod Brown (D-OH) was unusually precise in his criticism against the influence of pharmaceutical companies on the trade agreements with Australia and Morocco. He was the only member of Congress who named representatives of specific companies:

> […] in April, United States Trade Rep, Ambassador Zoellick, gave Assistant U.S. Trade Representative for Southeast Asian public affairs,

> Ralph Ives, additional responsibilities as the Assistant U.S. Trade Rep for pharmaceutical policy. He was the chief negotiator in the Australia FTA, which included these provisions we talked about which, of course, benefit the pharmaceutical industry. Now, Mr. Speaker, we hear that this same Mr. Ives, who I said was the chief Australia FTA negotiator on pharmaceutical interests on behalf of the Bush administration, we find out next month he will leave USTR to become vice president of AdvaMed, a medical supply company. We have also learned that Claude Burke, another negotiator for U.S. taxpayers, paid by our government, a Bush appointee for intellectual property rights, has already left and now is working for another drug company, working for Abbott Labs. Is there no shame with this crowd, with my Republican friends who have fronted for this drug industry that is fleecing the American public and with the administration? (U.S. GOVERNMENT PUBLISHING OFFICE, July 22, 2004, p. H6641).

Abbott was a member of PhRMA at the time, which is one of the members of the IFAC-3 that undersigned the private reports on both the Australian and the Moroccan agreements (PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, 2003, 2004). AdvaMed was not part of the IFAC-3 and was not part of any of the trade associations making up the committee at the time, either.

As we explained in section 3.1, House member Gilbert Gutknecht (R-MN) and Senators John McCain (R-AZ) and Charles Schumer (D-NY) also complained about the composition of the advisory committees when debating the importation provisions included in the agreements with Singapore, Australia, and Morocco.

Table 3, on the next page, summarizes the views of members of Congress on the industry advisory committees.

Table 3: Summary of views of members of the U.S. Congress on the industry advisory committees on intellectual property rights (2001 – 2012)

	Criticizes the lack of consumer representatives in the committees	Criticizes the lack of seniors' representatives in the committees	Criticizes the lack of advocates pro importation of pharmaceuticals in the committees	Criticizes campaign contributions by pharmaceutical companies to Republicans	Suggests the creation of a public health advisory committee	Criticizes the lack of market access advocates in the committees
Fortney Stark (H – D – CA) [Preferential trade agreements in general]	X	X	X	-	-	-
Sherrod Brown (H – D – OH) [Preferential trade agreements in general]	X	X	X	X	-	
Charles Schumer (S – D – NY) [Preferential trade agreements in general]	X	-	-	-	X	-
Gilbert Gutknecht (H – R – MN) [Australia]	X	X	-	-	-	X
John McCain (S – R – AZ) [Singapore; Australia; Morocco]	X	X	-	-	-	-

Based on statements delivered in Congress. Data from Congressional Record (2001 – 2012). Names of members of Congress are followed by the house (H = House of Representatives; S = Senate), party (D = Democratic; R = Republican), and the abbreviation of the state they represent. In brackets are the parties to the trade agreements they refer to.

3.4 Impacts on access to medicines in developing countries and in the preferential trade partners

Several members of Congress debated how the agreements would affect healthcare systems abroad. The potential impacts of the trade agreements on access to medicines in the trade partners and in developing countries in general were emphasized by them. In this sense, House member Sherrod Brown (D-OH) considered that the concession of fast-tracks by Congress may result in the inclusion of "[…] bad provisions [slipped by corporations] in good trade agreements […] that will abuse the most vulnerable of society". Examples of such provisions would be the limitations on compulsory licensing included in the trade agreement with Jordan due to brand-name drug industry influence on the USTR; according to him, they would prevent both trade partners from addressing excessive drug prices. (U.S. GOVERNMENT PUBLISHING OFFICE, July 31, 2001, p. H4877).

In a similar vein, House member John Conyers (D-MI) transcribed a letter sent to him by the "National Association for the Advancement of Colored People" (NAACP) stating opposition to the fast-track bill and supporting the inclusion of enforceable protections for public interest regulations in all new trade agreements[49]. The NAACP also urged the Bush administration to consult "[…] closely with Congress and the public, especially with communities of color, before negotiating any new trade agreements and to release draft negotiating texts […]" (U.S. GOVERNMMENT PUBLISHING OFFICE, July 26, 2002, p. H5981). Still according to the NAACP, one of the reasons for that would be that

> […] pharmaceutical companies have used the intellectual property rules in trade agreements to threaten developing countries with retaliation if they violate patent rules in order to provide affordable access to essential life-saving medicines, even medicines needed to treat people with HIV/AIDS […] (U.S. GOVERNMMENT PUBLISHING OFFICE, July 26, 2002, p. H5980-H5981).

In addition, the association stated that the fast track had been failing to make progress on the protection of public health (U.S. GOVERNMENT PUBLISHING OFFICE, July 26, 2002, p. H5981).

[49] The NAACP was founded in 1909. It is self-described as a "civil rights organization" that aims "[…] to ensure the political, educational, social and economic equality of minority group citizens of United States and eliminate race prejudice". It regularly comments on public affairs (NATIONAL ASSOCIATION FOR THE ADVANCEMENT OF COLORED PEOPLE, 2019).

Similarly, House member Henry Waxman (D-CA) asserted on September 08, 2004, that the restrictions on the availability of generic pharmaceuticals included in the agreement with Jordan had led to sharp increases in the prices of AIDS medicines, which he describes as a "terrible impact" (U.S. GOVERNMENT PUBLISHING OFFICE, Sep. 08, 2004, p. E1528). He also considered – along with House member Tom Udall (D-NM) – that the trade agreements with Chile and Singapore would negatively impact the healthcare systems of these two U.S. trade partners (U.S. GOVERNMENT PUBLISHING OFFICE, July 24, 2003; July 25, 2003). Representatives Waxman (D-CA) and Udall (D-NM) also stated that the agreements would hamper access to life-saving medicines in Chile and Singapore due to patents that last longer than the general term established by the TRIPS Agreement (U.S. GOVERNMENT PUBLISHING OFFICE, July 24, 2003; Sep. 08, 2004; July 27, 2005).

As regards the trade agreement with Australia, House member James McGovern (D-MA) considered that the U.S. negotiators had tried to convince Australia to change the way it prices drugs, which would raise prices of prescription drugs in the trade partner and dismantle Australia's health care system. In this sense, he stated that "Not surprisingly, Australia rejected this proposal; but in a move to appease U.S. negotiators, Australia did agree to language calling for greater transparency in how it prices drugs and for recognizing the need for competitive pharmaceutical markets." (U.S. GOVERNMENT PUBLISHING OFFICE, July 14, 2004, p. H5663)[50].

In a similar vein, House member Louise Slaughter (D-NY) considered that the provisions on test data included in the agreement with Morocco would impair the trade partner's ability to respond to public health crises. She stated that, even though the U.S. and Morocco had concluded a side letter on public health, its legal status was uncertain: "According to Robert Weissman of Essential Action, 'This statement of understanding expresses noble sentiments, but is unlikely to make much, if any, material difference in the implementation of the agreement.' I hope Mr. Weissman is wrong." (U.S.

[50] He probably refers to a side letter reached between Australia and the U.S. on May 18, 2004, where Australia committed to allow pharmaceutical companies to opine about decisions on public procurement of pharmaceuticals. Such companies were to be allowed to consult with officials, contest determinations about which pharmaceuticals were to be listed under Australia's Pharmaceutical Benefits Scheme, and to request adjustments to prices. She also committed to provide an opportunity for independent reviews of its refusals to include pharmaceuticals on the list, and to expedite its process of selection, listing, and pricing of pharmaceuticals (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2004b).

GOVERNMENT PUBLISHING OFFICE, July 22, 2004, p. H6570)[51]. She emphasized that the impact of the trade agreement on Morocco would be particularly intense when it comes to addressing the HIV/AIDS epidemic, which would disproportionally affect women (U.S. GOVERNMENT PUBLISHING OFFICE, July 22, 2004).

While supporting the trade agreement with Morocco, House member David Dreier (R-CA) responded to Slaughter's remarks on the gender-biased impact of the agreement's patent provisions by stating that it would promote greater economic growth, which would be important for dealing with HIV/AIDS (U.S. GOVERNMENT PUBLISHING OFFICE, July 22, 2004).

The views on the health-related impacts of the CAFTA-DR on the Central American trade partners were heavily stressed by the Democrats. House members Dennis Kucinich (D-OH), Thomas Allen (D-ME), Sherrod Brown (D-OH), Lucille Roybal-Allard (D-CA), Bart Stupak (D-MI), Fortney Stark (D-CA), Henry Waxman (D-CA), Rosa DeLauro (D-CT), and Senator Richard Durbin (D-IL) considered that low-income populations in the CAFTA-DR trade partners would have their access to generic medicines limited by the patent extensions included in the agreement. According to them, these provisions had been negotiated by the administration to protect corporate rights. Representatives Kucinich (D-OH), Allen (D-ME), Roybal-Allard (D-CA), Stark (D-CA), Waxman (D-CA), and Senator Durbin (D-IL) mentioned protections for pharmaceutical test data as the main provisions that could delay the introduction of generic medicines into Central American markets (U.S. GOVERNMENT PUBLISHING OFFICE, May 04, 2005; May 11, 2005; June 30, 2005; July, 27, 2005; July 29, 2005).

According to Representative Kucinich (D-OH), governments in Central America would be unable to subsidize their healthcare systems, which would make them unable to meet their citizens' needs (U.S. GOVERNMENT PUBLISHING OFFICE, May 04, 2005; May 11, 2005). He further stated that all of those impacts of the CAFTA-DR would be particularly serious due to the prevalence of HIV/AIDS in the region, especially in Honduras:

[51] They refer to the "Side Letter on Public Health" reached by Morocco and the United States on June 15, 2004, whereby they agree that both parties should be able to take measures to promote access to medicines, in particular those for HIV/AIDS treatment. They also emphasized their commitment to the Doha Declaration and to the "Decision on the Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health" (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2004e). Robert Weissman is the president of Public Citizen, an NGO headquartered in Washington that deals with government accountability (PUBLIC CITIZEN, 2019a). He directed Essential Action from 1995 to 2009 (PUBLIC CITIZEN, 2019b). It was founded in 1982 by Ralph Nader. It later changed its name to "Essential Information" (ESSENTIAL ACTION, 2016).

> According to Dr. Manuel Munoz, the director of Medecins Sans Frontiere's AIDS treatment program in Honduras, "HIV/AIDS kills one person in Honduras every 2 hours, because the vast majority of people with HIV/AIDS cannot afford lifesaving AIDS medicines." (U.S. GOVERNMENT PUBLISHING OFFICE, May 11, 2005, p. H3178)[52].

He also quoted a statement from Dr. Robert Weissman on test data to support his lack of approval of the CAFTA-DR:

> According to Robert Weissman, an attorney specializing in international trade and pharmaceuticals, ''if the generics cannot rely on approvals granted based on the brand-name data, in most cases, they simply will not enter the market. This is especially true in small size markets, as in Central America, where prospective revenues are limited.'' (U.S. GOVERNMENT PUBLISHING OFFICE, May 11, 2005, p. H3179).

Senator Durbin (D-IL) mentioned Doctors Without Borders for the same purpose as Representative Kucinich (D-OH) did:

> Doctors Without Borders – you may have heard of this fabulous organization based out of France, doing wonderful work all around the world. They provide drugs to HIV patients, and 1,600 in Guatemala alone. They rely on generic drugs because they cannot afford the most expensive drugs. They cost less than brand-named drugs. They can keep a person alive with HIV/AIDS in Guatemala for $216 a year. If they had to pay for the brand name, it would be $4,818. […] I think when you look at this and you understand workers are losing, you have to understand as well that a lot of sick people with HIV/AIDS are going to lose, too. People are struggling to survive, and they will fall victim to the profit margins of American pharmaceutical companies. Those are the priorities—the priorities of CAFTA. Why aren't the American workers the priority of CAFTA? Why aren't the workers of Central America the priorities of CAFTA? (U.S. GOVERNMENT PUBLISHING OFFICE, June 30, 2005, p. S7673).

Like his peers, House member Fortney Stark (D-CA) mentioned a non-state actor to support his view. According to him, the Bush administration had negotiated the CAFTA-DR at the behest of PhRMA; he also suggested that Congress should request the renegotiation of the agreement (U.S. GOVERNMENT PUBLISHING OFFICE, July 27, 2005, p. H6924). In the same vein, Representatives Kucinich (D-OH) and Brown (D-OH)

[52] *Médecins sans Frontières* (translates to Doctors without Borders) is an NGO created in 1971 in France. It is headquartered in Geneva, Switzerland, and provides medical assistance to people affected by conflicts, epidemics, disasters, or otherwise excluded from healthcare (MÉDECINS SANS FRONTIÈRES, 2019; MÉDICOS SEM FRONTEIRAS, 2019).

emphasized their view that the U.S. government had acted on behalf of pharmaceutical companies due to political contributions given to the Republican Party. Representative Brown (D-OH) was more specific by stating that the pharmaceutical industry had influenced House member Thomas DeLay (R-TX), the Republican leadership, and the White House (U.S. GOVERNMENT PUBLISHING OFFICE, May 11, 2005, p. H3179). Moreover, Congressman Sherrod Brown (D-OH) also considered that the CAFTA-DR trade partners would be forced to pay more for prescription drugs because the USTR had a representative to deal specifically with pharmaceutical policies, i.e. he attributes the provisions on pharmaceuticals included in the trade agreement to the structure of the USTR (U.S. GOVERNMENT PUBLISHING OFFICE, June 09, 2005)[53].

Representative Thomas Allen (D-ME) also detailed how he considered the agreement had prevented Guatemala from expanding access to medicines:

> A year ago, the Guatemalan legislature changed its law to promote the availability of generic drugs in the Guatemalan market, and using CAFTA as a weapon, the United States has forced the Guatemalan legislature to repeal that legislation. In other words, we have done something for the pharmaceutical industry by forcing Guatemala to change its laws and for no benefit to anyone else in America. (U.S. GOVERNMENT PUBLISHING OFFICE, May 04, 2005, p. H2962).

House member Sander Levin (D-MI) also opposed the CAFTA-DR because what he perceived to be bad impacts on healthcare in Central America. He did so by quoting a statement delivered to the House Committee on Ways and Means by Harley Shaiken, a professor at the University of California (U.S. GOVERNMENT PUBLISHING OFFICE, June 28, 2005; CENTER FOR LATIN AMERICAN STUDIES, 2018). According to Shaiken:

> In [the provisions related to] pharmaceuticals, Professor Angelina Godoy has found that ‘‘the intellectual-property provisions in CAFTA actually extend the length of time during which the major pharmaceutical companies’ products are guaranteed sole access to markets’’ which, in her view as well as that of many other observers such as Amnesty International, ‘‘just may be a death sentence for many

[53] He refers to the fact that the USTR had an Assistant representative for Southeast Asia, the Pacific, and Intellectual Property. At the time, such representative was Barbara Weisel (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2004n; OFFICE OF THE FEDERAL REGISTER; NATIONAL ARCHIVES AND RECORDS ADMINISTRATION, 2006). Representative Brown (D-OH) considered that drug industries were being brought into the USTR, which was leading to higher costs of pharmaceuticals in the U.S. and in developing countries (U.S. GOVERNMENT PUBLISHING OFFICE, June 09, 2005, p. H4312).

> in the Dominican Republic and Central America.'' (U.S. GOVERNMENT PUBLISHING OFFICE, June 28, 2005, p. E1378).

