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GOOD FAITH IN TRIPS COMPULSORY LICENSING OF PHARMACEUTICAL PATENTS: LESSONS FROM PREVIOUS PANDEMIC CASES

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Abstract

The COVID-19 pandemic impacted the world of patents as countries prepared their legal frameworks to ease the process of compulsory licensing. Nations like India and South Africa went further by proposing a suspension of patents necessary to combat COVID-19, which was still under discussion. A patented drug effective against COVID-19 could see compulsory licensing in many countries where its patent holder was conducting business. This article discussed compulsory licensing as an essential issue by examining its legitimacy, previous cases of compulsory licensing, and the conduct of states in cases of compulsory licensing issuance, particularly looking at examples from Thailand, Brazil, and India. The article examined remedies against compulsory licensing, including the theoretical possibility for the constitutional review of treaties that included international and domestic measures, both litigation and alternative measures. This qualitative research regarded both primary and secondary legal sources, which results revealed that a combination of the soft law power of the Doha Declaration and the invocation of subsequent compulsory licensing cases supported the pillars of compulsory licensing practice. However, the practice of compulsory licensing, both by the patent holder and the state actors, was not entirely conducted in good faith according to the Vienna Convention on the Law of Treaties (VCLT) 1969 and the TRIPS Agreement. Hence, such patent holders needed to have adequate comprehension of both international and domestic remedies, especially the possibility for constitutional review of treaties remedies.

A. Introduction

The urgency for more accessible Coronavirus Disease 2019 (COVID-19) medications has led to risks that countries might adopt various measures. These range from waiving intellectual property enforcement as a means to combat COVID-19, as discussed around 15-16 October

2020,[1] to overriding the protection of intellectual property under Article 73 of the TRIPS Agreement as part of the security exception, to revocation and forfeiture under Article 32 of TRIPS, and, could be considered the most moderate approach aside from voluntary licensing, the Compulsory Licensing measures under Article 31 in conjunction with Article 31bis of TRIPS,[2] All these actions are part of the flexibilities under the TRIPS,[3] Agreement and could be potentially used by state parties to aid their efforts in combating the spread of COVID-19.[4]

For instance, the Saudi Arabia-Intellectual Property Panel and the Russia-Transit Panel acknowledged that the security exceptions of Article 73 of the Trade-Related Aspects of Intellectual Property Rights Agreements (TRIPS) could be invoked without the need to analyze less trade-restrictive measures or alternatives, provided that the actions are plausibly related to their objectives. However, the implementation of Article 73 could potentially trigger issues with other obligations in the form of domestic laws and Investment Agreements (IAs) that a country may hold.[5] This potential for triggering other obligation issues might explain the lack of utilization of Article 73 in appropriating COVID-19 medical materials.[6]

The approach of revocation and forfeiture of COVID-19 medicines under Article 32 of the TRIPS Agreement is inherently more lenient.[7] It merely requires a judicial review process mechanism before state parties can conduct forfeiture or revocation. However, this lenient requirement is balanced by the compulsory obligation to comply with the Paris Convention for the Protection of Industrial Property (Paris Convention 1979), specifically Articles 1 to 12 and 19. This stands in contrast to the regulations for compulsory licensing for pharmaceutical products under Article 31 in conjunction with Article 31 *bis* of TRIPS.

Compulsory licensing is a license issued by a country's government to a third party to produce a patented product without its owner's permission.[8] The general requirements of compulsory licensing include the supply of the domestic market. Unless the country does not have sufficient manufacturing capabilities in the pharmaceutical sector, the use shall be for public and non-commercial purposes and the rights holder must be informed promptly.[9] Compulsory licensing is often the preferred method by state parties in acquiring medical supplies.

In previous pandemic before COVID-19 pandemic, compulsory licensing was also implemented in coping with previous pandemics. For example, in the Human immunodeficiency virus/ Acquired Immunodeficiency Syndrome (HIV/AIDS) pandemic in

[1] Hans Morten Haugen, "Does TRIPS (Agreement on Trade-related Aspects of Intellectual Property Rights) Prevent COVID-19 Vaccines as a Global Public Good?," *The Journal of World Intellectual Property* 24, no. 3–4 (2021): 1–26, https://doi.org/10.1111/jwip.12187.

