BOSTON UNIVERSITY Global Development Policy Center

GEGI WORKING PAPER 030 • 06/2019


# Policy Space for Public Health & SDG3:

## A literature review on the impact of trade and investment treaties on access to medicines

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### Introduction

The trade regime has a complex relationship with public access to medicine. In particular, global trade rules which attempt to increase pharmaceutical innovation through increased intellectual property protection, could make it more difficult for countries to implement policies to encourage access to medicine. In 1995, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) introduced mandatory pharmaceutical patenting to the developing world for the first time. Alongside the regulatory challenges that this produced, TRIPS explicitly permitted some flexibilities enabling countries to protect intellectual property in diverse ways. Subsequently, modern bilateral and regional free trade agreements contain additional commitments, seeking to harmonize and escalate pharmaceutical intellectual property protection. These commitments become more concerning when paired with investor-state dispute settlement (ISDS), which permits private investors to challenge domestic access to medicine policy. Few countries (at the WTO) and investors (under international investment agreements) have sued under these rules to date. However, as the literature discussed below illuminates, intellectual property rules in the trade and investment treaties tip the scale in favor of the interests of innovators and away from those lacking access to medicines.

The literature addressing this interdisciplinary work is vast. In this paper we highlight the legal literature discussing how treaties could affect domestic policy-making toward access to medicines. This review is driven, in part, by sustainable development goal (SDG) number 3 which aims at ensuring healthy lives and promoting well-being for all at all ages. We focus on scholarship which analyzes the specific text of international treaties to assess the extent to which nation states can formulate policies under those treaties that expand the access to medicines for those in need. We also focus on literature that analyzes international case law where issues of intellectual property rights and access to medicine have arisen.

## Overview of Methods and Results

In order to limit the scope of our inquiry, we focus on literature identifying "crucial policy-related textual language" in multilateral and bilateral agreements pertaining to access to medicines, especially articles that examine specific treaty language or case law interpreting that language. After a thorough search of several legal and non-legal databases,[1] we found over sixty relevant articles that fell within our parameters. There is a much larger body of literature that analyzes IP commitments in treaties more generally and the impact on access to medicines but for the purposes of this review we included only legal articles that address the specific link between trade and investment treaties, IP, and access to medicines.

Within the literature we identified the key policy constraints and policy flexibilities that each article highlighted. We also categorized articles based on whether they looked primarily at treaty language or case law, and subsequently by which treaty(ies) they analyzed. Tables 1 and 2 define the aforementioned policy constraints and flexibilities, while Tables 3 and 4 break down the literature based on our categories. Although many articles mention various policy constraints, we only included literature that had an in-depth discussion of the policy constraint in relation to treaty language. Our examination of the case law was limited to international tribunals: either investor-state disputes or WTO dispute settlement cases.

## Flexibilities and Policy Constraints Defined

When TRIPS was signed, it represented a significant change to the international IP scheme that afforded increased IPRs globally. TRIPS included various policy constraints, requiring that members implement a patent regime, designate twenty-year patent terms, and consider all patent applications filed after the enactment of TRIPS in 1995. However, TRIPS also allowed for flexibility in the way in which member states could implement certain provisions by simply setting a baseline standard. In the subsequent Doha Declaration, signed in 2001, member states reaffirmed the flexibilities included in TRIPS. Legal scholars tend to frame legal literature in terms of these "TRIPS flexibilities": compulsory licenses, parallel imports, early working allowances, options to allow patent protection for plants and animals, patent revocation, and data protection (See Table 1).[2]

1 Databases searched include Wiley Online, Hein Online, JSTOR, WTO Website, Google Scholar, and WICO. Search terms include some combination of "intellectual property (rights)," "investment treaties," "pharmaceuticals," "access to medicine," "medicine," "bilateral agreement," "regional agreement," along with specific treaty names such as the TPP and specific international case names that appeared in the literature like Eli Lilly.

2 See e.g., Brook Baker & Katrina Geddes, Corporate Power Unbound: State Arbitration of IP Monopolies on Medicines - Eli Lilly v. Canada and the Trans Pacific Partnership Agreement 23 J. of Intell. Prop. 1 (2015); Rosa Castro Bernieri, Intellectual Property Rights in Bilateral Investment Treaties and Access to Medicines: The Case of Latin America, 9 J. of World Intell. Prop. 548 (2006); L. Liberti, Intellectual Property Rights in International Investment Agreements: An Overview, OECD Working Papers on Int'l Investment (2010).