Senator Richard Carper (D-DE) stands out for being the only Democrat who expressed approval of the intellectual property rights included in the CAFTA-DR. He considered that patent and other provisions would be important for Delaware businesses, such as AstraZeneca, a pharmaceutical company member of PhRMA (U.S. GOVERNMENT PUBLISHING OFFICE, June 30, 2005; PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, 2004).

House member Fortney Stark (D-CA) considered that the trade agreement with Bahrain and the other recent trade agreements would delay the availability of generic medicines in the U.S.A. and in the preferential trade partners (U.S. GOVERNMENT PUBLISHING OFFICE, Dec. 07, 2005). He stated that the agreements with Australia, Morocco, the CAFTA-DR members, and Bahrain were "a payback or a sell out to PhRMA" because of patent term extensions. He also remarked that, though Bahrain could wait longer for patents to expire due to its development level, adding such provisions to trade agreements was bad policy anyway (U.S. GOVERNMENT PUBLISHING OFFICE, Dec. 07, 2005, p. H11169).

House member Thomas Allen (D-ME) made a similar point as regards the trade agreement with Oman. He considered that it would negatively impact Oman's generic drugs market due to the influence of powerful drug makers over the administration. Moreover, he stated that the trade agreement would restrict the U.S. Congress' ability to legislate on healthcare because pharmaceutical companies would have access to trade dispute settlement mechanisms (U.S. GOVERNMENT PUBLISHING OFFICE, July 20, 2006).

Another House member who criticized the intellectual property rights included in the trade agreement with Oman was Betty McCollum (D-MN). She stated that "The intellectual property provisions of the agreement will hinder the spread of lower priced generic drugs, which could improve public health and stabilize populations in Oman." (U.S. GOVERNMENT PUBLISHING OFFICE, Sep. 29, 2006, p. E1919).

House member Denis Kucinich (D-OH) endorsed Public Citizen's views on the preferential free trade agreement with Panama. He described the NGO as "[…] an organization that dedicates itself to an impartial economic analysis of trade agreements". He pointed out that Public Citizen considered that the agreement with the Central

American nation had provisions to moderate the potential negative effects of patents on access to generic pharmaceuticals. Congressman Kucinich (D-OH) was probably referring to the provisions included in the trade agreement due to requirements made by the Democratic majority in Congress in May 2007 (U.S. GOVERNMENT PUBLISHING OFFICE, Oct. 12, 2011, p. H6806). He also remarked that the NGO had singled out that the trade agreement allowed foreign investors to challenge national policies through "private enforcement" in international tribunals (U.S. GOVERNMENT PUBLISHING OFFICE, Oct. 12, 2011, p. H6806)[54].

When stating his opposition to the agreement with Panama, Representative Kucinich (D-OH) also endorsed the AFL-CIO's view on the agreement. The trade union – described by the Congressman as "[…] one of the most important workers' organizations in the history of this country […]" – stated that the Panamanian agreement represented "[…] a wrong trade model at the wrong time […]." (U.S. GOVERNMENT PUBLISHING OFFICE, Oct. 12, 2011, p. H6806)[55].

Table 4, on the following pages, summarizes the views of members of Congress on the impacts of the preferential trade agreements on access to medicines in U.S. preferential trade partners.

[54] We will explain the patent provisions included in the agreement with Panama in greater detail in the next section. On dispute settlement proceedings established through private international tribunals, see footnote 37. On Public Citizen, see footnote 51.

[55] The American Federation of Labor and Congress of Industrial Organizations (AFL-CIO) is a federation of 55 labor unions in the U.S. and abroad. Its oldest union member was created in 1866. AFL and CIO have been merged since 1955 (THE AMERICAN FEDERATION OF LABOR AND CONGRESS OF INDUSTRIAL ORGANIZATIONS, 2019).

Table 4: Summary of views of members of the U.S. Congress on the impacts of preferential trade agreements on access to medicines in preferential trade partners (2001 – 2012)

	Fast-tracks prevent trade partners from addressing excessive drug prices	Agreements will limit access to medicines in trade partners due to patent extensions	Administration negotiated harmful provisions to protect interests of pharmaceutical companies	Criticize campaign contributions to the Republican Party	Agreements will delay introduction of generic medicines into trade partners' markets	Agreements will negatively affect trade partners' healthcare systems	Agreements will prevent trade partners from addressing public health crises	Agreements will help trade partners to deal with HIV/AIDS
Democrats	John Conyers (H – MI), Sherrod Brown (H – OH)	Bart Stupak (H – MI), Dennis Kucinich (H – OH), Fortney Stark (H – CA), Henry Waxman (H – CA), Lucille Roybal-Allard (H – CA), Richard Durbin (S –	Bart Stupak (H – MI), Dennis Kucinich (H – OH), Fortney Stark (H – CA), Henry Waxman (H – CA), Lucille Roybal-Allard (H – CA), Richard Durbin (S – IL), Rosa DeLauro (H – CT), Sherrod Brown (H –	Dennis Kucinich (H – OH), Sherrod Brown (H – OH)	Betty McCollum (H – MN), Dennis Kucinich (H – OH), Fortney Stark (H – CA), Henry Waxman (H – CA), Lucille Roybal-Allard (H – CA), Maxime	Dennis Kucinich (H – OH), Henry Waxman (H – CA), James McGovern (H – MA), Tom Udall (H – NM)	Louise Slaughter (H – NY)	-

		IL), Rosa DeLauro (H – CT), Sander Levin (H – MI), Sherrod Brown (H – OH), Thomas Allen (H – ME), Tom Udall (H – NM)	OH), Thomas Allen (H – ME)		Waters (H – CA), Richard Durbin (S – IL), Thomas Allen (H – ME)			
Republicans	-	-	-	-	-	-	-	David Dreier (H – CA)

Based on statements delivered in Congress. Data from Congressional Record (2001 – 2012). Names of members of Congress are in alphabetical order. They are followed by the house they are part of (H = House of Representatives; S = Senate) and by the abbreviation of the state they represent.

3.5 The 10 May Agreement and its impacts on the trade agreements with Peru, Colombia and Panama

Even though the renegotiation of provisions related to pharmaceuticals had been suggested in Congress before, as we explained in section 3.4, such idea only gained momentum during the debates about the trade agreements with Peru and Colombia. The agreement with Panama was also affected, since it was still under negotiation at the time.

The debates about these agreements took place after the 2006 mid-term elections, which resulted in a partial renovation of Congress on both the Democratic and the Republican sides. They also led to the creation of a Democratic majority in the House and in the Senate. Until then, Bush had been governing with a Republican majority in Congress[56].

An early request for adjustments to the trade agreements with Peru, Colombia, and Panama was made by House member Michael Michaud (D-ME) in March 2007. He considered that these agreements threatened U.S. intellectual property rights and infringed on access to medicines. He asserted that the new Democratic majority in Congress could be interpreted as a popular vote against the trade deals negotiated by the administration up to that point. In addition, he considered that the side letters could not make up for faulty provisions that could infringe on access to medicines (U.S. GOVERNMENT PUBLISHING OFFICE, Mar. 26, 2007).

He probably refers to the "Side Letter Concerning Patents and Certain Regulated Products", reached by the U.S. and Colombia on November 22, 2006 (OFFICE OF THE U.S. TRADE REPRESENTATIVE, 2006h). It sets that the parties are free to determine how to enforce specific provisions related to patent linkage, marketing approval of pharmaceuticals, and patents on pharmaceuticals. Following amendments to the

[56] In the 107th (2001-2003), 108th (2003-2005), and 109th (2005-2007) Congresses, Republicans were the majority in the House. From 2007 to 2009 (110th Congress), Democrats were the majority in the House. In the Senate, Republicans were the majority most of the time in the 107th Congress. The Democrats held the majority for six months because from January 03 to January 20, 2001, the Senate was divided evenly between the two parties, whereby outgoing Democratic Vice President Al Gore held the deciding vote. Beginning on January 20, 2001, Republican Vice President Richard Cheney held the deciding vote in the Senate, giving the majority to the Republicans. Party switches in May 2001 also temporarily shifted balance to the Democrats. Republicans were the majority in the Senate from 2003 to 2007 (108th and 109th Congresses). In the 110th Congress Democrats became the majority in both houses (UNITED STATES HOUSE OF REPRESENTATIVES, 2019; UNITED STATES SENATE, 2019). On the role of the vice president as a tie-breaker see Lowi et. al. (2017, p. 268) and the U.S. Constitution, art. I, sec. 3 (UNITED STATES SENATE, 2017).

preferential agreement on June 28, 2007, such provisions in the side letter no longer have legal effect[57].

House member Keith Ellison (D-MN) also considered that the elections were a symbol of the public preference for changing the course of trade policy. He also stated that the TRIPS-Plus provisions that "cut poor consumers off from access to medications and cause endless deaths in poor countries" had to be renegotiated with Peru and Colombia. He also called for a renegotiation of the investment provision that could allow foreign companies to challenge health safeguards (U.S. GOVERNMENT PUBLISHING OFFICE, Mar. 26, 2007, p. H3063)[58].

In this sense, the new Democratic majority persistently required the inclusion of specific provisions related to pharmaceuticals in trade agreements, even though the fast-track was still in force. The federal administration concluded an agreement with Congress on May 10, 2007, to secure the implementation of the trade agreements already negotiated and the ones under negotiation.

The new parameters it established for the ratification of the trade agreements with Peru, Colombia and Panama are:

- when trade partners relied on test data submitted by pharmaceutical companies in the United States, the five-year exclusive period should begin when the drug was first approved in the United States
- patent extensions due to delays in patent granting or marketing approval should not be mandatory
- the agreements should not require that drug regulatory agencies withhold approval of generics until they can certify that no patent would be violated if the generics were marketed (i.e. no linkage provisions should be included in the trade agreements)
- the provisions on public health that had been included in side letters to previous trade agreements should henceforth be made part of the main texts[59].

As a result, the administration had to renegotiate the agreements with Peru and Colombia. It also had to mind the new Congressional instructions to conclude the

[57] We will explain such amendment in greater detail as follows.
[58] On the investment provisions included in the final agreements, see footnote 37.
[59] The May 10 Agreement also included provisions on labor standards, the environment, government procurement, port security, and investments (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2007k; WAYS AND MEANS COMMITTEE, 2007).

negotiations with Panama. The agreements were renegotiated on June 25, 2007 (Peru) and June 28, 2007 (Colombia) (BENTES et. al., 2008). The agreement with Panama was concluded under the new Congressional instructions on June 28, 2007 (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2007g).

President Bush mentioned the May 10 Agreement in the message to Congress asking for the approval of the trade agreement with Colombia:

> […] my Administration has conducted several hundred further consultations, led congressional trips to Colombia, and last year renegotiated key labor, environmental, investment, and intellectual property rights provisions in the Agreement at the behest of the Congress. […] My Administration looks forward to continuing to work with the Congress on a bipartisan path forward to secure approval of this legislation that builds on the positive spirit of the May 10, 2007, agreement on trade between the Administration and the House and Senate leadership […] (U.S. GOVERNMENT PUBLISHING OFFICE, Apr. 08, 2008, p. S2741).

In fact, the provisions on test data, patent extensions, and public health in the agreements with these Latin American countries largely comply with the May 10 Agreement. The agreement with Panama does not specify that marketing approval authorities are not required to make patent validity or infringement determinations, as the agreements with Peru and Colombia do[60]. None of these agreements have valid side letters on pharmaceuticals attached to them (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2006d, 2006f, 2007g)[61].

Following the renegotiation, several Democrats expressed approval of the new provisions related to pharmaceuticals. Senator Harry Reid (D-NV) considered that the May 10 Agreement had resulted in important improvements, as compared to the

[60] See agreement with Peru arts. 16.9.6(b), 16.9.6(c), 16.10.2(c), 16.10.2(e), and 16.10.4(a) (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2006d); agreement with Colombia arts. 16.9.6(b), 16.9.6(c), 16.10.2(c), 16.10.2(e), and 16.10.4(a) (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2006g); agreement with Panama arts. 15.9.6(b), 15.9.6(c), 15.10.2(c), and 15.10.2(e) (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2007g).

[61] The trade agreements with Morocco, Bahrain, Oman, and the CAFTA-DR include side letters where the parties specify that they are able to use the mechanisms established in the Doha Declaration and subsequent related decisions reached at the WTO to protect public health by promoting access to medicines (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2004e, 2004h, 2004l, 2006b). The agreements with Peru, Colombia, Panama, and Korea include such provision in the main texts. See U.S. agreements with Peru, arts. 16.10.2(e) and 16.13; Colombia, arts. 16.10.2(e) and 16.13; Panama, arts. 15.10.2(e) and 15.12; and Korea, arts. 18.9.3 and 18.11 (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2006d, 2006g, 2007a, 2007g). The agreement with Chile merely states in the preamble to the chapter on intellectual property rights that the parties "recognize" the principles set out in the Declaration (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2003a). No such flexibility is included in the agreements with Singapore and Australia (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2003c, 2004a).

provisions included in previous agreements (U.S. GOVERNMENT PUBLISHING OFFICE, Dec. 04, 2007). When debating the Trans-Pacific Partnership, House member Peter DeFazio (D-OR) referred to the adjustments to the trade agreement with Peru as positive precedents in terms of enhancement of access to medicines (U.S. GOVERNMENT PUBLISHING OFFICE, Sep. 13, 2012).

In the same vein, House member Henry Waxman (D-CA) based his approval of the trade agreements with Peru and Panama on the changes introduced by the renegotiation. He directly mentioned the new provisions on patent extensions due to regulatory delays, patent linkage, and the fact that generic medicines could be made available in the trade partners at the same time as in the U.S. (U.S. GOVERNMENT PUBLISHING OFFICE, Nov. 07, 2007; Oct. 12, 2011). Due to these changes, the Congressman considered that the agreements were critical precedents for a trade policy that raises standards for public health in developing countries, instead of pharmaceutical industries' profits. Though he approved of the adjustments made to the agreement with Colombia, he decided not to vote for it for reasons unrelated to intellectual property rights (U.S. GOVERNMENT PUBLISHING OFFICE, Nov. 07, 2007; Oct. 12, 2011).

Despite his approval of the Peruvian agreement, Representative Waxman (D-CA) still expressed dissatisfaction with the investor-to-state dispute mechanism included therein, because it could lead to abusive challenges to health regulations. He also criticized the fact that the agreement requires member countries to protect pharmaceutical test data. Nevertheless, Congressman Waxman (D-CA) emphasized that Peru would be free to override the latter to address public health problems due to the renegotiation of the trade agreement (U.S. GOVERNMENT PUBLISHING OFFICE, Nov. 07, 2007).

Senator Patrick Leahy (D-VT) approved of the fact that the May 10 Agreement reinstated the members' commitment to the Doha Declaration, which would allow Peru to promote access to medicines to address public health problems. Nevertheless, he stated that the consultations between the USTR and Congress had not been sufficient: "I look forward to the Judiciary Committee's being consulted by the Office of the U.S. Trade Representative earlier, and more frequently, in the future, so that we can continue to improve on these issues." (U.S. GOVERNMENT PUBLISHING OFFICE, Dec. 04, 2007, p. S14720).

House member Jim McDermott (D-WA) stated his approval of the May 10 Agreement by endorsing a letter sent by the United States Conference of Catholic Bishops to a group of members of Congress on both sides of the aisle. The bishops considered that

the agreement had led to improvements in the agreements with both Peru and Colombia, in the sense of more readily ensuring access to life-saving medicines (U.S. GOVERNMENT PUBLISHING OFFICE, Feb. 27, 2008).