[2] Frederick M. Abbott, "The TRIPS Agreement Article 73 Security Exceptions and the COVID-19 Pandemic," *SSRN Electronic Journal*, no. 116 (2020): 1–22, https://doi.org/10.2139/ssrn.3682260.

[3] Carlos M. Correa, "Special Section 301: US Interference with the Design and Implementation of National Patent Laws," Research Paper (Geneva, 2020).

[4] Haugen, "Does TRIPS (Agreement on Trade-related Aspects of Intellectual Property Rights) Prevent COVID-19 Vaccines as a Global Public Good?"; Abbott, "The TRIPS Agreement Article 73 Security Exceptions and the COVID-19 Pandemic."

[5] Abbott, "The TRIPS Agreement Article 73 Security Exceptions and the COVID-19 Pandemic."

[6] *Ibid*.

[7] Haugen, "Does TRIPS (Agreement on Trade-related Aspects of Intellectual Property Rights) Prevent COVID-19 Vaccines as a Global Public Good?"

[8] Eduardo Urias and Shyama V. Ramani, "Access to Medicines after TRIPS: Is Compulsory Licensing an Effective Mechanism to Lower Drug Prices? A Review of the Existing Evidence," *Journal of International Business Policy* 3, no. 4 (2020): 367–84, https://doi.org/10.1057/s42214-020-00068-4.

[9] Haugen, "Does TRIPS (Agreement on Trade-related Aspects of Intellectual Property Rights) Prevent COVID-19 Vaccines as a Global Public Good?"; Dawn Dziuba, "Trips Article 31bis and H1N1 Swine Flu: Any Emergency or Urgency Exception to Patent Protection?," *Indiana International & Comparative Law Review* 20, no. 2 (January 2010): 195–212, https://doi.org/10.18060/17626.

countries including Kenya, Zimbabwe, Benin, Congo, Ivory Coast, Mozambique, Togo, Zambia, Central African Republic, Chad, Gambia, Guinea, Lesotho, Malawi, Niger, Rwanda, and Sierra Leone have invoked compulsory licensing.[10] Furthermore, compulsory licensing does not always take place in a pandemic. The United States of America (USA) issued a compulsory license for *sofosbuvir* to increase access for the treatment of Hepatitis. The British government also performed compulsory licenseing towards *lumacaftor/ivacaftor* to increase access to cystic fibrosis treatment.[11]

There are currently two COVID-19 medicines under compulsory licensing. Russia has issued a compulsory license towards Gilead, allowing local Russian company *Pharmsynthez* to produce COVID-19 emergency drug *remdesivir*. Israel also has issued a compulsory license for an experimental COVID-19 drug called *lopinavir/ritonavir* (LPV/r).[12] The lack of effective medicines caused number medicines under compulsory licensing low as the drugs are being developed. Existing drugs are in the experimental stage or have not yet shown significant clinical outcome towards COVID-19, thereby users were still hesitant.[13]

The prospect of developing an effective drug against COVID-19 raises the potential for countries around the globe to resort to either voluntary or compulsory licensing mechanisms to access such medications. For instance, Ecuador has taken proactive steps by approving a resolution that mandates its health minister to issue a compulsory license for all patents associated with COVID-19 treatments and technologies. Similarly, nations such as Brazil, Canada, Chile, and Germany have preemptively revised their patent laws. These amendments aim to expedite the process for granting compulsory licenses or to simplify the procedures for issuing licenses related to COVID-19.

This trend is further exacerbated with a proposal from India and South Africa, which calls for suspension of COVID-19 related intellectual property protection to extend the access of COVID-19 related materials for developing and least developing countries. Currently, this proposal is still being discussed.[14] Every relevant party needs to learn about previous cases of compulsory licensing invocation and available remedies against compulsory licensing to avoid past mistakes and ensure fairness in its implementation.