**Table 1**

| Policy Constraint | Definition | Number of Articles |
|---|---|---|
| Secondary Patents | Allowing companies to file for additional, defensive patents to thicken the protection around their original base patents based on slight changes to the original product. | 6 |
| Data Protection (Data Exclusivity) | Strengthening data protection for patent holders to prevent competitors from using the data to get their products to market faster or develop new medications. | 33 |
| Patent Term Extension | Extending the term of a patent to make up for delays in the patenting process. | 16 |
| Linkage | The application of a conditional relationship between the granting of marketing approval for a generic medicine and the patent status of the originator reference product. | 15 |
| Limits on Compulsory Licensing | Limiting a country's ability to authorize a party other then the holder of a patent on an invention to use that invention without the consent of the patent holder. | 18 |
| Limits on Parallel Imports | Limiting exhaustion rights so that pharmaceuticals cannot be imported through parallel importation. | 10 |
| Enforcement Mechanisms | Certain enforcement mechanisms such as investor-state dispute settlement can limit a government's ability to implement flexibilities for fear of retribution. | 5 |
| Patentability Criteria (Protection for new uses, patenting for plants and animals) | Broadening the eligibility criteria for granting patents such as requiring protection for inventions using plants and animals or requiring protection for new uses of already existing products. | 7 |
| Limiting Revocation | Limiting a government's ability to cancel patent rights already granted. | 3 |
| Burden of Proof | In a civil patent infringement proceeding, placing the burden of proof on the defendant to show that the defendant did not infringe on the plaintiff's patent. | 1 |
| Mailbox Rule | TRIPS provision that required countries that did not already have a patent system in place to consider all patent applications filed after the enactment of TRIPS in 1995. | 2 |
| Most Favored Nation (MFN) | Requirement in a treaty that each member treat the nationals of all other members on an equivalent basis in relation to IP protection. TRIPS gives members MFN status potentially requiring members to apply provisions from subsequent bilateral and multilateral treaties to all TRIPS members. | 3 |

The literature also agrees that subsequent bilateral and free trade agreements (FTAs) have ratcheted up commitments.[3] For example, a bilateral treaty will require that governments grant patent holders exclusive rights to the data used to develop their patented product, so that no competitors can use it to develop similar products.[4] Additionally, bilateral and regional treaties will contain stricter rules about exhaustion in order to limit the use of parallel importation.[5] It is important to understand these flexibilities and policy constraints going forward as they become the central focus in the literature examining international treaties.

## Results/Findings

### TIME TRENDS IN SUBJECT MATTER OF ARTICLES

Frequently the subject matter of the literature corresponds to the key issues that arose during that time. Articles written before the Doha Declaration focus on TRIPS because it was the first major international treaty relating to intellectual property.[6] After the end of 2001, scholars use TRIPS as a baseline to show the changes that subsequent treaties have made.[7] In the years following the Doha Declaration, the literature turned toward the potential impact of Paragraph 6 and the subsequent TRIPS amendment on developing countries issuing compulsory licenses. These are often compared with the provisions of subsequent bilateral and regional FTAs.[8] In the early to mid-2000s, the literature shifted to focus on the provisions of one treaty, such as the US-Jordan FTA or NAFTA, and discussed the effect on access to medicine.[9] As more bilateral and regional trade agreements including IP provisions were signed, more and more scholars began comparing and contrasting IPRs granted in multiple treaties. In fact, of the twelve articles which examine multiple trade agreements, ten were written after 2005.[10] With the negotiation and drafting of the TPP, new literature

3 See e.g., Carlos Maria Correa, Implications of Bilateral Free Trade Agreements on Access to Medicines, 84 Bulletin of the World Health Organization 399 (2006); Pedro Roffe, The Impact of FTAs on Public Health Policies and TRIPS Flexibilities, 1 Int. J. Intell. Prop. Management 75 (2006); Ping Xiong, Patents in TRIPS-Plus Provisions and the Approaches to Interpretation of Free Trade Agreements and TRIPS: Do They Affect Public Health, 46 J. of World Trade 155 (2012).

4 See e.g., Wael Armouti & Mohammad F.A. Nsour, Data Exclusivity for Pharmaceuticals: Was It the Best Choice for Jordan Under the U.S. Jordan Free Trade Agreement? 17 Or. Rev. Int'l L. 259 (2016); Rosa Castro Bernieri, Intellectual Property Rights in Bilateral Investment Treaties and Access to Medicines: The Case of Latin America, 9 J. of World Intell. Prop. 548 (2006); Cartagena & Amir Attaran, A Study of Pharmaceutical Data Exclusivity Laws in Latin America: Is Access to Affordable Medicine Threatened, 17 Health L. J. 269 (2009).

5 Sufian Jusoh, Free Trade Agreements and Implications on Public Health - An Analysis of FTA of Selected ASEAN Member States, 4 Asian J. of WTO & Int'l Health L. & Pol'y 187 (2009); Bashar H. Malkawi, Patent Protection and the Pharmaceutical Industry in Jordan, 4 Asian J. of WTO & Int'l Health L. & Pol'y 93 (2009).

6 See, Frederick M. Abbott, The TRIPS Agreement, Access to Medicines and the WTO Doha Ministerial Conference, 5 J. of World Intell. Prop. 15 (2001); Sara M. Ford, Compulsory Licensing Provisions Under the TRIPs Agreement: Balancing Pills and Patents, 15 Am. U. L. Rev. 941 (2000); Velasquez & Pascale Boulet, Globalization and access to drugs: Implications of the WTO/TRIPS Agreement, Health Economics and Drugs Series (1998) http://apps.who.int/medicinedocs/en/d/Jwhozip35e/.