On the other hand, Republican members of Congress heavily criticized the new provisions related to pharmaceuticals included in the agreement with Peru. Senators Orrin Hatch (R-UT) and Jon Kyl (R-AZ) considered that the new provisions would limit rather than improve access to medicines because they reduced incentives for pharmaceutical companies to make new medicines available in Peru. Since these provisions would also reduce incentives for research, they could diminish the availability of generic medicines in the long run. These members of Congress described the new provisions as "weakened" as compared to the original agreement and to the standard established by other U.S. trade agreements. Senator Hatch (R-UT) specified that the weak provisions were those related to linkage, data exclusivity (probably referring to protection for test data), and patent term restoration due to marketing approval delays (U.S. GOVERNMENT PUBLISHING OFFICE, Dec. 04, 2007). Senator Kyl (R-AZ) considered that the provisions renegotiated with Colombia and Panama were as bad as their Peruvian counterparts (U.S. GOVERNMENT PUBLISHING OFFICE, Dec. 04, 2007).

Moreover, the two Senators considered that such provisions would be harmful to the American pharmaceutical industries, which would result in job losses. Senator Hatch (R-UT) highlighted that changes to intellectual property rights alone would not necessarily improve access to medicines because it depends on the quality of health care systems in general (U.S. GOVERNMENT PUBLISHING OFFICE, Dec. 04, 2007). Despite all this criticism, he voted for the agreement with Peru:

> I have been assured by the Administration that the issues that I have raised today will never become a problem for the United States. While I am confident that my concerns remain valid, I am unwilling to stand in the way of the President's trade agenda. […] Therefore, I will reluctantly vote for the U.S.-Peru FTA before us today. However, I will not give up on improving future trade agreements in the critical areas of labor and intellectual property rights. (U.S. GOVERNMENT PUBLISHING OFFICE, Dec. 04, 2007, p. S14724).

On the other hand, Senator Kyl (R-AZ) decided not to vote for the agreement and emphasized that he would not vote for future agreements with similar provisions i.a. because they could set precedents for flexibilities on the intellectual property protection for other products, such as movies and computers (U.S. GOVERNMENT PUBLISHING OFFICE, Dec. 04, 2007). When explaining his decision, he complained about the USTR's

lack of attention for concerns raised by him and other members of Congress in letters and personal meetings with Susan Schwab, the head of the USTR at the time (U.S. GOVERNMENT PUBLISHING OFFICE, Dec. 04, 2007, p. S14724).

Table 5, on the following pages, summarizes the views of members of the U.S. Congress on the reasons for the renegotiation of preferential trade agreements and on the effects of the May 10 Agreement.

Table 5: Summary of views of members of the U.S. Congress on reasons for the renegotiation of trade agreements and on results of the May 10 Agreement between Congress and the federal administration, 2001 – 2012

	Agreement negotiated for PhRMA	Agreements infringe on access to medicines	Popular discontent with trade agreements	Foreign companies can legally challenge health safeguards	Consultations between the USTR and Congress had not been sufficient	May 10 Agreement improved trade agreements	Adjustments to the trade agreements enhanced access to medicines	Adjustments will reduce availability of new and generic medicines in trade partners	New provisions hurt American pharmaceutical companies
Fortney Stark (H – D – CA) [CAFTA-DR]	X	-	-	-	-	-	-	-	-
Michael Michaud (H – D – ME) [Peru; Colombia; Panama]	-	X	X	-	-	-	-	-	-
Keith Ellison (H – D – MN) [Peru; Colombia]	-	X	X	X	-	-	-	-	-
Harry Reid (S – D – NV) [Peru; Colombia; Panama]	-	-	-	-	-	X	-	-	-
Peter DeFazio (H – D – OR) [Peru]	-	-	-	-	-	-	X	-	-

Henry Waxman (H – D – CA) [Peru; Colombia; Panama]	-	-	-	X	-	-	X	-	-
Patrick Leahy (S – D – VT) [Peru]	-	-	-	-	X	-	X	-	-
Jim McDermott (H – D – WA) [Peru; Colombia]	-	-	-	-	-	X	X	-	-
Orrin Hatch (S – R – UT) [Peru]	-	-	-	-	-	-	-	X	X
Jon Kyl (S – R – AZ) [Peru; Colombia; Panama]	-	-	-	-	X	-	-	X	X

Yellow columns = views of members of the U.S. Congress on reasons for the renegotiation of trade agreements. Green columns = views of members of the U.S. Congress on results of the May 10 Agreement between Congress and the federal administration. Based on statements delivered in Congress. Data from Congressional Record (2001 – 2012). Names of members of Congress are followed by the house (H = House of Representatives; S = Senate), party (D = Democratic; R = Republican), and the abbreviation of the state they represent. In brackets are the parties to the trade agreements they refer to.

3.6 Conclusion: unstable party divisions

We have found a clear pattern as regards views on intellectual property protection for pharmaceuticals among Democratic members of Congress. Usually they criticized the impacts the trade agreements would have on access to medicines in the United States and abroad. Democrats also typically preferred the multilateral flexibilities established by the Doha Declaration and related decisions at the WTO over provisions that could lead to patent term extensions and less room for maneuver for trade partners to address public health emergencies.

They were also the ones who spearheaded the May 10 Agreement. This deal between the federal administration and the Congress directly influenced the trade agreements reached with three Latin American nations. This is one example of the importance of Congress in trade policymaking because the federal government depended on the approval of – and had to abide by the rules set by – Congress.

Nevertheless, such pattern was blurred in the sense that some Democratic members of Congress expressed views opposed to those approved of by the majority of their party. In the same vein, in some circumstances Republican members of Congress sided with the Democrats against provisions that had been negotiated by the (also Republican) federal administration.

Such pattern can also be described as unstable over time because it was sensible to shifts in party control of Congress. The mid-term elections in 2006 changed the majority in Congress, which gave the Democrats more leverage to influence the intellectual property protections for pharmaceuticals negotiated with U.S. trade partners. Also, following the elections Democratic members of Congress had a uniform stance when it comes to the ideal provisions on pharmaceuticals to be included in the trade agreements with Peru, Colombia, and Panama. In the same vein, Republicans were consistent when rejecting the adjustments required by the Democrats. These requirements for adjustments demonstrate that intellectual property protections for pharmaceuticals – along with other non-tariff issues – can be deal-breakers in the United States.

Congress members often relied on views expressed by private domestic actors when justifying their views on the provisions on intellectual property protection for pharmaceuticals included in the preferential trade agreements. Some of them also estimated the impacts the provisions would have on access to medicines by consumers in the U.S. and abroad, as much as the likely impacts on government procurement of

pharmaceuticals. Those views were not uniform; as predicted by the theories presented in chapter one, societal actors may have competing views on foreign policies; political decision-makers can rely on such actors to gauge informed views from society and to legitimate their preferred views.

Moreover, the indispensable role Congress plays in approving the U.S. trade policy also suggests that academic analyses of the U.S. trade must mind the domestic side. The results of the shift in party control of Congress and the strategy the federal administration chose to ratify trade agreements when the Democrats won the control of the legislature speak volumes about how trade policy outcomes may depend on domestic conciliation when governments are divided. Therefore, these events could be explained by the two-level games approach.

Members of Congress also mentioned many times the industry advisory committees on intellectual property. Both Republican and Democratic legislators complained that the USTR advisory committee system included representatives of private companies only; therefore, the information they provided to the U.S. decision-makers would be one-sided.

Despite this criticism, no projects of reforms to the advisory system were carried out in Congress, and the advisory committees produced reports on all the trade agreements negotiated and ratified by the United States from 2001 to 2012. The USTR published all such reports on its website.

Therefore, the advisory committees had the exclusive opportunity to advise decision-makers and to publicize their views to society at large. No other domestic actors had such a privilege. The intellectual property committees scrutinized the intellectual property rights chapters included in the preferential trade agreements, thereby expressing their views on the provisions negotiated with trade partners and suggesting approaches for future negotiations. They placed special attention on protections for pharmaceuticals.

In the next chapter we analyze the advisory committees' reports and contrast their views to the ones expressed in Congress. We also investigate which of these actors had a greater influence on the treaties that were eventually implemented by the United States.

4 IFAC-3 AND ITAC-15 REPORTS ON PHARMACEUTICALS

As we explained in the introduction and in section 2.3, the Trade Act of 2002 established the creation of an industry advisory committee on intellectual property rights. Such committee was initially called "IFAC-3", later rechristened "ITAC-15". The committee assesses trade agreements negotiated by the USTR with foreign partners and provides advice to the president and to the Congress. Pharmaceutical companies were members of all the committees that assessed the trade agreements negotiated according to the instructions Congress included in the 2002 trade law, as we will explain as follows.

The committee members are privileged domestic actors because they have direct and stable contacts with U.S. decision-makers, unlike other interest groups. Moreover, the U.S. government publishes their reports on trade agreements, allowing for them to reach a larger audience. Nevertheless, the committees have no voting or vetoing powers over trade agreements.

The members of the advisory committees are individual companies or trade associations whose members produce technology and knowledge typically protected by intellectual property rights, such as those embedded in books, software, pharmaceuticals, and pesticides. They also include legal and consultancy companies.

Most reports were undersigned by fifteen members; that is the case of the reports on the agreements with Singapore, Australia, Morocco, the CAFTA-DR members, Bahrain, Oman, and Peru (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2003d, 2004c, 2004f, 2004i, 2004j, 2004m, 2006c, 2006f). The reports on the agreements with Colombia, Panama, and Korea were produced by nineteen members (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2006j, 2007d, 2007h). The report on the agreement with Chile was authored by twenty-one committee members (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2003b).

Three pharmaceutical-company members undersigned all the reports: Eli Lilly, Merck, and the Biotechnology Industry Organization[62]. Pfizer undersigned all the reports,

[62] Eli Lilly was founded and is headquartered in the United States (ELI LILLY, 2019). Merck owns affiliates and research facilities in the U.S., but it was founded and is headquartered in Germany (MERCK, 2019). Created in 1993, the Biotechnology Industry Organization is a trade association representing biotechnology companies, academic institutions, state biotechnology centers, and related organizations from the U.S. and abroad (BIOTECHNOLOGY INNOVATION ORGANIZATION, 2019). In 2016 it changed its name to "Biotechnology Innovation Organization" (BUSINESS WIRE, Jan. 04, 2016).

except for those on the agreements with Colombia, Panama, and Korea[63]. PhRMA was a member of the committees that assessed the agreements with Chile, Singapore, Australia, Morocco, the CAFTA-DR, and Bahrain[64]. Table 6, on the next page, summarizes the membership of the committees that analyzed each preferential trade agreement.

[63] Pfizer is an American pharmaceutical company headquartered in New York (PFIZER, 2017). It was a member of the Biotechnology Industry Organization all along, whereby it was indirectly represented at the production of the reports on the agreements with Colombia, Panama, and Korea (BIOTECHNOLOGY INDUSTRY ORGANIZATION, Oct. 10, 2006).

[64] On PhRMA see footnote 34. Eli Lilly, Pfizer, and Merck were members of PhRMA when the reports were produced (PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, 2003, 2004, 2005, 2006, 2007).

Table 6: Pharmaceutical company and trade association members of the USTR industry advisory committees (2001 – 2012)

	IFAC – 3 (Chile)	IFAC – 3 (Singapore)	IFAC – 3 (Australia)	IFAC – 3 (Morocco)	IFAC – 3 (CAFTA – DR)	ITAC – 15 (Bahrain)	ITAC – 15 (Oman)	ITAC – 15 (Peru)	ITAC – 15 (Colombia)	ITAC – 15 (Korea)	ITAC – 15 (Panama)
Eli Lilly	X	X	X	X	X	X	X	X	X	X	X
Merck	X	X	X	X	X	X	X	X	X	X	X
Biotechnology Industry Organization	X	X	X	X	X	X	X	X	X	X	X
Pfizer	X	X	X	X	X	X	X	X	-*	-*	-*
PhRMA	X	X	X	X	X	X	-**	-**	-**	-**	-**

* Represented by the Biotechnology Industry Organization

** Some individual members were part of the committee

Sources: Office of the United States Trade Representative (2003b, 2003d, 2004c, 2004f, 2004i, 2004j, 2004m, 2006c, 2006f, 2006j, 2007d).

All reports produced by the IFAC-3 and the ITAC-15 were published during the negotiations of the trade agreements, i.e. before the member countries had concluded the final texts. Therefore, the committees based their views on drafts of the actual agreements. We turn to these opinions in the next section. Nevertheless, subsets of members also submitted comments on intellectual property rights related to pharmaceuticals after the final versions of the agreements had been negotiated, as we will explain in depth in section 4.2.

4.1 Partial approval of trade agreements: the main reports

The reports extensively analyze the provisions on intellectual property rights included in the agreements and suggest improvements to be included in future agreements. All committee members supported the agreements with Chile, Singapore, Australia, Morocco, the CAFTA-DR members, Bahrain, Oman, and Korea. Despite that, several aspects related to pharmaceuticals were criticized. Some of those criticisms are at odds with views of members of Congress.

The committee members consistently supported provisions that enhanced their control over the manufacturing and trade of their products. In this sense, they approved of those articles in the intellectual property rights chapters that increased the number of products and processes that could be protected by intellectual property rights. The IFAC-3 and the ITAC-15 approved of the provisions establishing patent protection for animals[65]

[65] The trade agreement with Morocco's article 15.9 requires member countries to grant patent protection for animals (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2004d). The CAFTA – DR and the agreements with Peru, Colombia, and Panama establish that in case their members allowed for patent granting for animals before they implemented the preferential trade agreements with the U.S., they should maintain such protection (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2004g, 2006d, 2006g, 2007g). On the other hand, the trade agreement with Bahrain establishes in article 14.8 that members are not required to grant patent protection for animals (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2004k). Likewise, the agreement with Oman establishes in article 15.8 that its members are not required to grant such protection, except for "[…] animals other than micro-organisms, and essentially biological processes for the production of animals other than non-biological and microbial processes [...]." (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2006a, p. 12). The agreements do not specify how animals could be protected by intellectual property rights. Nevertheless, they establish that all patents should be new, involve an inventive step, and be capable of industrial application (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2004d, 2004g, 2006a, 2006d, 2006g, 2007g). Therefore, any animal patent shall meet these criteria. One example of how this reasoning applies to real cases is the attempt to obtain patent protection for Dolly, the cloned sheep, in the United States. In May 2014, the U.S. Court of Appeals for the Federal Circuit in Washington, D.C. ruled that Dolly could not be patented because it was essentially identical to a natural animal (VAUGHAN, May 08, 2014). The final trade agreements with Chile, Singapore, Australia, and South Korea do not directly regard patenting for animals (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2003a, 2003c, 2004a, 2007a).

and plants[66] included in the agreements with Singapore, Australia, and Korea, which could extend patent eligibility for biotechnology products (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2003d, 2004c, 2007d). In this sense, they pointed out that the other agreements either required the protection of transgenic plants only or did not require intellectual property protection for animals and plants whatsoever (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2003b, 2004f, 2004i, 2004m, 2006c, 2006e, 2006h, 2007h).

The industries also commended provisions included in the agreements with Morocco, Bahrain, Oman, and Korea establishing that the parties shall provide patent protection for new uses of known products for the treatment of humans and animals (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2004f, 2004m, 2006c, 2007d). They explicitly complained that the agreements with Chile, the CAFTA-DR members, Peru, Colombia, and Panama did not include similar provisions (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2003b, 2004i, 2006e, 2006h, 2007h).