Tariq Kameel, Ramzi Madi, and Kawthar Kayed only discussed legal approaches in Arabian countries to identify when compulsory license could be issued and the right of a patent owner to fair compensation.[15] Hilary Wong did a discussion on the history of compulsory licensing in different pandemics. Unfortunately, legal avenues that countries or patent owners could take in the case of being served with compulsory licensing were not thoroughly discussed.[16] Hans Morten Haugen discussed how and when licensing could be legally invoked without discussing the medicines that could be taken by patent owners facing compulsory

[10] Marion Motari et al., "The Role of Intellectual Property Rights on Access to Medicines in the WHO African Region: 25 Years after the TRIPS Agreement," *BMC Public Health* 21, no. 1 (2021): 1–19, https://doi.org/10.1186/s12889-021-10374-y.
[11] Perehudoff, Thoen, and Boulet, "Overriding Drug and Medical Technology Patents for Pandemic Recovery: A Legitimate Move for High-Income Countries, Too."
[12] *Ibid*.
[13] Hilary Wong, "The Case for Compulsory Licensing during COVID-19," *Journal of Global Health* 10, no. 1 (June 2020): 1–5, https://doi.org/10.7189/jogh.10.010358.
[14] Ann Danaiya Usher, "South Africa and India Push for COVID-19 Patents Ban," *The Lancet* 396, no. 10265 (December 2020): 1790–91, https://doi.org/10.1016/S0140-6736(20)32581-2; Vijay Kumar Chattu, Shalini Pooransingh, and Hamid Allahverdipour, "Global Health Diplomacy at the Intersection of Trade and Health in the COVID-19 Era.," *Health Promotion Perspectives* 11, no. 1 (2021): 1–4, https://doi.org/10.34172/hpp.2021.01.
[15] Tariq Kameel, Ramzi Madi, and Kawthar Kayed, "The Compulsory Licensing for Exploiting Patented COVID-19 Pharmaceutical Treatment: Legal Approaches of Some Arab Countries," *Biotechnology Law Report* 40, no. 2 (2021): 104–16, https://doi.org/10.1089/blr.2021.29225.ka.
[16] Wong, "The Case for Compulsory Licensing during COVID-19."

licensing, and its main focus is the embedded progress of human rights in the intellectual property regime for the last twenty years.[17] The closest example to this article is a work by Alison Slade which discusses the good faith principle under TRIPS Agreement, yet it did not discuss the compulsory licensing.[18]

This research paper discusses the urgency of the compulsory licensing issue and the remedies that concerned parties could pursue should they find themselves served with compulsory licensing. This paper addresses the scholarly gap regarding the operation of good faith in compulsory licensing and the diverse legal remedies available in cases of compulsory licensing. It will delve into the historical evolution of compulsory licensing under the TRIPS Agreement, exploring its advantages and challenges. Additionally, the discussion will extend to methods through which affected parties can pursue remedies domestically and internationally against compulsory licensing.

This normative qualitative research regarded secondary data from literatures that included primary legal sources and secondary legal sources. First, this article discusses the required licensing method of the TRIPS Agreement. Second, this article discusses previous cases of compulsory licensing by citing examples of Thailand, Brazil, and India with the United States as the patent flag state. Thailand, Brazil, and India were selected as they represent case examples of compulsory licensing, which the TRIPS Agreement served as a legal source. Moreover, other materials about the three countries show the interplay between patent holder state and compulsory licensing state. The three countries also experienced issues from one patent holder state: The United States for exercising its aggressive role in defending patents. This research is expected to raise greater attention to compulsory licensing issues and their available legal remedies. Hence, both the rights of people and the pharmaceutical actors are well protected.

B. Discussion

1. Compulsory Licensing Method in TRIPS Agreement

Compulsory licensing, a practice that dates back to 1623 in the United Kingdom,[19] first gained significant attention as a punitive measure during World War I. Under the Trading with the Enemy Act of 1917, the United States government seized all patents held by German inventors and entities within the United States, subjecting 4,706 patents to compulsory licensing.[20] In contemporary times, the primary purpose of compulsory licensing has shifted towards mitigating the monopoly power of patent holders. This approach aims to enhance access to essential medicines and innovations by facilitating a substantial reduction in the prices of goods made available through compulsory licensing.[21]

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[17] Haugen, "Does TRIPS (Agreement on Trade-related Aspects of Intellectual Property Rights) Prevent COVID-19 Vaccines as a Global Public Good?"