7 See e.g., Rosa Castro Bernieri, Intellectual Property Rights in Bilateral Investment Treaties and Access to Medicines: The Case of Latin America, 9 J. of World Intell. Prop. 548 (2006); Christine Chung, A Cry for Cheap Drugs: CAFTA's Inflexible Intellectual Property Protections Create an Ominous Impact on Life-Saving Medicines, 13 Sw. J.L. & Trade Americas 171 (2006). However, there are a number of articles that discuss only TRIPS after the Doha Declaration, with articles focusing only on TRIPS appearing every couple of years up until 2012 (2 in 2002, 1 in 2003, 1 in 2005, 1 in 2009, 1 in 2011, 1 in 2012). Carlos Maria Correa, Unfair Competition Under the TRIPS Agreement: Protection of Data Submitted for the Registration of Pharmaceuticals, 3 Chi. J. Int'l L. 69 (2002); Donald Harris, TRIPs after Fifteen Years: Success or Failure, as Measured by Compulsory Licensing, 18 J. Intell. Prop. L. 367 (2011).

8 See, Frederick M. Abbott, The TRIPS Agreement, Access to Medicines and the WTO Doha Ministerial Conference, 5 J. of World Intell. Prop. 15 (2001); James T. Gathii, The Legal Status of the Doha Declaration on TRIPS and Public Health Under the Vienna Convention of the Law of Treaties, 15 Harv. J.L. & Tech. 291 (2002); Paul Vandoren, Clarification of the Relationship between TRIPS and Public Health resulting from the WTO Doha Ministerial Declaration, 5 J. of World Intell. Prop. 5 (2005); Christine Chung, A Cry for Cheap Drugs: CAFTA's Inflexible Intellectual Property Protections Create an Ominous Impact on Life-Saving Medicines, 13 Sw. J.L. & Trade Americas 171 (2006); Pedro Roffe, The Impact of FTAs on Public Health Policies and TRIPS Flexibilities, 1 Int. J. Intell. Prop. Management 75 (2006).

9 See e.g., Peter Drahos, Expanding Intellectual Property's Empire: The Role of FTAs (2003) https://www.ictsd.org/sites/default/files/downloads/2008/08/drahos-fta-2003-en.pdf; Aaron Fellmeth, Secrecy, Monopoly, and Access to Pharmaceuticals in International Trade Law: Protection of Marketing Approval Data Under the TRIPs Agreement, 45 Harv. Int'l L.J. 443 (2004).

10 See e.g., Rosa Castro Bernieri, Intellectual Property Rights in Bilateral Investment Treaties and Access to Medicines: The Case of Latin America, 9 J. of World Intell. Prop. 548 (2006); Carlos Maria Correa, Implications of Bilateral Free Trade

has sprung up highlighting how this new mega-regional agreement might impact access to medicine for its developing country members.[11]

## ANALYSIS OF TREATY LANGUAGE: TRIPS FLEXIBILITIES, DOHA, TRIPS-PLUS

The vast majority, about ninety percent, of literature that we found focuses on the effect of specific treaties on access to medicine as opposed to the effect of case law. Almost all of the literature concludes that strengthening IPRs in treaties will have decreased policy space for access to medicines in developing countries.[12] While articles discussing only the TRIPS agreement tend to have a more optimistic outlook,[13] articles examining bilateral and regional trade agreements have a much more negative outlook on access to medicine in the developing world.[14] As discussed above, scholars tend to concur that TRIPS contains more policy space than other, subsequent, agreements for access to medicine. Furthermore, about ten percent of the literature makes specific policy recommendations in the hopes of reducing the negative impacts of IPR treaty provisions.

Table 1 identifies policy constraints included in the literature. Data protection was the most discussed policy constraint with two thirds of the articles analyzing how treaty provisions provide increased data protection.[15] Eleven articles focused primarily on data protection or data protection in conjunction with another policy constraint.[16] Many of those articles discuss the ambiguity surrounding data protection in the TRIPS agreement and how this ambiguity can allow for greater flexibility. About one third of the literature discusses how treaties can restrict policy space and access to medicine through provisions that require a linkage between drug registration and patent protection, patent term extensions, and limits to compulsory licensing.[17] Other policy constraints are less ubiquitous in the literature, especially policy constraints that are not facially IP provisions such as ISDS enforcement provisions in investment treaties and the role of most favored nation treatment in multilateralizing intellectual property commitments.[18]

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Agreements on Access to Medicines, 84 Bulletin of the World Health Organization 399 (2006); Carsten Fink & Patrick Reichenmiller, Tightening TRIPS: The Intellectual Property Provisions of Recent US Free Trade Agreements, World Bank (2005) http://documents.worldbank.org/curated/en/173901468140377145/Tightening-TRIPS-the-intellectual-property-provisions-of-recent-US-free-trade-agreements.

11 See e.g., Deborah Gleeson, The Trans Pacific Partnership Agreement, intellectual property and medicines: Differential outcomes for developed and developing countries, 18 Global Social Pol'y 7 (2017); Morris, Emily Michiko, Much Ado About the TPPs Effect on Pharmaceuticals, 20 SMU Sci. & Tech. L. Rev. 135 (2017).

12 See e.g., Cynthia M. Ho, A New World Order for Addressing Patent Rights and Public Health, 82 Chi.-Kent L. Rev. 1467 (2007); Susan K. Sell, TRIPS-plus Free Trade Agreements and Access to Medicines, 28 Liverpool L. Rev. 41 (2007).