The reports expressed the industries' view that patent holders should be able to control exports and imports of their products, even after they have been legally introduced into national markets. In other words, the members of the IFAC-3 and the ITAC-15 supported the establishment of national exhaustion regimes, as opposed to regimes that would allow for freer international markets of patented products[67]. The committees approve of the provisions in the agreements with Singapore, Australia, and Morocco that restrict the authority of countries to establish international exhaustion regimes of patent rights (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2003d, 2004c, 2004f). Notwithstanding, in the report on the trade agreement with Australia the IFAC-3 also suggested that future trade agreements should be clearer in that regard (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2004c).

The preferential trade agreement with Singapore establishes in article 16.7.2 that member countries should prevent the procurement of pharmaceuticals that have been distributed without the consent of the patent holder (OFFICE OF THE UNITED STATES

[66] The preferential trade agreements require member countries to accede to the "International Convention for the Protection of New Varieties of Plants" (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2003a, 2003c, 2004a, 2004d, 2004g, 2004k, 2006a, 2006d, 2006g, 2007a, 2007g). The TRIPS requires member countries to grant intellectual property protection for plant varieties, but does not mandate accession to other related international agreements (WORLD TRADE ORGANIZATION, 2017b).

[67] On the different patent exhaustion regimes see footnote seven.

TRADE REPRESENTATIVE, 2003c). Even though it approved of the provision, the committee suggested greater clarity in future agreements:

> IFAC-3 notes that the underlying right being protected is implicitly acknowledged to be the right of the patent owner to exercise its exclusive right to prohibit importation of products subject to the patent. Future agreements should explicitly provide this understanding. (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2003d, p. 11).

On the other hand, the committees complain that the other preferential trade agreements do not require the establishment of national patent exhaustion regimes whatsoever (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2003b, 2004i, 2004m, 2006c, 2006f, 2006j, 2007d, 2007h). The agreements in fact do not include provisions similar to the ones found in the agreements with Singapore, Australia, and Morocco (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2003a, 2004g, 2004k, 2006a, 2006d, 2006g, 2007a, 2007g).

They also supported provisions that extend patent terms. One such provision requires trade partners to grant patent term restorations due to delays in the marketing approval process. The committees originally approved of the related articles included in all the preferential trade agreements, despite complaining about the transition period Panama had for the implementation of this provision (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2003b, 2003d, 2004c, 2004f, 2004i, 2004j, 2004m, 2006c, 2006f, 2006j, 2007d, 2007h)[68].

Committee members also disapproved of the fact that the U.S. and Australia had acknowledged in a side letter that Australia could permit the export by a third party of a pharmaceutical product covered by a patent during patent term extensions. Such exportations are those aimed at meeting marketing approval requirements of Australia itself or of other territories (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2004c)[69]. Article 17.10.4 of the Australian agreement establishes that no third parties that rely on safety and efficacy information can market products

[68] As regards transition periods, the ITAC-15 was particularly pleased that the agreement with Oman had established no transition periods for patent and test data provisions, unlike the agreements with Chile, the CAFTA-DR members, and Morocco (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2006c). The committees also complained about transition periods included in the agreements with Peru, Colombia, and Korea, as we will explain in greater detail as follows.

[69] They refer to a side letter reached between the two governments on May 18, 2004. Available at: <https://ustr.gov/sites/default/files/uploads/agreements/fta/australia/asset_upload_file948_3913.pdf>. Accessed Dec. 09, 2019. No equivalent complaint is included in the reports on the other agreements.

protected by patents during the term of the patents (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2004a). Therefore, the IFAC-3 stated that it believed that "[…] there should not be any differentiation between the protections provided pharmaceutical patents during the initial patent term or during the extension, as is the current practice in the United States." (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2004c, p. 15).

The committees also approved of the provisions setting patent term adjustments due to delays in the issuance of patents by the national patent offices, despite complaints about the transition periods granted to the CAFTA-DR members, Peru, Colombia, Panama and Korea. They also remarked their preference for the definition of "unreasonable delay" included in the agreements with Chile, Singapore, Australia, Morocco, Bahrain, Oman, and the CAFTA-DR over the definition included in the other trade agreements[70] (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2003b, 2003d, 2004c, 2004f, 2004i, 2004j, 2004m, 2006c, 2006f, 2006j, 2007d, 2007h). The report on the agreement with Peru exemplifies the difference in approach criticized by the industries:

> The PTPA [Peru Preferential Trade Agreement] recognizes, in Article 16.9.6(a), the delays that patent owners face in the issuance of their patents by the patent office and requires patent term adjustments to compensate for these delays. ITAC-15, however, notes with some concern that the definition of an "unreasonable delay" used in the most recent FTAs – a delay in the issuance of the patent of more than four years from the date of filing of the application in the territory of the Party or two years after a request for examination of the application, whichever is later – was not used in the PTPA, which defines "unreasonable delay" as the later of five years from filing or three years after an examination request. (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2006f, p. 15).

Even though patent offices can examine patent applications on their own, they can also base patent concessions on previous examinations from abroad. In this sense, the reports on the agreements with Bahrain and Oman approve of provisions that require member countries to extend the terms of patents based on foreign decisions following extensions in the countries that issued the first patents (OFFICE OF THE UNITED

[70] Despite that, on August 07, 2007, the ITAC-15 issued an addendum to the original report on the agreement with Korea where they stated that the provisions on patent term restoration included therein should be used as a precedent for future trade negotiations. They also considered that the agreement's provisions on test data exclusivity should become benchmarks (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2007e).

STATES TRADE REPRESENTATIVE, 2004m, 2006c). In the same vein, in the report on the trade agreement with Singapore, committee members disapprove of the lack of a provision requiring member countries to grant patents directed to the same invention of a U.S. or other previously examined patent, upon request by the patent owner (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2003d).

Committee members also approved of the fact that the trade agreements prohibit generic drug approvals during the term of a patent (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2003b, 2003d, 2004c, 2004f, 2004i, 2004j, 2004m, 2006c, 2006f, 2006j, 2007d, 2007h). Examples of such provision are article 16.8.4(c) of the agreement with Singapore and article 15.10.4(a) of the agreement with Panama (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2003c, 2007g).

The reports on the agreements with Singapore and Australia oppose the fact that the trade agreements did not include provisions on pipeline protection. They also suggested that future agreements should require member countries to grant such right to patent holders, especially those negotiated with countries that did not provide patent protection for pharmaceutical products (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2003d, 2004c). The other reports do not mention pipeline protections whatsoever (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2003b, 2004f, 2004i, 2004j, 2004m, 2006c, 2006f, 2006j, 2007d, 2007h). The committee members mentions of pipeline were not specific, but they probably meant that the rules related to protection of pharmaceutical products that had not been protected up to that point should be extended beyond the WTO standard, in the sense of increasing terms of protection. Some developing countries had until January 01, 2005, to apply the TRIPS Agreement to pharmaceutical products, which probably motivated the committee members to request the inclusion of such TRIPS-Plus provisions in future preferential agreements (WORLD TRADE ORGANIZATION, Sep. 21, 2006). As we explained in the introduction, WTO developing and least-developed members had transition periods to implement provisions related to pharmaceutical patents, but they also had to set “mailboxes” for pharmaceutical patent applications before they fully implemented the TRIPS Agreement. Such pharmaceutical products would eventually be protected, albeit for terms shorter than those granted by developed countries. The patent applications waiting for such protection were said to be “in the pipeline” (WORLD TRADE ORGANIZATION, Sep. 21, 2006).

As regards test data, the IFAC-3 and the ITAC-15 members approved of restrictions on how a third party may use an invention to generate data needed for the marketing approval of generic pharmaceutical products (i.e. Bolar – type uses) (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2003b, 2003d, 2004c, 2004f, 2004i, 2004j, 2004m, 2006c, 2006f, 2006j, 2007d, 2007h)[71].

The committees also commended the provisions determining that the protection for test data shall remain valid even if the underlying patents expire (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2003d, 2004c, 2004f, 2004m, 2006c, 2006f, 2006j, 2007d)[72]. Such requirement can potentially raise the effective terms of patents. Nevertheless, committee members complained about the clarity of the provision in the Chilean agreement and about the fact that the CAFTA-DR did not include such provision (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2003b, 2004i). In fact, though article 17.10 of the agreement with Chile requires member countries to protect pharmaceutical test data, it does not directly establish that such data shall outlast patents (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2003a). In addition, the article on test data in the CAFTA-DR (15.10) does not specify if protection for test data should remain in force when patents expire (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2004g).

The agreement with Panama also includes such provision on test data protection expiration (art. 15.10.5), but no mention of that was made in the committee report about the agreement (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2007g, 2007h). The agreements with Peru, Colombia, Panama, and Korea are different than the others in that regard because they explicitly specify that the continuation of the validity of test data protection is contingent on the member countries' need to protect public health in accordance with the Doha Declaration (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2006d, 2006g, 2007a, 2007g). Such exclusive requirement is due to the May 10 Agreement[73].

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[71] Article 17.9.4 of the trade agreement with Chile and article 18.8.5 of the trade agreement with Korea, for example, establish that such inventions can only be used for the obtainment of marketing approval and further establish that they shall only be exported for purposes related to meeting requirements for issuing marketing approval in the exporting party (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2003a, 2007a). On Bolar-type uses of patented products see footnote forty-six.

[72] See e.g. agreements with Australia and Colombia, arts. 17.10.3 and 16.10.5, respectively (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2004a, 2006g).

[73] On the Congressional views that led to the May 10 Agreement and to the inclusion of new provisions related to access to pharmaceuticals in trade agreements, see section 3.5. We will refer to the May 10 Agreement again in this chapter when we explain the reactions of specific private committee members to it.

The agreements with Australia, Morocco, Bahrain, Oman, and Korea require members to protect test data on new uses of chemical components previously approved in the member countries or abroad[74]. The reports on these agreements commend such provision (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2004a, 2004f, 2004m, 2006c, 2007a). The reports on the agreements with the CAFTA-DR members, Peru, Colombia, and Panama complain about the fact that they do not require such additional protection for test data (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2004i, 2006f, 2006j, 2007h).

All reports specify that the committee members approve of the provisions that expedite marketing approvals of pharmaceuticals by regulating the protection for test data based on information previously submitted in other territories (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2003b, 2003d, 2004c, 2004f, 2004i, 2004j, 2004m, 2006c, 2006f, 2006j, 2007d, 2007h)[75]. However, in the report on the agreement with Chile, the committee members complain about the clarity of the provision, contrasting it to the one included in the agreement with Singapore (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2003b). While the Chilean preferential trade agreement establishes in article 17.10 that test data on pharmaceuticals shall be protected for five years, it does not specify that the same term shall apply to information originated from marketing approvals in other countries, as the Singaporean agreement does in article 16.8.2 (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2003a, 2003c).

The reports on the agreements with Australia, the CAFTA-DR, Panama, and Korea also support provisions that can increase the number of pharmaceutical products eligible for test data protection (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2004c, 2004i, 2007d, 2007h). TRIPS article 39.3 requires WTO members to protect data about pharmaceuticals that utilize new chemical entities against unauthorized disclosure and unfair commercial use (WORLD TRADE ORGANIZATION, 2017b, p. 19). The definition included in these preferential trade

[74] See agreements with Australia art. 17.10.2; Morocco, art. 15.10.2; Bahrain, art. 14.9.2(a)(b); Oman, art. 15.2.2(a)(b) (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2004a, 2004d, 2004k, 2006a).

[75] The report on the trade agreement with Australia points out that the parties to the trade agreement stated that neither of them relies on unauthorized imported data when analyzing pharmaceutical marketing approval requests (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2004c). This is also mentioned in the trade agreement itself, in article 17.10(c) (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2004a).

agreements does not require the chemical entities underlying the protection to be new. Instead, they use marketing approval as the standard for eligibility for pharmaceutical test data protection (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2004a, 2004g, 2007a, 2007g)[76].

The agreement with Morocco includes such definition in article 15.10.1, but it is not mentioned in the private report (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2004d; 2004f). The other agreements do not include such definition, and no mention of that is made in the committee reports (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2003a, 2003b, 2003c, 2003d, 2004k, 2004m, 2006a, 2006c).

Moreover, the TRIPS Agreement does not define a minimum term of protection for test data submitted for marketing approval of pharmaceuticals. The preferential trade agreements do so – setting a minimum five-year term – and the committee reports approved of such complement (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2003a, 2003b, 2003c, 2003d, 2004a, 2004c, 2004d, 2004f, 2004g, 2004i, 2004k, 2004m, 2006a, 2006c, 2006d, 2006f, 2006g, 2006j, 2007a, 2007d, 2007g, 2007h)[77]. The reports on the agreements with the CAFTA-DR members, Peru, Colombia, and Panama are more detailed because industry states that the five-year term of protection should be interpreted to mean that subsequent delays by national health authorities in the grant of marketing approvals would not adversely affect granted protections (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2004i, 2006f, 2006j, 2007h).

The report on the agreements with Peru, Colombia, and Panama are also specific in that regard because committee members stated that the provisions on test data protections on pharmaceuticals were good complements to the TRIPS Agreement, but that they fall short of the positive precedent set by the agreements with Bahrain and Oman. They do not specify why the agreements with the middle Eastern countries would be better when it comes to test data, though (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2006f, 2006j, 2007h).

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[76] See trade agreements with Australia, art. 17.10.1(d); CAFTA-DR, art. 15.15.1(c); and Korea, art. 18.9.1(c) (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2004a, 2004g, 2007a). The final agreements with Peru, Colombia, and Panama do not include such definition (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2006f, 2006g, 2007g). Therefore, the agreement with Panama was adjusted in the meantime, probably as a result of the May 10 Agreement. We will explain the TRIPS Agreement criteria for patentability in greater detail as follows.

[77] As we explained in footnote 35, the agreements with Peru, Colombia, and Panama merely suggest a 5-year term, while the other agreements are explicit about it.

The reports on the agreement with Chile and on the accession of the Dominican Republic to the CAFTA also contain specific requirements related to pharmaceuticals. Committee members considered that the two Latin American countries had rushed to approve copies of products that were supposed to have been granted patent and test data protection for, since they had not yet fully implemented the TRIPS Agreement and had not concluded the negotiations of trade agreements with the U.S. In this sense, the reports required the USTR to prevent the two Latin American countries from continuing such approvals. The report on Chile further requested the USTR to seek the removal of the products already on the Chilean market from the stream of commerce. These special requirements suggest that industries viewed the state of patent and test data protection in Chile and in the Dominican Republic as particularly inadequate (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2003b, 2004j).

Similarly, all reports – except the one on the Korean agreement – suggested that in future negotiations the USTR should request trade partners that had not yet implemented the TRIPS Agreement to provide a standstill with respect to the approval of generic copies of pharmaceutical products (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2003b, 2003d, 2004c, 2004f, 2004i, 2004j, 2004m, 2006c, 2006f, 2006j, 2007d, 2007h).

The reports approve of the provision that requires member countries to notify patent holders of the identity of generic applicants seeking marketing approval while the patent covering a product is still valid (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2003b, 2003d, 2004c, 2004f, 2004i, 2004j, 2004m, 2006c, 2006f, 2006j, 2007d, 2007h)[78]. Even though the TRIPS requires member countries to grant pharmaceutical patents and to protect test data, it makes no such requirement regarding the identity of applicants (WORLD TRADE ORGANIZATION, 2017b). Therefore, the provisions included in the preferential agreements and approved of by the committee members can be described as “TRIPS-Plus”.