[18] Alison Slade, "Good Faith and the TRIPS Agreement: Putting Flesh on the Bones of the TRIPS 'Objectives,'" *International and Comparative Law Quarterly* 63, no. 2 (April 2014): 353–83, https://doi.org/10.1017/S0020589314000098.

[19] Ebenezer Durojaye, "Compulsory Licensing and Access to Medicines in Post Doha Era: What Hope for Africa?," *Netherlands International Law Review* 55, no. 1 (May 2008): 33–71, https://doi.org/10.1017/S0165070X08000338.

[20] *Ibid*.

[21] Petra Moser, "Patents and Innovation: Evidence from Economic History," *Journal of Economic Perspectives* 27, no. 1 (February 2013): 23–44, https://doi.org/10.1257/jep.27.1.23; Sara M Ford, "Compulsory Licensing Provisions Under the TRIPs Agreement: Balancing Pills and Patents," *American University Journal of International Law & Policy* 15, no. 4 (2000): 941–74, https://digitalcommons.wcl.american.edu/auilr/vol15/iss4/5/.

Compulsory licensing was included in Article 5 of the Paris Convention 1979,[22] before later complemented with Article 31 of the TRIPS Agreement 1994, foreign patents could be issued with compulsory licenses in case of national emergencies.[23] The Doha Declaration further eases the compulsory licensing requirements by providing the freedom to determine the grounds on which compulsory licenses are granted which clarifies the objectives and principles in interpreting the TRIPS Agreement.[24] The objectives and principles of the TRIPS Agreement are put into details in Article 7 and Article 8. Among the objectives stipulated in Article 7 is the promotion of social and economic welfare. This means the enforcement of intellectual property rights is a reward for its holder and creators that contributes to society in socio-economic welfare.[25]

Before the Doha Declaration, there were two interpretations of the TRIPS Agreement objectives and purposes between South Africa, which favors the developing country approach, and the United States, which favors the developed countries' approach. This difference was originated from South African legislation, which allowed compulsory licensing for pharmaceutical products.[26]

In 1997, South Africa contended that issuing compulsory licenses would lead to a reduction in prices, thereby enhancing access to essential medicines required to address the AIDS crisis.[27] The United States countered that the solution lies in a strong patent system, complemented by a mix of social, economic, and health policies, rather than relying on compulsory licenses. This approach, according to the U.S., would foster innovation and facilitate the development of new drugs.[28] Regardless, the United States and the developed countries have moved away from their previous stance. This mainly started from a turning point in the negotiation process when it is known that the United States threatened Bayer AG Corporation during the *Anthrax*[29] to issue a compulsory license unless the corporation sold its ciprofloxacin license for a lower price.[30]

Despite the consensus reached in the Doha Declaration, its legal status remains ambiguous;[31] (not categorized as a proper and official interpretation tool under Article IX.2 of the Marrakesh Agreement Establishing the World Trade Organozation).[32] There are three

[22] Margaret Dowie-Whybrow, "Paris Convention for the Protection of Industrial Property," in *Core Statutes on Intellectual Property* (London: Macmillan Education UK, 2013), 516–43, https://doi.org/10.1007/978-1-137-35471-6_5.

[23] Antony Taubman, Hannu Wager, and Jayashree Watal, eds., "Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) (as Amended on 23 January 2017)," in *A Handbook on the WTO TRIPS Agreement* (Cambridge University Press, 2020), 295–337, https://doi.org/10.1017/9781108883511.015.

[24] James Thuo Gathi, "The Legal Status of the Doha Declaration on TRIPS and Public Health Under the Vienna Convention of the Law of Treaties," *Harvard Journal of Law & Technology* 15, no. 2 (2002): 292–317, https://lawecommons.luc.edu/cgi/viewcontent.cgi?article=1419&context=facpubs; Moser, "Patents and Innovation: Evidence from Economic History."

[25] Thamara Romero, "Articles 7 and 8 as the Basis for Interpretation of the TRIPS Agreement" (Geneva, 2020).

[26] Ford, "Compulsory Licensing Provisions Under the TRIPs Agreement: Balancing Pills and Patents."