13 See e.g., Sara M. Ford, Compulsory Licensing Provisions Under the TRIPs Agreement: Balancing Pills and Patents, 15 Am. U. L. Rev. 941 (2000).

14 See e.g., Rosa Castro Bernieri, Intellectual Property Rights in Bilateral Investment Treaties and Access to Medicines: The Case of Latin America, 9 J. of World Intell. Prop. 548 (2006); Carlos Maria Correa, Implications of Bilateral Free Trade Agreements on Access to Medicines, 84 Bulletin of the World Health Organization 399 (2006); Fink & Patrick Reichenmiller, Tightening TRIPS: The Intellectual Property Provisions of Recent US Free Trade Agreements, World Bank (2005) http://documents.worldbank.org/curated/en/173901468140377145/Tightening-TRIPS-the-intellectual-property-provisions-of-recent-US-free-trade-agreements.

15 See e.g., Rosario Cartagena & Amir Attaran, A Study of Pharmaceutical Data Exclusivity Laws in Latin America: Is Access to Affordable Medicine Threatened, 17 Health L. J. 269 (2009); Carlos Maria Correa, Unfair Competition Under the TRIPS Agreement: Protection of Data Submitted for the Registration of Pharmaceuticals, 3 Chi. J. Int'l L. 69 (2002); Susan Scafidi, The 'Good Old Days' of TRIPS: The US Trade Agenda and the Extension of Pharmaceutical Test Data Protection, 4 Yale J. Health Pol'y L. & Ethics 341 (2004).

16 See e.g., Wael Armouti & Mohammad F.A. Nsour, Data Exclusivity for Pharmaceuticals: Was It the Best Choice for Jordan Under the U.S. Jordan Free Trade Agreement? 17 Or. Rev. Int'l L. 259 (2016); Rosa Castro Bernieri, Intellectual Property Rights in Bilateral Investment Treaties and Access to Medicines: The Case of Latin America, 9 J. of World Intell. Prop. 548 (2006); Rosario Cartagena & Amir Attaran, A Study of Pharmaceutical Data Exclusivity Laws in Latin America: Is Access to Affordable Medicine Threatened, 17 Health L. J. 269 (2009).

17 See e.g., Frederick M. Abbott, Intellectual Property Provisions of Bilateral and Regional Trade Agreements in Light of U.S. Federal Law, ICTSD (Feb. 2006) https://www.ictsd.org/sites/default/files/research/2008/06/frederick20abbott201220final.pdf; Cynthia M. Ho, A New World Order for Addressing Patent Rights and Public Health, 82 Chi.-Kent L. Rev. 1467 (2007); Susan K. Sell, TRIPS-plus Free Trade Agreements and Access to Medicines, 28 Liverpool L. Rev. 41 (2007).

18 See e.g., Wee Loo Ng-Loy, IP Chapter in the US-Singapore Free Trade Agreement, 16 Singapore Academy of L. J. 42

Along with policy constraints, we identified a number of flexibilities that allow governments to create policies that affect access to medicine (Table 2). Over two thirds of the articles examine compulsory licensing as a method of increasing access to medicines.[19] Additionally, the issue of parallel importation and flexibility relating to domestic exhaustion policies is touted by many articles to be a method through which countries can increase access to medicines.[20]

**Table 2**

| Flexibility | Definition | Number of Articles |
|---|---|---|
| Compulsory Licensing | An authorization granted by a government to a party other than the holder of a patent on an invention to use that invention without the consent of the patent holder. | 36 |
| Parallel Imports | Products marketed by the patent owner or with the patent owner's permission in one country and imported into another country without the approval of the patent owner. This is based on the concept of exhaustion which holds that once a patent owner has sold a patented product for the first time, they no longer have control over it: the buyer can use, sell, license, or destroy it as they wish. | 23 |
| Bolar/Early working | Allows generic drug producers to place their products on the market as soon as a patent expires, reducing the price of the medicine immediately after the patent expiration. | 9 |
| Protection for plants and animals | Flexibility for members to adopt different approaches to patentability of inventions relating to plants and animals. | 3 |
| Revocation | Cancellation of rights granted to a person by the grant of a patent. | 1 |
| TRIPS Based Data Protection | Maneuverability in how much data protection is granted to patent holders to prevent competitors from using that data to develop similar products. | 33 |

There are a number of articles that focus on one flexibility and see how the flexibility either constrains or loosens government's ability to create policies that facilitate greater access to medicine.[21] In the early days of TRIPS, four articles concentrated on the ambiguity of the TRIPS provision relating to data protection, concluding that the ambiguity could allow for more flexibility, but could also threaten flexibility in policy space if developed countries interpret the provision more narrowly.[22] Another group of literature focuses on

(2004); Pedro Roffe, The Impact of FTAs on Public Health Policies and TRIPS Flexibilities, 1 Int. J. Intell. Prop. Management 75 (2006).