The committee members approved of the fact that the preferential trade agreements prohibit interference with the use of trademark rights in pharmaceuticals that

[78] In the agreements with Chile, Singapore, Peru, Colombia, and Panama, the provision referred to in the reports is general, related to any pharmaceutical marketing approval request. In the other agreements the equivalent provision refers to products whose data on safety and efficacy are protected (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2003a, 2003b, 2003c, 2003d, 2004a, 2004c, 2004d, 2004f, 2004g, 2004i, 2004j, 2004k, 2004m, 2006a, 2006c, 2006d, 2006f, 2006g, 2006j, 2007a, 2007d, 2007f, 2007g).

are also subject to requirements regarding the use of generic or common names of products. They considered that such provisions clarified and enhanced the TRIPS Agreement (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2003b, 2003d, 2004c, 2004f, 2004i, 2004j, 2004m, 2006c, 2006f, 2006j, 2007d, 2007h).

The TRIPS Agreement establishes in article 20 that WTO members shall not set special requirements that would unjustifiably encumber the use of trademarks (WORLD TRADE ORGANIZATION, 2017b, p. 9). The provisions included in the preferential trade agreements build on that article to establish that measures mandating the use of the term customary in common language as the common name for a product shall not encumber the use of a trademark[79]. Nevertheless, the trade agreements do not refer specifically to pharmaceuticals; therefore, the reports state an interpretation preferred by industries.

In the report on the preferential trade agreement with Singapore, committee members complained that TRIPS article 29 was not used as a ceiling for provisions on disclosure of information about the subject matter of a patent by applicants (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2003d). Such article defines the information patent applicants need to submit when requesting patents:

> […] an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application. (WORLD TRADE ORGANIZATION, 2017b, p. 13).

Such limitation could prevent trade partners from imposing tighter requirements aimed at avoiding patent grants based on requests for protection for frivolous inventive steps or for products or processes that are not yet ready for industrial application[80]. In the

[79] See e.g. trade agreements with Morocco and Peru, arts. 15.2.3 and 16.2.3, respectively (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2004d, 2006d).

[80] The three basic criteria for patentability, as established by TRIPS article 27, are novelty, industrial applicability, and the inclusion of an inventive step (WORLD TRADE ORGANIZATION, 2017b, p. 12). Cisneros (2008) explains why patentees may prefer to apply for patents before industrial applicability is clear: "Failing to disclose the use may cause the invention not to fulfill the requirements of industrial applicability and disclosure, a disclosure that needs to be more than pure speculation but supported by real experimentation and tangible results. These testing results that may be necessary to demonstrate the industrial applicability of the invention are usually available only in later stages of the development. This may force the delay in the filing of the patent application thus putting at risk the possibility to generate an early priority and the consequent anticipation of the invention by third parties." (CISNEROS, 2008, p.50, footnote omitted). Improperly granted patents that are too vague or based on minor inventive steps can be described as frivolous. They are meant to extract excessive licensing fees from manufacturers or to provide the basis for frivolous – yet lengthy and costly – infringement

reports on the agreements with Australia and Korea, committee members state that future trade agreements should seek to preserve the TRIPS standard (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2004c, 2007d). The Korean report further specifies that such requirement would apply especially to negotiations with countries in advanced stages of development (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2007d).

One specific concern in that regard relates to genetic resources. The committee on the agreement with Singapore approved of the fact that it preserves the TRIPS general standard for the protection of intellectual property rights, so that trade partners do not impose special rules for disclosures related to the origin of such resources (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2003d). In the reports on the agreements with Australia and Korea, the committees stated that future trade agreements should include such provision (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2004c, 2007d).

In this sense, the ITAC-15 also approved of the "understandings" on biodiversity and traditional knowledge reached between the U.S., Colombia, and Peru. They establish basic rules for the use of genetic resources and for the distribution between users and providers of benefits arising from the use of genetic resources and traditional knowledge (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2006e, 2006f, 2006i, 2006j). In the same vein, in the report on the agreement with Panama the ITAC-15:

> […] welcomes the pledge made by Panama and the United States to work together in the World Intellectual Property Organization Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge, and Folklore in addressing matters related to traditional knowledge and folklore. (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2007h, p. 16)[81].

Since industries sought to enhance their control over products and processes through intellectual property rights, in the reports the committee members either criticized

litigations. Therefore, those patents may harm innovators, clog the legal system, and eventually impact consumers (SHRESTHA, 2010).

[81] They refer to the "Side Letter on Traditional Knowledge", where the parties also establish that if the U.S. signs another free trade agreement with provisions on traditional knowledge or folklore, they will discuss whether they should apply similar provisions between each other. Available at: <https://ustr.gov/sites/default/files/uploads/agreements/fta/panama/asset_upload_file608_10510.pdf>. Accessed on Feb. 04, 2019.

the flexibilities related to access to pharmaceuticals included in the preferential trade agreements or supported interpretations that limit their effects. In the reports – except the ones on the preferential trade agreements with Australia and Singapore – the committee members complained about the lack of a provision reinstating the conditions established by the TRIPS Agreement and by the Paris Convention for the concession of compulsory licenses for patents[82]. They also state that future agreements should include such limitations (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2003b, 2003d, 2004c, 2004f, 2004i, 2004j, 2004m, 2006c, 2006f, 2006j, 2007d, 2007h).

On the other hand, the reports approve of the fact that the grounds for the revocation of patents are limited to issues that would have justified a refusal to grant them in the first place (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2003b, 2003d, 2004c, 2004f, 2004i, 2004j, 2004m, 2006c, 2006f, 2006j, 2007d, 2007h). Nevertheless, the reports on the agreements with the CAFTA-DR members, Peru, Colombia, and Panama include complaints about the scope of such restrictions, since they do not mandate member countries to provide that fraud, misrepresentation, or inequitable conduct can also be the basis for revoking a patent (OFFICE OF THE UNITED STATES, 2004i, 2006f, 2006j, 2007h)[83].

The report on the agreement between the U.S. and Morocco remarked that the two countries had reached a side letter where they established that the intellectual property rights chapter should not prevent them from taking "[…] necessary measures to protect public health by promoting medicines for all, in particular concerning cases such as HIV/AIDS, tuberculosis, malaria, and other epidemics as well as circumstances of extreme urgency or national emergency." (OFFICE OF THE UNITED STATES TRADE

[82] The "Paris Convention for the Protection of Industrial Property" is one of the first multilateral agreements on intellectual property rights. It was signed in 1883, and it has been amended many times since. The number of signatories has also increased over time (WORLD INTELLECTUAL PROPERTY ORGANIZATION, 2019b; SELL, 2003). It is one of the founding agreements of the World Intellectual Property Organization. TRIPS article two requires its members to comply with some of the provisions of the Paris Convention, including the ones on compulsory licensing (WORLD TRADE ORGANIZATION, 2019b). The Convention's article 5 establishes that members may grant compulsory licenses to prevent abuses which might result from the exercise of the exclusive rights conferred by a patent (WORLD INTELLECTUAL PROPERTY ORGANIZATION, 1979). On the (more specific) TRIPS provisions on compulsory licensing for pharmaceuticals see introduction.

[83] The TRIPS Agreement does not mandate its members to allow for patent revocations. Notwithstanding, its articles 32 and 62 establish basic guidelines for member countries that allow for revocations of intellectual property rights (WORLD TRADE ORGANIZATION, 2017b, p. 16; p. 27). The provisions on revocation included in the agreements with Chile, Morocco, Bahrain, Oman, and Korea are identical to the ones found in the agreements with Peru, Colombia, and Panama. Nevertheless, the committee members do not complain about them (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2003a, 2003b, 2004d, 2004f, 2004k, 2004m, 2006a, 2006c, 2007a, 2007d).

REPRESENTATIVE, 2004e). In this sense, committee members emphasized that the side letter specifies the epidemics to which the provision would apply. Moreover, they requested the USTR to ensure that the terms of the side letter would not be used to weaken the agreement's intellectual property protections (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2004f).

The committee members also stressed their interpretations of the mentions of the Doha Declaration included in the preferential trade agreements. As regards the agreement with Morocco, they stated that the Declaration did not amend TRIPS article 8. Such article establishes that measures adopted by WTO members to protect public health shall be consistent with the TRIPS Agreement (WORLD TRADE ORGANIZATION, 2017b, p. 5). Therefore, the reports emphasize their preference for the maintenance of the minimum standards set by the TRIPS Agreement over more recent flexibilities related to trade of pharmaceuticals meant to address critical situations.

All committee members maintained their approval of the agreement with Morocco, despite that criticism about provisions related to the Doha Declaration. Nevertheless, their reactions to flexibilities included in other trade agreements were more intense, as we explain in the next section.

4.2 Reversing views due to Congressional demands: the addenda to the original reports

The Doha Declaration and subsequent decisions related to pharmaceuticals at the WTO were among the main issues addressed through the May 10 Agreement, as we explained in section 3.5. The new provisions included in the agreements with Peru, Colombia, and Panama triggered reactions by a subset of members of the advisory committees.

A prelude to that was included in the main report on the agreement with Panama, where the committee stated that the discussions on pharmaceuticals between Congress and the administration could lead to future shifts in approval of the agreement (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2007h). The report was released fifteen days before the May 10 Agreement was concluded in the U.S. In the main report on the agreement with Korea, the committee also announced that it could file addenda to the report due to the discussions between Congress and the Bush

administration, ongoing at the time (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2007d).

In fact, the committees issued two addenda on August 09, 2007, encompassing the agreements with Peru, Colombia, Panama, and Korea. They were authored by the representatives of The Gorlin Group, Merck, the Intellectual Property Owners Association, the Biotechnology Industry Organization and CropLife America[84]. The five co-authored the reports on the four agreements, except for CropLife, that did not undersign the original report on the Peruvian agreement. Though Pfizer and Eli Lilly were not directly represented, they were members of the Biotechnology Industry Organization when the addenda were issued (BIOTECHNOLOGY INDUSTRY ORGANIZATION, 2007a, 2007b).

In the addendum to the reports on the agreements with Peru, Colombia, and Panama the authors stated that the changes included in the agreements would discriminate against pharmaceuticals by allowing member countries to provide patent and test data protection at a level inferior to that found in the United States (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2007j). In this sense, they disapprove of the fact that certain provisions are no longer mandatory, which would be a deviation from the good precedent set by the other preferential trade agreements. The first example they provide in that regard is the revised article on patent term extensions for pharmaceutical patents.

As we explained in section 3.5, the agreements with the three Latin American countries do not require them to extend patent terms of pharmaceuticals due to delays related to patent granting or marketing approval. Such extensions are mandatory in the other agreements, even those negotiated with other Latin-American nations[85].

The second non-mandatory provision directly mentioned in the report is the one on linkage. The agreements with Peru and Colombia specify in article 16.10.4(a) that marketing approval authorities are not required to determine the validity of patents

[84] On Merck and the Biotechnology Industry Organization see footnote sixty-two. The Gorlin Group is a Washington-based consultancy that provides advice and analysis on the connections between intellectual property rights and trade (THE GORLIN GROUP, 2019). The Intellectual Property Owners Association is a trade association established in 1972. Among its activities is the provision of support for members on issues related to international law (INTELLECTUAL PROPERTY OWNERS ASSOCIATION, 2019). CropLife America is the trade association representing the manufacturers, formulators, and distributors of pesticides. Its offices are in Washington, D.C. (CROPLIFE, 2019). CropLife was probably particularly interested in the provisions on test data protection for agricultural chemical products because they can be applied to pesticides.

[85] See preferential trade agreement with Chile, arts. 17.9.6 and 17.10.2(a); and CAFTA-DR, art. 15.9.6 (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2003a, 2004g).

underlying pharmaceutical products (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2006d, 2006g, 2007g). On the other hand, the other preferential trade agreements do not include such specification (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2003a, 2003c, 2004a, 2004d, 2004g, 2004k, 2006a, 2007a, 2007g). As we explained in section 3.5 such discrepancy is due to the May 10 Agreement.

The addendum also disapproved of the new method for counting the period of non-reliance on imported pharmaceutical test data. The agreements with Peru (art. 16.10.2(c)), Colombia (art. 16.10.2(c)), and Panama (art. 15.10.2(c)) establish that when such data is imported from the U.S., the term of protection shall be counted from when marketing approval was granted in the United States (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2006d, 2006g, 2007g). The other agreements establish that such period shall be counted from when marketing approval is granted in the country importing the data, whereby protection lasts longer (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2003a, 2003c, 2004a, 2004d, 2004g, 2004k, 2006a, 2007a).

The five co-authors approved of the provisions included in the preferential trade agreements with Peru, Colombia, and Panama aimed at expediting the resolution of disputes related to marketing approvals for patented pharmaceuticals[86]. Nevertheless, they contrasted such provisions to their preferred, more general articles that prohibit the concession of marketing approvals for pharmaceuticals to third parties[87]. The agreements with Peru (art. 16.10.4), Colombia (art. 16.10.4), and Panama (art. 15.10.4) only mention that member countries could enact such prohibition (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2006d, 2006g, 2007g).

In the same vein, the authors of the addendum to the reports criticized the fact that, even though the agreements with Peru, Colombia, and Panama provided for the concession of extensions to patent terms due to delays in patent granting, member

[86] They establish that member countries shall provide "[…] sufficient time and opportunity for a patent holder to seek, prior to the marketing of an allegedly infringing product, available remedies for an infringing product." (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2006d, p. 16).

[87] Such restriction is included in all other trade agreements. For example, the agreement between the U.S. and the CAFTA-DR members establishes in article 15.10.2(a) that the parties shall implement measures in their marketing approval processes to prevent persons requesting access to previously submitted test data on pharmaceuticals from marketing products covered by valid patents. Evidently, such provision does not regard the persons who submitted the original data (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2004g).

countries are not required to apply the provision to pharmaceutical products. As we explained in section 3.5, this was one of the outcomes of the May 10 Agreement. No other trade agreement allows member countries to discriminate pharmaceuticals in that regard (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2003a, 2003c, 2004a, 2004d, 2004g, 2004k, 2006a, 2007a).

They conclude the addendum by reversing their approval of the agreements:

> […] we do not believe that these changes [included in the intellectual property chapters due to renegotiations] will advance the claimed objectives of fostering access to medicines in the partner countries, and in fact are more likely to be counter-productive to that goal. Furthermore, these changes will almost certainly undermine U.S. jobs and companies in one of the most innovative sectors of the American economy. As a result, the undersigned do not support the Free Trade Agreements with Peru, Colombia and Panama. (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2007j).

That was the only time members of the advisory committees did so.

In the addendum to the advisory committee report on the agreement with Korea, the subset of members asserted that changes introduced in the final agreement – as compared to the draft on which they had based the initial report – were not warranted, especially due to Korea's advanced stage of development (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2007e).

They criticized articles 18.9.3 and 18.11 of the Korean agreement. The provisions establish that the chapter on intellectual property rights should be "[…] interpreted and implemented in a manner supportive of each Party's right to protect public health and, in particular, to promote access to medicines for all" (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2007a, p.34). In addition, the parties stressed their commitment to the Doha Declaration and subsequent decisions reached at the WTO by clarifying that "[…] this Chapter [on intellectual property] does not and should not prevent the effective utilization of the TRIPS/health solution" (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2007a, p. 34). Furthermore, the U.S. and Korea agreed that they would adapt the preferential trade agreement if the TRIPS were amended as a result of the Doha Declaration and related decisions reached by the WTO members.

In this sense, the authors of the addendum criticized such flexibilities of the revised agreement because they had been "[…] primarily drawn from the provisions of

the WTO Declaration on the TRIPS Agreement and Public Health, which was intended to deal with public health crises that may occur in developing countries." (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2007e).