[27] *Ibid.*

[28] Gathi, "The Legal Status of the Doha Declaration on TRIPS and Public Health Under the Vienna Convention of the Law of Treaties."

[29] Anthrax is caused by a spore-forming bacterium. It mainly affects animals.

[30] Divya Murthy, "The Future of Compulsory Licensing: Deciphering the Doha Declaration on the TRIPs Agreement and Public Health," *American University International Law Review* 17, no. 6 (2002): 1299–1346, https://digitalcommons.wcl.american.edu/auilr/vol17/iss6/4/.

[31] Steve Charnovitz, "The Legal Status of the Doha Declarations," *Journal of International Economic Law* 5, no. 1 (March 2002): 207–11, https://doi.org/10.1093/jiel/5.1.207.

[32] Putu Ayu and Sriasih Wesna, "Doha Declaration Sebagai Perlindungan Masyarakat Atas Akses Obat Esensial Di Negara Berkembang Pasca Trips Agreement," *Jurnal Warmadewa Kertha Wicaksana* 14, no. 1 (2020): 56–62, https://doi.org/10.22225/kw.14.1.1585.56-62; Eric M. Solovy and Pavan S. Krishnamurthy, "TRIPS Agreement Flexibilities and Their Limitations: A Response to the UN Secretary-General's High-Level Panel Report on Access

possibilities regarding the legal status of the Doha Declaration: As a subsequent agreement under Article 31.3 (a) of the Vienna Convention on Law of Treaties (VCLT) 1969, as evidence of subsequent practice under the TRIPS Agreement, or as a legally non-binding statement of intent and commitment.[33]

However, recent publications agree that the Doha Declaration is a legally non-binding statement of intent or "soft law" based on its text and negotiating history.[34] There are differences of opinion among scholars about the role of soft law, mainly centered on whether it could be classified as a law in the first place.[35] Positivist scholars such as Jan Klabbers strictly adhered to a view that "soft law" is not a law because the binding power of law cannot be uncertain,[36] and Malcolm N. Shaw and Dinah Shelton further explain that instruments of "soft law" that have become legally binding are not soft law but rather international conventions or international customary law adopted from soft law.[37]

Some scholars took an interactionist approach towards soft law and they did not express if "soft law" could be classified as law. Peter Malanczuk claims that soft law is a crossroad between law and politics; a soft law with high legitimacy could structure international conduct even though the soft law was intended to be non-legally binding.[38] This shows a mutual reinforcing and supplementing approach towards hard and soft law relations, which Fuller supports.[39]

Aside from the positivist and interactionist approach, recent reviews by constructivists are argument towards the status of soft law as law. The constructivist approach claims that earlier scholars are biased because of positivist domination in the legal school of thought and ignore formal and informal law. For the constructivist, the law is not a closed system, and therefore the quality of legal argument determines the truth of the legal proposition instead of the other way around.[40] Therefore, informal law such as soft law can support hard law and *vice versa* in establishing legal order because both are separate entities.[41]

Regardless of the difference of positions about soft law power, all theories agree that soft law influences global legal order. Thereby, Doha Declaration has the legitimacy to be followed by states and bring humanist influence towards intellectual property legal regimes, as proven

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to Medicines," *George Washington International Law Review* 50, no. 1 (2017): 69–124, https://ssrn.com/abstract=2984951.

[33] Gathi, "The Legal Status of the Doha Declaration on TRIPS and Public Health Under the Vienna Convention of the Law of Treaties."

[34] Sharifah Sekalala and Haleema Masud, "Soft Law Possibilities in Global Health Law," *Journal of Law, Medicine & Ethics* 49, no. 1 (April 2021): 152–55, https://doi.org/10.1017/jme.2021.20; Solovy and Krishnamurthy, "TRIPS Agreement Flexibilities and Their Limitations: A Response to the UN Secretary-General's High-Level Panel Report on Access to Medicines."

[35] Vita Cita Emia Tarigan and Eka N.A.M. Sihombing, "Kebijakan Pengendalian Pencemaran Di Selat Malaka Yang Bersumber Dari Kecelakaan Kapal," *Jurnal Penelitian Hukum De Jure* 19, no. 4 (December 2019): p. 484., https://doi.org/10.30641/dejure.2019.V19.479-502; Anthony Aust, *Handbook of International Law*, 2nd ed. (Cambridge: Cambridge University Press, 2010).