19 See e.g., Robert Galantucci, Data Protection in a U.S.-Malaysia Free Trade Agreement: New Barriers to Market Access for Generic Drug Manufacturers., 17 Fordham Intell. Prop. Media & Ent. L.J. 1083 (2007); Katherine M. Van Maren, Bartering with a Nation's Health or Improving Access to Pharmaceuticals - The United States-Australia Free Trade Agreement, 14 Pac. Rim L. & Pol'y J. Association 801 (2005); Paul Vandoren, Clarification of the Relationship between TRIPS and Public Health resulting from the WTO Doha Ministerial Declaration, 5 J. of World Intell. Prop. 5 (2005).

20 See e.g., Gaëlle P. Krikorian & Dorota M. Szymkowiak, Intellectual Property Rights in the Making: The Evolution of Intellectual Property Provisions in US Free Trade Agreements and Access to Medicine, 10 J. of World Intell. Prop. 388 (2007); Keith E. Maskus, Parallel Imports in Pharmaceuticals: Implications for Competition and Prices in Developing Countries, WIPO Report (2001).

21 See e.g., Carlos Maria Correa, Unfair Competition Under the TRIPS Agreement: Protection of Data Submitted for the Registration of Pharmaceuticals, 3 Chi. J. Int'l L. 69 (2002); Robert Galantucci, Data Protection in a U.S.-Malaysia Free Trade Agreement: New Barriers to Market Access for Generic Drug Manufacturers., 17 Fordham Intell. Prop. Media & Ent. L.J. 1083 (2007); Keith E. Maskus, Parallel Imports in Pharmaceuticals: Implications for Competition and Prices in Developing Countries, WIPO Report (2001).

22 See e.g., Carlos Maria Correa, Unfair Competition Under the TRIPS Agreement: Protection of Data Submitted for the Registration of Pharmaceuticals, 3 Chi. J. Int'l L. 69 (2002); Aaron Fellmeth, Secrecy, Monopoly, and Access to Pharmaceuticals in International Trade Law: Protection of Marketing Approval Data Under the TRIPs Agreement, Harv. 45 Int'l L.J. 443 (2004);

compulsory licensing as an indicator of how treaties impact access to medicine, including comparing TRIPS with subsequent treaties, which make compulsory licensing less accessible.[23]

**Table 3**

| Treaty | Number of Articles | Author, Year | Flexibility | Constraint |
|---|---|---|---|---|
| TRIPS | 16 | Ford, 2000<br>Boscheck, 2012<br>Harris, 2011<br>Correa, 2002 | Compulsory Licensing<br>Parallel Imports<br>Data Protection<br>Patentability Criteria | Data Protection<br>Limiting Compulsory Licensing<br>Limiting Parallel Imports<br>Mailbox Rule<br>Patentability Criteria<br>Secondary Patents<br>Patent Term Extension |
| US FTAs | 24 | Roffe, 2004<br>Ng-Loy, 2004<br>Liberti, 2010 | Compulsory Licensing<br>Parallel Imports<br>Bolar/Early working<br>Patentability Criteria<br>Revocation<br>Data Protection | Secondary Patents<br>Data Protection<br>Patent Term Extension<br>Linkage<br>Limiting Compulsory Licensing<br>Limiting Parallel Imports<br>Enforcement Mechanisms<br>Patentability Criteria<br>Limiting Revocation<br>Most Favored Nation (MFN) |
| Non-US Bilateral Agreements | 3 | Jusoh, 2009<br>Liberti, 2010<br>Cartagena, 2009 | Parallel importation<br>Compulsory<br>Licensing<br>Bolar<br>Revocation | Data protection<br>Patent Term Extension<br>Limiting Parallel Imports<br>Limiting Compulsory<br>Licensing Limiting Bolar<br>Secondary Patents<br>Enforcement Mechanisms<br>Limiting revocation |

G. Lee Skillington & Eric M. Solovy, The Protection of Test and Other Data Required by Article 39.3 of the TRIPS Agreement, 24 Nw. J. Int'l L. & Bus. 1 (2003).

23 See e.g., Frederick M. Abbott, The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health, 99 Am. J. of Int'l L. 317 (2005); Sandra Bartelt, Compulsory Licenses Pursuant to TRIPS Article 31 in the Light of the Doha Declaration on the TRIPS Agreement and Public Health, 6 J. of World Intell. Prop. 283 (2003); Ralf Boscheck, Intellectual Property Rights & Compulsory Licensing: The Case of Pharmaceuticals in Emerging Markets, 35 World Competition: L. & Econ. Rev. 621 (2012); Sara M. Ford, Compulsory Licensing Provisions Under the TRIPs Agreement: Balancing Pills and Patents, 15 Am. U. L. Rev. 941 (2000).