Due to their disagreement with the provisions, they stated that the U.S. should ensure that the new provisions were not abused or misinterpreted. In that regard, they also suggested that the USTR should ensure Korea's full implementation of the patent and test data provisions of the agreement, especially because the two countries had signed a side letter where they agreed not to start dispute settlement proceedings regarding linkage for eighteen months, counting from when the agreement entered into force[88].

Despite explicitly opposing the changes, the five authors maintained their approval of the agreement. In fact, they start and finish the addendum by highlighting that the preferential trade agreement contains strong protection for intellectual property rights that would benefit American companies and workers.

Therefore, in the addendum to the report on the agreement with Korea, a subset of the advisory committee members criticized the inclusion of flexibilities related to the production and international trade of pharmaceuticals for the very fact that the U.S. trade partner is a developed country. This relates to the fact that in the main reports the advisory committees acknowledged the flexibilities related to pharmaceuticals included in the agreements with three developing countries (Morocco, Peru, and Colombia), while also emphasizing that such provisions should be used in specific circumstances only, such as when actions to address emergencies in public health became necessary.

4.3 Conclusion: the industry advisory committees' role in the U.S. trade policymaking

As the previous sections demonstrate, the activities carried out by the committees were restricted to their main purpose: giving advice to U.S. decision-makers. The IFAC – 3 and the ITAC – 15 had no voting or vetoing powers over trade agreements, as defined by the trade law in place at the time.

Though several provisions on pharmaceuticals included in the preferential trade agreements were aligned with the committees' preferences, Congress prevailed when its

[88] They refer to a letter exchanged between the parties on June 30, 2007 where they pledge to consult in case any disputes on the marketing approval of patented goods based on disclosed test data arose, thereby refraining from starting dispute settlement proceedings (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVES, 2007b). On linkage, see also footnote forty-three.

majority's views diverged from those of the advisory committees. Nevertheless, these divergences between Congress and industry representatives show that at the time the United States did not have a coherent, stable, objective national interest when it comes to intellectual property protection for pharmaceuticals. Instead, the definition of the best course of action depended on which views were able to prevail according to the laws on the negotiation, renegotiation, and ratification of trade agreements. Even the executive had to step back and negotiate with the Congress to advance its trade agenda. Therefore, these facts corroborate theories that give due credit to the importance of the domestic political game in shaping international trade agreements.

Moreover, our analysis of the reports produced by the industry advisory committees also demonstrates that powerful economic sectors did not have the final say in matters that affect their businesses in the U.S. and abroad. Despite the severe objections by representatives from several private companies to the renegotiated provisions on pharmaceuticals, the trade agreements with Peru, Colombia, and Panama were implemented and remain in force. This fact supports the theories that emphasize that the influence of interest groups over foreign policy is limited by the interests of state decision-makers. They ultimately judge if advice provided by interest groups is useful and worth trust; therefore, such groups are signalers uncappable of always shaping political actors' preferences.

On the other hand, both Democratic and Republican members of Congress complained about the fact that the advisory committees represented the interests of pharmaceutical companies only, thereby failing to represent other societal actors. Despite that, it was merely suggested that the advisory committee system should be reformed. No concrete proposals to reach this goal were advanced in Congress during the period. Moreover, this shortcoming in representation was actually even more prevalent than the situation described by Congress members, because – as we explained in the introduction to this chapter – a very limited number of pharmaceutical companies were members of all the intellectual property committees that produced reports on the trade agreements. Therefore, representation was deficient even when only the pharmaceutical sector is taken into account.

As we explained in section 4.1, the committees also expressed approval of several provisions related to pharmaceuticals included in all the preferential trade agreements. Nevertheless, we cannot establish a causal relationship between their advice and the text of the trade agreements that were eventually implemented by the United States. But even

if we assume that members of the advisory committees were the minds behind those provisions that benefit pharmaceutical intellectual property right holders, the renegotiation of the trade agreements with Peru, Colombia, and Panama show that the influence of the committees over the intellectual property provisions negotiated with trade partners was limited in scope and in time.

5 CONCLUSIONS

Our analysis corroborates International Relations theories that emphasize that, under certain conditions, the interactions between domestic actors are crucial for states' foreign policies. Although we did not aim to validate those theories in a generalized fashion, our results provide original insights as to how they seem to robustly apply to specific circumstances of the U.S. trade policy in recent years. In fact, our analysis show that, at least from 2001 to 2012, the U.S. trade policy depended on a legally defined, complex set of interactions between some of its domestic actors.

The U.S. domestic institutions and trade laws have been designed to disperse power over trade treatymaking. The president defines the trade policy agenda and decides whether to negotiate, adjust, and implement international trade agreements. The government agency that negotiates such agreements and oversees their standing is under presidential purview. As we explained in chapter two, politicians that have nation-wide constituencies are theoretically expected to favor economic policies that enhance the public welfare.

The federal administration was rather active in advancing the U.S. trade policy from 2001 to 2012. The Bush administration negotiated and implemented most trade agreements currently in force for the U.S. It significantly expanded the number of countries the U.S. has preferential trade relations with, most notably in Latin America. Such enlargement included the diffusion of specific intellectual property standards related to the production and trade of pharmaceuticals.

The Congress also influences trade agreements, especially when fast tracks are effective. They typically instruct the president and specify that legislators can participate in trade negotiations. The U.S. Congress also votes on approval of agreements submitted by the president, thereby fulfilling a Constitutional prerogative. Theoretically, members of Congress are expected to be concerned with their local districts and favor protections for import-competing producers. In this sense, legislators would reject trade agreements that could improve the national welfare in case they resulted in economic losses to their constituents. As we explained in chapter two, that would happen because the constituencies of Congress members are relatively small.

Nevertheless, from 2001 to 2012 Congress concurred with an unprecedented expansion of the U.S. preferential trade relations. Despite that, the fast track defined

specific objectives trade agreements should meet, which includes intellectual property protections for pharmaceuticals.

In the same vein, during the negotiations the USTR was advised by private committees on intellectual property. Though they had no voting or blocking power over trade agreements, their members were given the chance to make their views known by policy makers and society at large. Moreover, the reports written by the industry advisory committees demonstrate that views on intellectual property protection for pharmaceuticals were not uniform in the U.S., since their authors' views often diverged from those of members of Congress and of other American societal actors.

Therefore, systemic theories based on the existence of a national interest rationally defined and carried out by indifferent bureaucracies could not have shed light on the formulation and implementation of trade policies by the United States over the period. Examples of this are the stricter conditions for the ratification of trade agreements negotiated by the federal administration with developing countries in Latin America due to shifts in party control of Congress following the mid-term elections in 2006. As predicted by the theories presented in chapter one, it was harder for a divided U.S. government to achieve international cooperation, which forced the executive to renegotiate with foreign countries to secure the support of domestic stakeholders.

At least when it comes to intellectual property rights related to pharmaceuticals in trade agreements, the U.S. did not have a unified, coherent, rational position based on its national interest over the period. Its policies were dependent on the views of domestic actors, to the point of being affected by shifts in party control of Congress.

A Democrat-controlled Congress pushed for provisions on pharmaceuticals that aimed at ensuring access to inexpensive medicines in the U.S. and abroad, while Republicans usually emphasized the role of intellectual property rights in fostering pharmaceutical innovation and investments in developing countries. Nevertheless, this division does not account for the whole picture, since in many cases statements and votes by members of Congress deviated from the majority of their parties.

The core of the discussions was the way the administration was dealing with the instructions given by Congress through the Trade Act of 2002. Some members of Congress emphasized that the Trade Act determined that the Doha Declaration should be respected, while others emphasized that the very same Act required the federal administration to ensure the protection of American intellectual property rights abroad.

In this sense, several members of Congress accused the Bush administration of siding with pharmaceutical companies by negotiating harmful provisions with trade partners, instead of following Congressional instructions. The reason for that would be the campaign contributions made by such industries to Republicans. Responses to that pointed out that the administration had consulted with Congress during the negotiation of trade agreements and that such provisions would probably not have significant negative consequences for the U.S. or its trade partners.

The Doha Declaration and related decisions were viewed by many members of Congress as benchmarks to assess the extent to which the Bush administration was considering Congressional views on access to pharmaceuticals. In fact, compliance with these multilateral agreements was the most concrete requirement included in the May 10 Agreement. It had a very important, practical effect because the Agreement set the standards for the renegotiation of the provisions related to pharmaceuticals included in the trade agreements with Peru, Colombia, and Panama. It is also an example of the crucial role Congress may play in shaping the U.S. trade policy, since the May 10 Agreement forced the federal administration to go back to the negotiating table to obtain the ratification of the trade agreements with these Latin American countries.

Therefore, as we have been pointing out, this agreement between Congress and the Bush administration is a clear example of power sharing over policymaking at the domestic level. It is also an example of a situation where the definition of the so-called "national interest" as regards intellectual property rights depended on negotiations between different stakeholders in the U.S. Moreover, the May 10 Agreement also corroborates the theories that do not regard international negotiators as powerful actors; those that misinterpret domestic preferences may end up negotiating agreements that will not be ratified after all.

The May 10 Agreement eroded the fast track procedures established by a previous, Republican-led Congress. Therefore, even though the Bush administration succeeded in ratifying the agreements, it had to abide by the rules defined by Congress, adapt to shifts in party control of Congress and even face objections by Republican Senators who strongly disagreed with the new provisions on pharmaceuticals.

Several of the statements by members of Congress had to do with the ability of trade partners to address their own health-related problems and to provide pharmaceuticals produced under compulsory licenses to developing countries. As an example of this, the TRIPS-Plus provisions included in agreements with Latin American

nations were much more contested than those included in the agreements with developed countries. As a result, the May 10 Agreement applied to Peru, Colombia, and Panama, but not to South Korea, whose agreement was being negotiated at the time.

Development was also the key word for Republicans who asserted that healthcare problems in developing countries were the result of several causes, not by-products of intellectual property rights. In this sense, they asserted that trade agreements that include strong provisions on intellectual property rights help developing trade partners by promoting exports and providing safer investment environments for pharmaceutical companies.

Advocacy groups, NGOs, trade unions, academics, and even a religious organization had their views taken into account by Congress members when debating about the provisions on pharmaceuticals included in the preferential trade agreements. Nevertheless, these domestic actors did not have the same stable and formalized channel of communication with the executive as the members of the IFAC-3 and the ITAC-15 had. PhRMA stands out among the members of the USTR advisory committees because it was the private actor most frequently criticized by members of Congress when addressing trade agreements.

These private advisory committees consistently tried to influence the intellectual property rights related to pharmaceuticals included in preferential trade agreements, but their success was ultimately limited by the prevailing views in Congress. This finding corroborates the theoretical approaches that view interest groups as information providers, rather than actors that are fully capable of shaping political actors' preferences.

The advisory committees on intellectual property supported provisions that enhanced the control of right holders over their products. They often suggested that the USTR should seek the maintenance of the TRIPS standards for patentability, which could limit trade partners' ability to impose more rigorous requirements for granting patents.

Nevertheless, the committees widely supported TRIPS-Plus provisions. Among them are extensions to patent terms due to granting or marketing approval delays. Other provisions approved of by the IFAC-3 and by the ITAC-15 in that regard are those that make it harder for generic pharmaceuticals to enter markets when patents expire, such as protections for test data. Stricter rules for granting Bolar-type exceptions were also commended by the private committees.

They also supported provisions that could result in patentability of pharmaceuticals that would otherwise be in the public domain, such as the one allowing

for protection for new uses of known products. Moreover, the advisory committees clearly stated preference for national exhaustion regimes, which could prevent member countries from allowing importations of relatively inexpensive medicines.

Provisions on compulsory licenses and revocation of patents included in the agreements were criticized by the advisory committees. They preferred interpretations that limit the scope of flexibilities over the ones advanced by the Doha Declaration and related decisions at the WTO. Despite criticizing these and other provisions related to pharmaceuticals, the committees supported most trade agreements.

Nevertheless, as we explained in chapter four, a subset of the advisory committee members reversed their approval of the trade agreements with Peru, Colombia, and Panama due to changes requested by a Democratic-led Congress. The new provisions negotiated with these three countries due to the May 10 Agreement caused the only apparent division within the intellectual property rights advisory committees during the period. That was also the only time members of advisory committees on intellectual property officially withdrew approval of trade agreements, which suggests that the intellectual property protection for pharmaceuticals is exceptionally important for American industries, as compared to the importance they place on protections granted for other products.

The addendum to the main reports was written after the agreements had been renegotiated. No adjustments or side letters were negotiated with trade partners as a result of the industry advisory committees' complaints. Therefore, Congress prevailed despite the explicitly negative response by members of the IFAC-3 and of the ITAC-15.

A subset of advisory committee members also issued an addendum to the report on the agreement with Korea. They were particularly disappointed that the trade agreement had included flexibilities that were originally meant to address public health problems in developing countries. Nevertheless, as we explained in the introduction, the Doha Declaration and related decisions reached at the WTO set legal and technical requirements for the production and exportation of generic medicines necessary to address public health emergencies in countries with insufficient pharmaceutical production. Therefore, even though Korea would not need to rely on such mechanisms to address domestic health crises due to its high level of development, it could still export medicines produced under compulsory licenses.

The views of the advisory committees were often at odds with those of several members of Congress, but they agreed with some of the views expressed by legislators.

The provisions on importation are examples of that. While some Congress members – from both parties – supported international exhaustion regimes as a way to drop prices of pharmaceuticals, another bipartisan group preferred the national standard advocated by the industries.

In the same vein, while industries supported strict interpretations of the flexibilities included in the preferential trade agreements, a significant group of Democratic members of Congress complained that the administration was dodging Congressional concerns to negotiate trade agreements that undermined the Doha Declaration and negatively affected healthcare systems in developing countries. An example of that is the difference of view between House member Louise Slaughter (D-NY) and the IFAC-3 on the side letter on public health attached to the agreement with Morocco. Democrats and the advisory committees frequently diverged on patent extensions too.

On the other hand, other Republican and Democratic legislators considered that the agreements would not have significant negative impacts on trade partners, particularly on developed ones. Republican Senators considered that patent and test data protections would provide incentives for the development of new products needed by developing countries. Therefore, according to these senators, strong intellectual property rights would promote rather than limit access to medicines by low-income patients. As a result, these Republican legislators supported the same argument advanced by private advisory committee members in the addendum to the reports on the trade agreements with Peru, Colombia, and Panama.

Though these and other members of Congress shared views expressed by industries in the reports, all direct mentions of the IFAC-3 and the ITAC-15 by legislators were negative. Congress members complained that the advisory committees included private companies only, most notably pharmaceutical industries. Therefore, they asserted that the U.S. advisory system should be enlarged to include a broader, more diverse group of domestic actors capable of assessing the intellectual property rights negotiated with trade partners. Nevertheless, no concrete proposals to reform the advisory system were advanced in Congress.

Though this dissertation has focused on the role of the U.S. domestic actors in including provisions on pharmaceuticals in preferential trade agreements, the final intellectual property rights chapters also depended on the trade partners' requests and concessions. In this sense, members of Congress mentioned that foreign negotiators had

rejected specific U.S. proposals. They also suggested that trade partners should not accept intellectual property rights that could harm public health and access to medicines.