[36] *Ibid*. p. 484.

[37] Malcolm N. Shaw, *International Law*, 6th ed. (Cambridge: Cambridge University Press, 2008), p. 117; David Armstrong, *Routledge Handbook of International Law*, ed. David Armstrong et al., 1st ed. (New York: Routledge, 2009), p. 3.

[38] Peter Malanczuk, *Akehurst´s Modern Introduction to International Law*, 7th ed. (New York: Routledge, 2002). P. 54.

[39] Bart van Klink and Oliver W. Lembcke, "A Fuller Understanding of Legal Validity and Soft Law," in *Legal Validity and Soft Law* (Berlin: Springer, 2018), 145–64, https://doi.org/10.1007/978-3-319-77522-7_7.

[40] Jaap Hage, "What Is Legal Validity? Lessons from Soft Law," in *Legal Validity and Soft Law* (Berlin: Cham : Springer International, 2018), 19–45, https://doi.org/10.1007/978-3-319-77522-7_2.

[41] Van Klink, B.M.J, and Lembcke, O.W., "A Fuller Understanding of Legal Validity and Soft Law." *Vrije Universiteit Amsterdam*, (2018), P. 160.

by increasing call and progress towards greater access to medicines for the last twenty years.[42] This statement proves the cooperation between WHO, WIPO, and WTO to handle public health issues in capacity-building activities and collaborate on matters relating to public health, intellectual property, and trade affairs.[43]

Further progress in the WTO also exists in amendments to the TRIPS Agreement, especially the creation of Article 31*bis*.1, which allows granting compulsory licenses towards non-domestic entities to produce pharmaceutical products. Article 31*bis*.1 is a boon to Least Developing Countries (LDCs) which often do not have sufficient pharmaceutical infrastructure to produce locally effectively.[44]

2. Benefit and Issues of Compulsory Licensing Method

a. Lessons from Previous Use of Compulsory Licensing Method

Compulsory licensing in the pharmaceutical industry frequently carries enormous legitimacy as a result of the Doha Declaration. However, compulsory licensing has its benefits and consequences. The following paragraphs shall discuss compulsory licensing based on several previous cases after the Doha Declaration to determine the benefits gained and the consequences incurred.

The study will commence by exploring the application of compulsory licensing within the contexts of Thailand, Brazil, and India. In 2007, Thailand implemented compulsory licensing for Anti-Retroviral Drugs (ARVs), notably including Efavirenz by Merck and both Lopinavir/ritonavir and Kaletra by Abbott. This initiative was expanded in August 2010 when Thailand extended its compulsory licensing to cover Merck and Abbott ARVs until the expiration of their patents.[45]

Thailand's motivation to issue compulsory licenses stems from the high percentage of HIV cases in its country. Thailand in 2009 had around 580.000 cases of HIV out of its 66 million population while the United States had around 410.000-880.000 range of HIV cases out of 306 million population. In other words, HIV infects 1,3% of Thailand's population while the percentage of the US is at 0,6%.[46] Thailand seeks to reduce drug prices to ensure greater accessibility for its people to measure public health security. However, Thailand struggles to keep the price low despite compulsory licensing measures and international aid drugs.[47] This raises the specter of Thailand's government's motive of profitability rather than public health security.

The Government Pharmaceutical Organization (GPO), a state-owned enterprise in Thailand that manufactures pharmaceutical products, has been documented marking up prices by as much as 1000% for 60% of its pharmaceutical products sold above market prices in 2002. Moreover, GPO's profits in 2010 were projected to double the 2005 profits of 10 billion baht.[48]

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[42] World Trade Organization, *Promoting Access to Medical Technologies and Innovation, 2nd Edition*, 2nd ed. (Geneva: WTO, 2020), https://doi.org/10.30875/fa323700-en; Haugen, "Does TRIPS (Agreement on Trade-related Aspects of Intellectual Property Rights) Prevent COVID-19 Vaccines as a Global Public Good?"

[43] *Ibid*.