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|---|---|---|---|---|
| Regional Trade Agreements | 13 | Krikorian, 2001<br>Correa, 2004<br>Fellmeth, 2004<br>Bernieri, 2006<br>Baker, 2008 | Compulsory Licensing<br>Parallel Importation<br>Revocation<br>Bolar | Data Protection<br>Linkage<br>Patent Term Extension<br>Limiting Revocation<br>Patentability Criteria<br>Limiting Compulsory Licensing<br>Limiting Parallel Importation<br>Enforcement Mechanisms |
| TPP | 4 | Morris, 2017<br>Baker, 2015<br>Gleeson, 2017 | Protections for Plants and Animals<br>Compulsory Licensing<br>Parallel Imports<br>Bolar | Secondary Patents<br>Patent Term Extensions<br>Data Protection<br>Linkage<br>Patent Criteria<br>Enforcement Mechanisms |

Table 3 shows the distribution of articles that discuss different treaties  Almost all the articles begin by discussing the provisions of TRIPS to describe the baseline for international IP law.[24]  The nine articles discussing the Doha Declaration, for example, tend to focus on the changes to international law and TRIPS relating to compulsory licensing, as Doha made specific clarifications relating to that flexibility.[25] The literature discussing Doha highlights the benefits of the declaration on access to medicine because it reaffirmed the importance of certain flexibilities like compulsory licensing.  Twenty-four of the articles examine US FTA provisions, concluding that US FTAs include TRIPS-plus provisions, which negatively affect access to medicine.[26]  Only a small sample of the literature examines treaties to which the US is not a party, the vast majority of which also discusses US bilateral agreements.[27]  This suggests that there is a need for more examination of non-US treaties, especially treaties beetween and among developing countries (South-South treaties). Recently, for obvious reasons, scholarship has focused on the negotiations of the TPP and the potential IPR provisions that will be included in that agreement.[28]

24 See e.g., Rosario Cartagena & Amir Attaran,  A Study of Pharmaceutical Data Exclusivity Laws in Latin America: Is Access to Affordable Medicine Threatened, 17 Health L. J. 269 (2009); L. Liberti, Intellectual Property Rights in International Investment Agreements: An Overview, OECD Working Papers on Int'l Investment (2010); Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines, United Nations Secretary-General's High-Level Panel on Access to Medicines (Sept. 2016) https://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/57d9c6ebf5e231b2f02cd3d4/1473890031320/UNSG+HLP+Report+FINAL+12+Sept+2016.pdf.

25 See e.g., Frederick M. Abbott, The TRIPS Agreement, Access to Medicines and the WTO Doha Ministerial Conference, 5 J. of World Intell. Prop. 15 (2001); James T. Gathii, The Legal Status of the Doha Declaration on TRIPS and Public Health Under the Vienna Convention of the Law of Treaties, 15 Harv. J.L. & Tech. 291 (2002).

26 See e.g., Carsten Fink & Patrick Reichenmiller, Tightening TRIPS: The Intellectual Property Provisions of Recent US Free Trade Agreements, World Bank (2005) http://documents.worldbank.org/curated/en/173901468140377145/Tightening-TRIPS-the-intellectual-property-provisions-of-recent-US-free-trade-agreements; Ping Xiong, Patents in TRIPS-Plus Provisions and the Approaches to Interpretation of Free Trade Agreements and TRIPS: Do They Affect Public Health, 46 J. of World Trade 155 (2012).

27 Rosario Cartagena & Amir Attaran,  A Study of Pharmaceutical Data Exclusivity Laws in Latin America: Is Access to Affordable Medicine Threatened, 17 Health L. J. 269 (2009); Sufian Jusoh, Free Trade Agreements and Implications on Public Health - An Analysis of FTA of Selected ASEAN Member States, 4 Asian J. of WTO & Int'l Health L. & Pol'y 187 (2009); L. Liberti, Intellectual Property Rights in International Investment Agreements: An Overview, OECD Working Papers on Int'l Investment (2010).

28 See e.g., Deborah Gleeson, et al, The Trans Pacific Partnership Agreement, intellectual property and medicines: Differential outcomes for developed and developing countries, 18 Global Social Policy 7 (2018); Emily Michiko Morris, Much Ado About the TPPs Effect on Pharmaceuticals, 20 SMU Sci. & Tech. L. Rev. 135 (2017).

## ANALYSIS OF INTERNATIONAL DISPUTES

Although the scholarship discussing access to medicine case law is still in its infancy, there has been some literature discussing the WTO and ISDS disputes surrounding pharmaceutical intellectual property rights. Since the advent of the TRIPS agreement, there have been three WTO disputes and one NAFTA dispute interpreting treaty language in a way that could affect access to medicines.

### WTO DISPUTES

The WTO disputes were concluded in 2000 and 2001. The Canada-Patent Protection dispute, while not directly pertaining to pharmaceutical patents, represented an early interpretation of TRIPS language affecting patent terms in developed countries. The dispute involved a US challenge to a Canadian law that did not extend patent protection to the 20 year term if the patent was granted prior to TRIPS.[29] The WTO Panel found that Canada needed to adjust its patent terms to come into compliance with Article 70.2 of TRIPS by extending the 20 year patent term to patents granted prior to the TRIPS agreement.[30] This demonstrates that the introduction of TRIPS impacted not only developing countries but the developed world as well, as they brought their IP laws into compliance with the agreement.