We see ways in which future research could expand our results. Further empirical analyzes could investigate whether other aspects of the U.S. trade policy also corroborate the two-level theories. Further research could expand our time frame to investigate whether debates about the provisions on pharmaceuticals included in other U.S. trade agreements – such as the one with Israel and NAFTA – resulted in party divisions similar to the ones we have found. The recent implementation of the USMCA also provides excellent material for such analyses, especially because it has updated NAFTA's intellectual property rights chapter. In a similar vein, other projects could verify if Congress also prevailed in other situations where it collided with the federal administration and with privileged domestic advisory committees.

Other projects could also investigate the interactions between executives, legislatures, and private domestic actors that take place in other countries to create and implement intellectual property rights negotiated with foreign partners. Democracies that provide open and organized access to official documents related to the negotiation and implementation of trade agreements would be good options.

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ANNEX 1: PRIMARY DATA

	Description and use in the dissertation	Main sources
Congressional Record	Developed and published by the U.S. Library of Congress. Digital version available online. Transcribes statements delivered in both houses of Congress. Allows for searches for specific words and combinations of words. Used to gauge views of members of Congress on intellectual property protection for pharmaceuticals as defined by preferential trade agreements.	Website of the Congressional Record
The U.S. Constitution. Trade Acts of 1974 and 2002	Enacted by Congress to define tariff and nontariff objectives presidents must pursue. Grant discretion to the U.S. president on trade matters. Used to explain the development of Congressional views on intellectual property and the role of the president. Also used to explain the U.S. laws and institutions on the negotiation and implementation of trade agreements.	Websites of the Government Publishing Office, the House of Representatives, and the Senate
GATT and WTO international agreements	Describe the rules of the multilateral trade system and their development. Establish minimum standards for intellectual property protection. Used to describe TRIPS-Plus provisions and describe U.S. positions on developments related to pharmaceuticals.	WTO website
U.S. preferential trade agreements	Versions of the preferential trade agreements implemented by the U.S. and partners. Used to explain mentions of	Office of the United States Trade Representative website

	intellectual property provisions in Congress and in advisory committee reports. Also allow for comparisons with the TRIPS Agreement.	
Reports by the industry advisory committees	Reports where official industry advisory committees express their views on intellectual property protections for pharmaceuticals and other knowledge-intensive products. Used to summarize their views, contrast them to the ones expressed in Congress, and investigate the extent to which they represent U.S. societal actors.	Office of the United States Trade Representative website
Addenda to the main reports on trade agreements produced by the advisory committees	Committees express views on renegotiated versions of preferential trade agreements. Used to analyze how the committee views evolved and to explain their influence on the U.S. trade treatymaking.	Office of the United States Trade Representative website

ANNEX 2: PAPER BASED ON DATA FROM YEARS 1995 – 2000

The Impacts of International Intellectual Property Rights on Domestic Legislative Debates: Evidence from the 104th to the 106th U.S. Congresses[1]

ABSTRACT

Despite the large body of literature on the connection between intellectual property rights and trade at the international level, less attention has been paid to the impacts of such rights included in preferential trade and investment agreements on domestic legislative debates. This article fills this gap by analyzing debates in the U.S. legislature where members of Congress mentioned the intellectual property rights included in preferential trade and investment agreements. We consider the statements delivered in both houses from 1995 to 2000 (104th to 106th Congresses). These data suggest that the intellectual property rights negotiated with foreign partners may affect Congress voting on the concession of trade promotion authority to the president, thereby affecting his ability to conclude new trade agreements. They may also trigger urges for adjustments to trade agreements in force. Our results also suggest that the two-level games approach and similar theoretical models that emphasize the role of private domestic actors are useful in explaining the U.S. trade policy.

1 Introduction

The mutual interactions between the national and the international levels have increasingly drawn the attention of political scientists and International Relations scholars. Since at the least the late 1980s, the assumption that states at the international level can be described as rational, unitary actors – or billiard balls, to recall Stephen Walt`z analogy – has been challenged by both theoretical and empirical works[2].

Robert Putnam`s influential article on the two-level games (PUTNAM, 1988) emphasizes that domestic politics are fundamental for international relations because agreements negotiated by diplomats with foreign countries can only be implemented if

[1] An expanded version of this article has been published by the Journal of World Intellectual Property. It includes improvements suggested by the journal's reviewer. See: TEODORO, J.P.H. The impacts of trade-related intellectual property rights on legislative debates: Evidence from the 104th to the 112th U.S. Congresses. **Journal of World Intellectual Property**, v. 23, n. 3 – 4, p. 430-453, July 2020. Due to copyright restrictions, we cannot reprint the article in this annex.

[2] On Walt`z billiard balls model and his support for treating the international level as a separate and sufficient level of analysis see Waltz (1979).

politicians at the domestic level agree with them - i.e. international cooperation is only achieved when different countries' interests overlap. According to the theoretical perspective developed by him and others, states' international policies are not guided by national interests rationally defined a priori by states' bureaucracies. Rather, they are heavily dependent on the preferences of domestic actors, who strive to achieve power and influence public policies. Institutions such as Congress and the presidency, as much as the legal system in place, delimit such interest groups' actions (MILNER, 1997; GOLDSMITH, POSNER, 2005; BUENO DE MESQUITA, 2010).

One area where this type of building through overlapping preferences may be observed is international trade. The current multilateral trade framework is the outcome of a dense and controversial set of international negotiations that spanned from 1986 to 1994, which resulted in the creation of the World trade Organization (WTO). It builds on the tariff and non-tariff barriers negotiated since 1947 under the framework of the General Agreement on Tariffs and Trade (GATT), but its most original features are the minimum common grounds on services, investments, and intellectual property rights, which are valid for all member countries.

Though the first international agreements on intellectual property rights date back to the late nineteenth century, the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) was the first to connect such rights to a multilateral trade institution. The agreement sets standards on copyright and related rights, trademarks, geographical indications, industrial designs, patents, topographies of integrated circuits and on the protection of undisclosed information (WORLD TRADE ORGANIZATION, 2017). Moreover, members can submit TRIPS-related complaints to the Organization's Dispute Settlement Body and to its higher instance, the Appellate Body (BARTON et al., 2006).

Despite the creation of this multilateral trade framework including an agreement on intellectual property rights and mechanisms to facilitate monitoring and enforcement, preferential trade and investment agreements have strongly proliferated as alternatives to multilateral trade negotiations, and the inability of developed countries to push for stricter intellectual property rights at the multilateral level is one of the reasons for such a trend (CHOREV, 2007)[3].

[3] Preferential trade agreements set exclusive trade-related rules, valid only for a relatively small group of countries. They can take the form of bilateral trade agreements, regional trade agreements and inter-regional trade agreements, i.e. trade agreements signed jointly between all members of two or more regional trade agreements (BHAGWATI, 1995; MAVROIDIS, 2011). We prefer this definition over the WTO terminology - regional trade agreements - because the latter has often been used indiscreetly to refer to trade agreements between countries not belonging to a same region (for the WTO definition see World Trade Organization (2019)). For the sake of precision, we have also decided not to refer to them as "bilateral trade agreements"

Also, since the intellectual property rights have been included in both the TRIPS Agreement and preferential trade agreements, they are part of the debate on whether the latter are building or stumbling blocks for the multilateral trade framework. Some researchers consider that preferential trade agreements harm the multilateral system by diminishing its relative importance and undermining the most-favorite nation principle (e.g. Bhagwati (2008)), while others claim that preferential trade agreements contribute to the WTO mission by commencing agendas and setting concessions that may be later extended to the multilateral organization (e.g. Baldwin (2006) and Barton et al. (2006)). In this sense, the intellectual property rights included in preferential agreements that have been signed since 1995 have been described as "TRIPS-Plus" because they usually update the TRIPS provisions by protecting products and services not directly mentioned in the TRIPS agreement and by setting more rigorous rules for the protection of intellectual property rights, which includes stricter enforcement procedures[4]. The U.S. has been one of the key players in the creation of TRIPS-Plus agreements because since 1995 the country has negotiated and implemented several such agreements.

These agreements triggered legislative debates in the U.S., influencing Congress members' statements and votes on both national and international policies. They also motivated trade unions and industry associations to lobby and campaign on different sides. These domestic reactions further corroborate the theoretical assertion that states cannot be regarded as rational, goal-maximizing actors; the models developed by i.a. Epstein and O'Halloran (1995), Milner (1997), Goldsmith and Posner (2005) and Bueno de Mesquita (2010) complement the two-level games approach by emphasizing how domestic actors – which includes constituencies in democracies – may succeed in their attempts to influence international policies.

In this sense, some researchers consider that both campaign contributions and the labor lobby were important for Congress members' lack of support for granting trade promotion authority to President Clinton, as requested by him in the spring of 1997 (BARDWELL, 2000; SCHNIETZ, NIEMAN, 1999; KAROL, 2000). Widely known as "fast-track," such authority is a set of instructions given by Congress to the president on how to negotiate trade agreements; moreover, through the trade promotion authority Congress commits to expeditiously vote on agreements without amending them. It can go as far as determining the participation of Congress members as part of trade negotiating delegations. The fast-track is meant to be both

either, because some U.S. trade agreements are composed of more than two members.

4 For instance, the U.S. trade agreements with Korea and Colombia include provisions that could be described as "TRIPS-Plus". See Office of the United States Trade Representative (2007; 2006).

a symbol of good standing between the president and Congress and a positive signal to trade partners – since they can better estimate what U.S. Congress members think of trade issues and then estimate the probability of ratification of trade agreements (WROBEL, 1998; CONLEY, 1999; SCHNIETZ; NIEMAN, 1999; BARDWELL, 2000; GOLDSMITH; POSNER, 2005; LANTIS, 2005; BARTON et al., 2006; HATHAWAY, 2008; ANDERSON, 2012; FERGUSSON, 2015). In this sense, "[…] the fast track sends important signals to potential trading partners about how far, where, and on which issues, the United States is prepared to advance in trade negotiations." (ANDERSON, 2012, p. 611).

Researchers have also pointed out other causes for Clinton's inability to obtain a vote of confidence from Congress on trade. Some of these are party identification, the level of Congress members loyalty to the president (BARDWELL, 2000; KAROL, 2000), interbranch disagreements on labor and environmental clauses (KAROL, 2000), Clinton's policies on the budget and the welfare system (CONLEY, 1999), and the strategy Clinton pursued when trying to convince Congress members to vote for the fast-track bill (WROBEL, 1998; SCHNIETZ; NIEMAN, 1999).

Despite the important contributions provided by these and other studies on the topic, they do not account for how the intellectual property rights included in trade and investment agreements were important for Congressional voting on fast-track. They also do not account for the effects of such rights on legislative debates about changes to the U.S. patent system and on early urges for reforming the U.S. trade agreements. This article addresses these shortcomings by analyzing the mentions of the intellectual property rights included in trade and investment agreements in the U.S. legislature. We consider statements delivered by members of both the U.S. House of Representatives and the Senate from 1995 (104th Congress) to 2000 (106th Congress).

We start in 1995 because that was when both the WTO and the North American Free Trade Agreement (NAFTA) became effective for the United States, sparking legislative debates about them, which includes their intellectual property rights. We finish in 2000 because that was the last year of the Clinton administration. We cannot extend our analysis to the George W. Bush administration's trade policy because it was quite transformative, whereby it shall be dealt with separately. To the best of our knowledge, this set of congressional discourses had not yet been analyzed for the same purposes.

We also estimate the impact of intellectual property rights on policies implemented by the United States at that time by verifying which of the bills supported by Congress members based on such rights made it through all the legislative steps required to eventually become

law.

2 Congress views on trade and investment-related intellectual property rights

For sections two and three we rely on the transcriptions of the statements by both the U.S. House of Representatives and the U.S. Senate members from the 104th to the 106th Congresses. They were made public in pdf format; we searched the database for ["intellectual property rights" AND trade] on May 02, 2018 at 10:30[5]. We considered the results labeled as "Congressional Record", "Treaty Documents", "House Communications" and "Senate Communications". We narrowed the results down to the documents issued from 1995 to 2000, and finally selected the ones where Congress members stated views on trade and investment-related intellectual property rights. We also rely on congressional online information about the status of the bills Congress members introduced, discussed and voted on during that time frame[6].

Congress members of one political party very often stated their positive appreciation of the intellectual property rights included in agreements that were negotiated and signed into law by presidents of the other party. One example of that is the resolution submitted by Senator Richard Lugar (R – IN) advising the president to accept Trinidad and Tobago's request for accession to NAFTA. He suggests the president should do so as soon as similar negotiations with Chile were concluded i.a. because Trinidad and Tobago "[…] has signed both a Bilateral Investment Treaty [BIT] and Agreement on Intellectual Property Rights with the United States." (GOVTRACK, Feb. 2019)[7]. Both agreements were negotiated and signed into law by Clinton. Even though the resolution was not enacted, it exemplifies that some Congress members were satisfied with investment agreements created by the other party – including their intellectual property rights (GOVTRACK, Feb. 2019). It also shows that some Congress members approved of NAFTA as a whole, to the point of supporting Clinton's intention to include new member countries to it.

Another example of that is the statement by Senator Daniel Inouye (D – HI) when he mentioned the "Agreement on the Protection and Enforcement of Intellectual Property Rights

5 Available at https://www.congress.gov/congressional-record

6 Available at https://www.congress.gov/

7 He alludes to Clinton's projects to enlarge NAFTA by including Chile and other Latin American and Caribbean countries to it, which eventually could become a keystone for the Free Trade Area of the Americas, a hemispheric project launched by the Clinton administration in 1995 (WROBEL, 1998; SCHNIETZ; NIEMAN, 1999; BARDWELL, 2000).

Between The United States of America and The Democratic Socialist Republic of Sri Lanka" as a positive example of the U.S. relations with that Asian country. The agreement was both negotiated and signed into law by George Bush, the senior. Senator Inouye also expressed his approval of the intellectual property rights included in the "The U.S. – Sri Lanka Investment Treaty", another agreement negotiated and signed during the administration of George Bush the senior, later signed into law by Clinton (U.S. GOVERNMENT PUBLISHING OFFICE, Jan. 26, 1996). Representative Frank Pallone (D – NJ) also supported the intellectual property rights included in the investment agreement with Sri Lanka (U.S. GOVERNMENT PUBLISHING OFFICE, Apr. 28, 1998).

NAFTA stands out because it was the agreement that drew more Congressional attention. It is also a bipartisan agreement in the sense that it was largely negotiated during the senior Bush administration and later concluded and signed into law by Clinton (WROBEL, 1998; SCHNIETZ, NIEMAN, 1999; ANDERSON, 2012). Both Republicans and Democrats approved of the intellectual property rights included in the trade agreement with Canada and Mexico. For example, when debating if the U.S. should prevent its trade partners from imposing trade sanctions against third countries, Congresswoman Nancy Johnson (R – CT) stated that "Put at risk by unilateral U.S. action are the benefits to the U.S. economy created by strong protection of intellectual property rights […] all of which were improved and expanded by NAFTA and GATT" (U.S. GOVERNMENT PUBLISHING OFFICE, June 18, 1996).

On the other hand, NAFTA's intellectual property rights were also mentioned in a more negative context, since Representative David Bonior (D – MI), complained in April 1997 that though the trade agreement with Canada and Mexico included an intellectual property rights chapter, it did not include proper labor and environmental standards (U.S. GOVERNMENT PUBLISHING OFFICE, Apr. 10, 1997).

These statements demonstrate that some members of Congress were largely satisfied with the intellectual property rights negotiated with trade and investment partners, to the point that most Republicans were neither requesting substantive changes to agreements in force nor obstructing the federal government's trade policy. Nevertheless, the intellectual property rights included in trade and investment agreements were used by Democratic Congress members as arguments for denying Clinton a congressional vote of confidence on trade. They were also tapped into by Congress members of both parties during debates about other trade issues and about reforms to the U.S. patent system. We explain these actions in greater detail in the next section.