In the Canada-Pharmaceutical dispute the European Communities alleged that the Canadian Patent Act violated TRIPS articles 27.1, 28 and 33.[31] The WTO Panel found that the regulatory review exception[32] in Canada's Patent Act was not inconsistent with Article 27.1 of the TRIPS and was covered by the "limited exception" in Article 30.[33] By contrast, the panel concluded that the stockpiling exception[34] in the Canadian Patent Act was inconsistent with Article 28.1 of the TRIPS and did not fall under the exception in Article 30.[35] The last WTO case between the US and Brazil ended in a private settlement. [36] In that case the US requested consultations with Brazil with respect to Brazil's local working requirement provision[37] claiming that the provision was inconsistent with Brazil's obligations under Articles 27 and 28 of TRIPS.[38]

### NAFTA DISPUTES

In the investor-state arbitration context, Eli Lilly, a pharmaceutical company, sued Canada claiming that a Canadian court's interpretation of Canada's patent law violated Canada's obligations under NAFTA.[39] The Canadian court had revoked Eli Lilly's pharmaceutical patent because the patent application "promised

29 DS170: Canada — Term of Patent Protection, World Trade Organization (2019) https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds170_e.htm.

30 Id.

31 DS114: Canada — Patent Protection of Pharmaceutical Products, World Trade Organization (2019) https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds114_e.htm

32 Under the regulatory review exception, potential competitors of a patent owner are permitted to use the patented invention, without the authorization of the patent owner during the term of the patent, for the purposes of obtaining government marketing approval, so that they will have regulatory permission to sell in competition with the patent owner by the date on which the patent expires.

33 DS114: Canada — Patent Protection of Pharmaceutical Products, World Trade Organization (2019) https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds114_e.htm.

34 Under the stockpiling exception, competitors are allowed to manufacture and stockpile patented goods during a certain period before the patent expires, but the goods cannot be sold until after the patent expire.

35 DS114: Canada — Patent Protection of Pharmaceutical Products, World Trade Organization (2019) https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds114_e.htm.

36 DS199: Brazil — Measures Affecting Patent Protection, World Trade Organization (2019) https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds199_e.htm.

37 A provision requiring that pharmaceutical companies practice their patented invention (i.e. manufacture, produce, study, etc.) in Brazil in order to get exclusive patent rights.

38 DS199: Brazil — Measures Affecting Patent Protection, World Trade Organization (2019) https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds199_e.htm.

39 NAFTA - Chapter 11 – Investment, Global Affairs Canada (Dec. 19, 2017) https://www.international.gc.ca/trade-agreements-accords-commerciaux/topics-domaines/disp-diff/eli.aspx?lang=eng

a specific utility" that was not met. Eli Lilly argued that the "promise doctrine"[40] was a violation of the protections afforded under NAFTA Article 1110 (Expropriation and Compensation), Article 1105 (Minimum Standard of Treatment) and Article 1102 (National Treatment).[41] The NAFTA tribunal dismissed Eli Lilly's claims, confirming that Canada was in compliance with its NAFTA obligations.[42]

## LITERATURE REVIEW OF INTERNATIONAL DISPUTES

We found ten articles discussing relevant disputes and the potential impacts on access to medicine policies.[43] Table 4 identifies these articles, including the case they examine and the articles' conclusions.

The literature comments on the impact of specific tribunal decisions on policy space and later interpretation of the decisions by the countries impacted by them.[44] One interesting trend is the different ways scholars respond to Canada-Pharmaceuticals as opposed to Eli Lilly. Despite the not-entirely positive outcome of the Canada-Pharmaceutical case, most authors conclude that the outcome of the case will have a net positive outcome on policy space. On the other hand, the literature about Eli Lilly remains wary of the effects on policy space, highlighting that ISDS is itself a threat to sovereign states, even when the outcome is in their favor.[45] These articles go beyond the results of the NAFTA tribunal to comment on the larger chilling effect that ISDS has on policy space.[46]

40 The promise doctrine provides that where a patent specification is found to promise a specific utility, that utility must be specifically demonstrated or soundly predicted as of the patent's filing date. Steve Brachmann, Supreme Court of Canada Rules on Promise Doctrine in Favor of Pharma Patent Owners, IP Watchdog (July 6, 2017) https://www.ipwatchdog.com/2017/07/06/supreme-court-canada-rules-promise-doctrine/id=85420/. Canada's promise doctrine was intended to prevent speculative over-patenting and had the effect of raising the standard specifically for secondary patents. Id.

41 Brook Baker & Katrina Geddes, The Incredible Shrinking Victory: Eli Lilly v. Canada, Success, Judicial Reversal, and Continuing Threats from Pharmaceutical ISDS, 49 Loy. U. Chi. L.J. 490 (2017).

42 Id.

43 See e.g., Cynthia M. Ho, A New World Order for Addressing Patent Rights and Public Health, 82 Chi.-Kent L. Rev. 1467 (2007); Maria Victoria Stout, Crossing the TRIPS Non-discrimination Line: How CAFTA Pharmaceutical Patent Provisions Violate TRIPS Article 27.1, 17 B.U. J. of Sci. & Tech. 177 (2008).

44 See e.g., Pedro Roffe, Bilateral agreements and a TRIPS-plus world: the Chile-USA Free Trade Agreement, Quaker International Affairs Programme (2004) https://quno.org/sites/default/files/resources/Bilateral%2BAgreements%2Band%2BTRIPS%2Bplus%2BEnglish.pdf; Maria Victoria Stout, Crossing the TRIPS Non-discrimination Line: How CAFTA Pharmaceutical Patent Provisions Violate TRIPS Article 27.1, 17 B.U. J. of Sci. & Tech. 177 (2008).