3 Intellectual property rights in trade and investment agreements as references for assessing trade-related and domestic patent legislation

The intellectual property rights included in U.S. trade and investment agreements were tapped into by Congress members when debating about a wide range of trade issues, including the level of discretion the president should have to negotiate with foreign partners, the general trade objectives of the United States and the criteria the U.S. should use when granting benefits to specific groups of developing countries.

In this sense, the intellectual property rights were used as arguments even in debates about the U.S. trade relations with specific countries. Congressman Phillip Crane (R – IL) mentioned the intellectual property rights included in the "Agreement between the U.S. and Vietnam on Trade Relations" (under negotiation at that time) when supporting the renewal of the waiving of the Jackson-Vanik Amendment as regards Vietnam. Such amendment was included in the 1974 Trade Act to deny unconditional normal trade relations to certain countries that had non-market economies and restricted emigration rights, but both Congress and the president could waive its application (THE WHITE HOUSE – PRESIDENT GEORGE W. BUSH, Nov. 13, 2001; GINSBERG, July 02, 2009).

Representative Crane asserted that the U.S. should renew the waiver to Vietnam despite its formally Socialist regime because doing otherwise would damage the normalization of relations between the two countries, which according to him had led to "[…] increased accounting of our missing in action, increased trade and investment opportunities for U.S. firms and workers, and substantial progress toward resolution of the remaining emigration cases." (U.S. GOVERNMENT PUBLISHING OFFICE, Aug. 03, 1999). He also considered that the waiver could contribute to the U.S. ability to support economic reforms already under way in Vietnam. In addition, he considered that the waiver should be maintained because its positive effects would be more significant after the conclusion of the trade agreement with the southeast Asian country, which would benefit the U.S. i.a. because of its intellectual property rights.

In this sense, Representative Crane urged for a no vote on House Joint Resolution 58, sponsored by Representative Dana Rohrabacher (R – CA), which aimed at disapproving the extension of the waiver with respect to Vietnam. He transcribes a letter he had received from several companies urging for the renewal of the Jackson-Vanik waiver and stating their opposition to the resolution. Some of the signatories produce goods usually protected by intellectual property rights, such as pharmaceuticals, electronics, software, movies, aircraft, footwear, and wines. These private actors stated that the waiver would make possible the

conclusion and implementation of the trade agreement under negotiation with Vietnam, which would improve the access of U.S. companies to the Vietnamese market i.a. due to the protection it would grant for intellectual property rights (U.S. GOVERNMENT PUBLISHING OFFICE, Aug. 03, 1999).

In 2000, another resolution in the House (House Joint Resolution 99, also sponsored by Representative Rohrabacher) again aimed at ending the waiver to the Jackson-Vanik amendment as regards Vietnam. Representative Crane spoke against it once more, relying on similar arguments, which included another mention of the intellectual property rights chapter of the trade agreement under negotiation (U.S. GOVERNMENT PUBLISHING OFFICE, July 26, 2000). He also transcribed a letter where companies supported his view i.a. due to the intellectual property rights included in the Vietnam trade agreement (U.S. GOVERNMENT PUBLISHING OFFICE, July 26, 2000).

Both resolution 58 and 99 failed House, paving the way for the conclusion of negotiations with Vietnam on July 13, 2000 and later to the implementation of the trade agreement; it became effective in 2001 (OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2000; EXPORT.GOV, July 12, 2018).

The intellectual property rights of trade agreements were also used by Congress members as arguments to deny the renewal of the trade promotion authority requested by President Clinton in September 1997. Some Democratic Congress members asserted that since the U.S. government had reached an agreement on intellectual property rights with Canada and Mexico – the one included in NAFTA – it could also push for the inclusion of labor and environmental provisions in future agreements. The most vocal advocate for this argument was David Bonior; he summarized his views on the issue by stating that

> […] before we ever think about expanding NAFTA to other countries, we need to fix a very flawed NAFTA here. We need to give workers the same kind of labor and health protections that we gave companies for things like intellectual property. We need to include labor and environmental standards in the core agreement, not in some flimsy side agreement. And we need to raise Mexico's standard to our level, not lower ours to theirs. (U.S. GOVERNMENT PUBLISHING OFFICE, Mar. 19, 1997)[8].

Therefore, he not only uses NAFTA's intellectual property rights chapter as a benchmark for assessing other trade-related issues, but also suggests that NAFTA itself should be

[8] He refers to the side agreements on labor and environmental standards Clinton reached with Mexico to secure NAFTA's ratification. For further information on such agreements see Bardwell (2000), Lantis (2005) and Anderson (2012).

renegotiated[9].

Representatives Bart Stupak (D – MI), William Lipinski (D – IL), Richard Gephardt (D – MO) and Jerrold Nadler (D – NY) also mentioned NAFTA's intellectual property rights chapter when complaining about the trade promotion authority bill, advocating for its repeal (U.S. GOVERNMENT PUBLISHING OFFICE, Sep. 16, 1997; Sep. 26, 1997 ["What Americans think about fast track and NAFTA expansion"]; Sep. 26, 1997 ["Fast-track negotiations"]; Nov. 09, 1997). Senator Paul Wellstone (D – MN) considered that the United States - Canadian Free Trade Agreement (later superseded by NAFTA) had properly protected intellectual property rights, but had failed to benefit small farmers; he therefore conditioned his vote for the fast-track and for NAFTA`s expansion upon the concession of loans to such farmers (U.S. GOVERNMENT PUBLISHING OFFICE, July 16, 1998).

In November 1997, despite senatorial and lobby support, Clinton requested the bill to be pulled from the House calendar after failing to convince Democratic Representatives to vote for the trade authority (WROBEL, 1998; SCHNIETZ; NIEMAN, 1999). Republican Congress members approved granting a TPA to the federal administration, as much as they had approved NAFTA, as requested by Clinton in 1993 (KAROL, 2000). Clinton would not be granted fast-track authority until the end of his administration, despite a further attempt in 1998 (SCHNIETZ; NIEMAN, 1999; BARDWELL, 2000; DEVAULT, 2010; ANDERSON, 2012; CARROLL, May 17, 2015).

The intellectual property rights included in trade and investment agreements were also used as parameters for extending the "Generalized System of Preferences" (GSP). Established in 1974, it provides preferential duty-free entry for products originating from developing countries. The system requires periodical reauthorization in order to remain in effect (U.S. CUSTOMS AND BORDER PROTECTION, July 28, 2018). The bill submitted by Senators William Roth (R – DE) and Daniel Moynihan (D – NY) allowed the president to use intellectual property rights as criteria for extending the GSP to countries in the Caribbean Basin. When doing so, the president should use NAFTA's intellectual property rights chapter as a parameter, but he should also require trade partners to protect test data for agricultural chemicals for ten

[9] Despite these initial Democratic criticisms of NAFTA, no significant congressional moves for denunciation or renegotiation were made at that time. The political dissatisfaction with the agreement reached its peak in July 2020, when the USMCA superseded NAFTA, including a new chapter on intellectual property (TAUBE, Dec. 06, 2018; WISEMAN, Feb. 2019; OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2020). Since the presidential campaign President Donald Trump had made it clear he would push for either denouncing or renegotiating NAFTA; he described the agreement as "[…] one of the worst deals ever made of any kind, signed by anybody." (CBS NEWS, Oct. 19, 2016).

years (U.S. GOVERNMENT PUBLISHING OFFICE, Oct. 22, 1999). NAFTA requires its member countries to protect such data for five years only (NAFTA SECRETARIAT, 2014).[10]

The proposals submitted by Senator Trent Lott (R – MS) on October 27, 1999; by Senators Daniel Moynihan and Carl Levin (D – MI) on October 28, 1999; and by Senator William Roth on November 03, 1999, maintained Roth and Moynihan's original provisions on intellectual property (U.S. GOVERNMENT PUBLISHING OFFICE, Oct. 27, 1999); U.S. GOVERNMENT PUBLISHING OFFICE, Oct. 28, 1999; U.S. GOVERNMENT PUBLISHING OFFICE, Nov. 03, 1999). Following discussions and voting in the Senate, the final law did not include the mentions of NAFTA, despite requiring Caribbean Basin countries to grant protections for intellectual property rights (CONGRESS.GOV, May 18, 2000).

In the same vein, the "Reciprocal Trade Agreement Authorities Act of 1998" submitted by Representative William Archer (R – TX) lists intellectual property rights among the principal negotiating objectives of the United States and determines that the intellectual property rights provisions of any trade agreement entered into by the country should be at least as strong as the ones included in NAFTA (U.S. GOVERNMENT PUBLISHING OFFICE, Sep. 25, 1998). Though the bill did not prosper in the House, it is another example of Republican approval of NAFTA's intellectual property rights chapter at that time (CONGRESS.GOV, Sep. 25, 1998).

Adding to these trade-related bills, the intellectual property rights included in trade and investment agreements were also used as arguments by members of the U.S. Congress when debating about reforms to the country's domestic patent legislation. Representative Michael Forbes (R – NY) complained about the "Moorhead-Schroeder Act", arguing that its patent provisions were as bad as the ones included in NAFTA and in the GATT (i.e. the TRIPS Agreement) (U.S. GOVERNMENT PUBLISHING OFFICE, July 09, 1996)[11].

According to Representative Forbes, the Act would require the U.S. Patent and Trademark Office (USPTO) to disclose the content of patent applications 18 months after their submissions, which would lead powerful multinational corporations – especially foreign ones – to plainly steal American innovations (U.S. GOVERNMENT PUBLISHING OFFICE, July 09, 1996). The Act would also reduce the term of patents by mandating that they should be measured from the filing date. It would also stimulate litigation against patent applications i.a.

[10] Test data is the technical information on the safety, effectiveness and quality of pharmaceuticals and agricultural chemicals that are being considered for marketing approval, as legally required by national health authorities. Such information is highly valuable due to the scientific and regulatory costs to obtain them (MUZAKA, 2011).

[11] House Resolution 3460, sponsored by Congressman Carlos Moorhead (R – CA), and Representative Patricia Schroeder (D – CO).

by imposing the burden of proof on innovators, rather than on their challengers (U.S. GOVERNMENT PUBLISHING OFFICE, July 09, 1996). Moreover, still according to Representative Forbes, the Act could lead to the privatization of the USPTO, thereby undermining its neutrality (U.S. GOVERNMENT PUBLISHING OFFICE, July 09, 1996)[12].

Representative Forbes asserted that if all these changes were implemented, the U.S. patent system would no longer be viable, thereby contributing to the erosion of American competitiveness on patented creations. Congressman Forbes supported the "Rohrabacher bill" instead because it:

> […] strengthen[s] the U.S. patent term to 17 years from grant or to 20 years from filing, whichever is longer. All patentee's inventions will be published 60 months after initial application is filed. The Moorhead/Schroeder bill would publish it 18 months after the initial application is filed." (U.S. GOVERNMENT PUBLISHING OFFICE, July 09, 1996)[13].

Also, the House Resolution 359 would ensure the maintenance of other features of the U.S. patent system which, according to Congressman Forbes, had led to the US leadership on fundamental patents since it had been established (U.S. GOVERNMENT PUBLISHING OFFICE, July 09, 1996).

Even though the Rohrabacher bill did not pass the house, the Moorhead-Schroeder's did not either. This fact is another piece of evidence - along with the discussions and votes on the TPA and on the Vietnam agreement - that the members of the U.S. Congress' mentions of the intellectual property rights included in trade and investment agreements had more significant impacts on the U.S. domestic legislation on patents than on trade-related legislation.

4 Conclusions

On a theoretical level, our analysis corroborates the two-level games framework when it comes to the importance of the interactions between national and international levels. The intellectual property rights included in international trade and investment agreements in force for the U.S. were tapped into by its domestic legislature when debating and voting on issues that would primarily affect the U.S. domestic environment. They were also used to justify

[12] Congressman Forbes transcribed a letter where Raymond Damadian states some of these concerns. He is the president and Chairman of Fonar Corporation, which held the first patent for the magnetic resonance scanning machine (U.S. GOVERNMENT PUBLISHING OFFICE, July 09, 1996).

[13] House Resolution 359, sponsored by Representative Dana Rohrabacher.

decisions that would affect foreign countries, since Clinton`s ability to conclude new trade agreements was diminished when Congress in practice denied him the trade promotion authority.

Our results also corroborate models that emphasize the importance of private domestic actors in defining foreign policies. Two Congress members relied on statements issued by companies while using international intellectual property rights to either justify changes to domestic legislation (Representative Forbes) or to provide the legal basis for the implementation of a new international trade agreement (Representative Crane). In this sense, our results complement other articles that also corroborate such models by highlighting the importance of lobby and campaign contributions for the Congressional approval of Clinton`s trade policies – or lack thereof.

Even though such kind of congressional interference in international affairs is intuitive, as the very requirement of approval by domestic legislatures in democracies suggests, we cannot stretch the theoretical aspects of our results beyond the United States. Nevertheless, as since the mid-1990s no significant reforms to the U.S. separation of powers when it comes to negotiating and signing trade agreements into law have occurred, it is very likely that the two-level games approach and its subsequent theoretical developments are still useful in explaining the U.S. trade politics.

Though the number of Congress members who mentioned the intellectual property rights negotiated with foreign partners when debating changes to the U.S. domestic legislation was relatively small, such mentions might have influenced their votes, and might also have convinced other members of Congress to vote accordingly. Though we cannot establish a causal relationship between mentions of intellectual property rights and legislative change, the examples we offered in sections two and three demonstrate that the intellectual property rights were not ignored by Congress members, and that they were at least nominally used to justify or repeal legislation that affected policies carried out by the United States.

The intellectual property rights included in international trade and investment agreements were more often used by Congress members as arguments in discussions about international trade than when strictly domestic legislation was at stake. In this sense, such rights were considered both for deciding about the trade relations with a single country – Vietnam – and for justifying policies that affected the prospects of further trade liberalization as a whole (fast-track). The counterintuitive party division that contributed to Clinton`s failure to obtain the fast-track exemplifies how complex the formulation of the U.S. trade policy can be, which discredits simplistic expectations based on party affiliation only.

So far, the literature on the U.S. trade policy in the mid and late 1990s had emphasized many reasons why Congress refused to grant the trade promotion authority to President Clinton, but the likely effects of intellectual property rights on this and other decisions had been ignored. Therefore, our findings fill this gap by showing how Congress members used the intellectual property rights negotiated with trade and investment partners when debating about and voting on both domestic and international affairs. Future academic analyzes of the U.S. trade policy should take intellectual property rights into higher account, thereby avoiding the creation of gaps in the literature in the first place.

NAFTA`s renegotiation included the revision of its intellectual property rights chapter, which is a more recent piece of evidence of the importance of intellectual property rights in trade policy making. Despite the Trump administration`s energetic actions against NAFTA, the criticisms of the trade agreement can be traced back to its early years, as shown i.a. by the statements by Representative David Bonior. This finding is particularly interesting because he was a Democratic Representative. NAFTA survived through Clinton's, Bush's and Obama`s administrations, despite occasional criticism, but it was eventually renegotiated by Trump, which demonstrates how sensitive trade policies can be to both Congressional and executive preferences.

Further research could contribute to the academic understanding of the importance of intellectual property rights for the U.S. national legislature by analyzing other Congresses. Other studies could also investigate whether intellectual property rights in trade and investment agreements have been tapped into by congress members in other countries, and for what purposes.

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