45 E.g. compare, Cynthia M. Ho, A New World Order for Addressing Patent Rights and Public Health, 82 Chi.-Kent L. Rev. 1467 (2007) with Brook Baker & Katrina Geddes, The Incredible Shrinking Victory: Eli Lilly v. Canada, Success, Judicial Reversal, and Continuing Threats from Pharmaceutical ISDS, 49 Loy. U. Chi. L.J. 479 (2017).

46 Id.

**Table 4**

| Author, Year | Disputes | Treaties | Conclusions |
|---|---|---|---|
| Champ, 2002 | US-Brazil Dispute | TRIPS | There is a question after US-Brazil of whether governments can use the data to approve a generic. |
| Lazzarini, 2003 | US-Brazil Dispute | TRIPS | Brazil's domestic implementation could be a model for other countries who wish to facilitate greater access to medicine but there could be backlash from developed countries like the US. |
| Roffe, 2004 | Canada Patent Protection | US-Chile FTA | The decision in the Canada Patent Protection case will apply to the US-Chile FTA because the US-Chile FTA includes almost the exact language of article 70 of TRIPS. |
| Bartelt, 2005 | Canada Pharmaceuticals | TRIPS, Doha Declaration | Canada Pharmaceuticals demonstrates how art 7 and 8 of TRIPS can be used to allow broader exceptions to patent protections but the panel settled on a strict textual approach. |
| Ho, 2007 | Canada Pharmaceuticals | TRIPS, FTAs | The panel's finding that Canada's regulatory provision was compatible with TRIPS suggests that patent rights under TRIPS are not absolute, but the full scope of flexibility under article 30 of TRIPS remained undefined. |
| Stout, 2008 | Canada Pharmaceuticals | TRIPS, CAFTA | Canada Pharmaceuticals demonstrates the TRIPS dispute settlement system is an effective enforcement tool that has been and can be used to raise a TRIPS Article 27.1 claim. |
| Du, 2014 | Canada Pharmaceuticals | TRIPS | In Canada Pharmaceuticals,51 the WTO panel rejected a restrictive reading of Article 27.1 as forbidding any different treatment of the various fields of technology. Rather, unfair discrimination must be distinguished from differential treatment for legitimate reasons. |
| Baker, 2015 | Eli Lilly | TRIPS, TPP | With the Eli Lilly case, we see the advent of combining investor protection with pharma IP protection and it exposes countries even more extremely to litigation based on access to medicine legislation. |
| Baker, 2017 | Eli Lilly | TRIPS | Even though the outcome of Eli Lilly is seen as a "victory" for proponents of access to medicine, there is a continued danger of using private arbitration to bypass domestic courts in order to uphold monopolies that limit access to medicine. |
| Gervais, 2018 | Eli Lilly | NAFTA | Eli Lilly represents an emerging trend where investors use a country's ISDS obligations as a response to changes in that country's policy space relating to patents. |

## CONCLUSION

There is extensive literature analyzing IP provisions in international treaties and the expected effect of those provisions on access to medicines. While the literature that examines TRIPS and the subsequent Doha Declaration emphasizes the importance of flexibilities within TRIPS provisions as a method of ensuring access to medicines, later articles discuss how subsequent treaties often include TRIPS-plus provisions that limit policy space. These articles discussing bilateral and regional trade agreements tend to focus on the negative effects of these treaties on access to medicine, with many focusing on constraints on data exclusivity and compulsory licensing.

There remain several gaps in the literature analyzing treaty provisions. The majority of the literature examining regional and bilateral trade agreements focuses on the US, so there is a need for literature that examines non-US treaties. This is especially true for South-South treaties in order to understand the state of international IP law and whether developing countries are imposing TRIPS-plus provisions in their own treaties.

Additionally, the majority of the literature examines only the IP provisions of treaties, but there are other treaty elements including MFN, investment provisions, and enforcement mechanisms that can have an effect on a country's policy space to regulate access to medicines. There also seems to be a general acceptance that treaties with TRIPS-plus provisions will limit policy space for access to medicines, but few attempt to study the actual correlation/causation between the two.

We also found a smaller subset of literature examining the effect of international trade and investment disputes about access to medicine. The literature often discussed the broader implications of the decision on policy space hinting about the effects on access to medicine, with a few articles concluding that the mere existence of these avenues for recovery has a chilling effect on policy space. The volume of literature discussing these cases, however, is too small. There cannot be a deep and varied scholarly discussion with so few articles on the matter. Therefore, there is a need for more literature examining the effects of relevant international disputes, as they arrive, because the decisions could limit policy space that affects access to medicines.

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## ACKNOWLEDGEMENTS

I would like to express my gratitude to Rachel Thrasher for giving me the opportunity to work on this fascinating project and for guiding me through the process. I would also like to thank Warren Kaplan for his help with the planning the direction of the project. Another special thanks to everyone at the BU Global Development Policy Center for their support and guidance.