[44] Eduardo Urias and Shyama V. Ramani, "Access to Medicines after TRIPS: Is Compulsory Licensing an Effective Mechanism to Lower Drug Prices? A Review of the Existing Evidence." *Journal of International Business Policy*, (2020), P. 368.

[45] Donald Harris, "TRIPS After Fifteen Years: Success or Failure, as Measured by Compulsory Licensing," *Journal of Intellectual Property Law* 18, no. 2 (2011): 1–35, https://digitalcommons.law.uga.edu/jipl/vol18/iss2/3.

[46] Sheikh Shahnawaz, "The Optimal Timing of Compulsory Licensing: A Story of Thailand's Winter of Discontent," *Global Economy Journal* 12, no. 4 (November 2012): 1–17, https://doi.org/10.1515/1524-5861.1903.

[47] Kristina M. Lybecker and Elisabeth Fowler, "Compulsory Licensing in Canada and Thailand: Comparing Regimes to Ensure Legitimate Use of the WTO Rules," *Journal of Law, Medicine & Ethics* 37, no. 2 (January 2009): 222–39, https://doi.org/10.1111/j.1748-720X.2009.00367.x.

[48] *Ibid*.

These circumstances raise questions about the Thai government's commitment to using compulsory licensing as a means to control drug prices. This is particularly concerning given that, at the time, public health expenditure accounted for 10% of Thailand's total government budget.[49]

Arguments that the inability to further keep down prices was due to supply issues was negated by Thailand's government policy of not allowing private manufacturers procurement contracts, citing compulsory licensing could assure universal coverage,[50] especially since Thailand conducts its compulsory licensing based on the grounds of public non-commercial use.[51] The situation is further complicated by disputed allegations suggesting that Thailand does not engage in serious negotiations with pharmaceutical manufacturers before resorting to compulsory licensing. These allegations add to the skepticism regarding Thailand's use of compulsory licensing, insinuating that the practice might not genuinely be based on public, non-commercial interests as claimed.[52]

Thailand's HIV/AIDS compulsory licensing program has several key outcomes. Firstly, it did make drugs more affordable but primarily served domestic industries rather than significantly improving public health.[53] Secondly, the program raised doubts about the Thai government's motives, with concerns that savings were being diverted for profit rather than patient care. Thirdly, Thailand's actions sparked international disputes, leading to the US threatening trade sanctions and pharmaceutical company Abbott stopping the launch of new drugs in Thailand.[54] This backlash affected not just Thailand but discouraged other developing countries from using compulsory licensing due to fear of similar retaliation.[55]

In contrast, Brazil's approach to compulsory licensing was more proactive and strategic. On May 4, 2007, Brazil issued a compulsory license for the HIV/AIDS drug Efavirenz, owned by Merck, after failed negotiations over price reductions.[56] This move, aimed at saving $30 million annually for its HIV/AIDS program, drew criticism from Merck.[57] The company argued that Brazil's actions could deter foreign investment in pharmaceuticals and set a damaging

[49] Jerome H. Reichman, "Comment: Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options.," *The Journal of Law, Medicine & Ethics : A Journal of the American Society of Law, Medicine & Ethics* 37, no. 2 (January 2009): 247–63, https://doi.org/10.1111/j.1748-720X.2009.00369.x.

[50] Kristina Lybecker and Elisabeth Fowler, *Loc.Cit*.

[51] Jamie Feldman, "Compulsory Licenses : The Dangers Behind the Current Practice," *Journal of International Business and Law* 8, no. 1 (2009): 137–67, https://scholarlycommons.law.hofstra.edu/jibl/vol8/iss1/9/.

[52] Cynthia Ho, "Unveiling Competing Patent Perspectives," *Houston Law Review* 46, no. 4 (2009): 1047–1114, https://houstonlawreview.org/article/4270-unveiling-competing-patent-perspectives; Lybecker and Fowler, "Compulsory Licensing in Canada and Thailand: Comparing Regimes to Ensure Legitimate Use of the WTO Rules"; Shahnawaz, "The Optimal Timing of Compulsory Licensing: A Story of Thailand's Winter of Discontent."

[53] Kristina Lybecker and Elisabeth Fowler, *Op.Cit.*, p. 223."

[54] Sebastian Haunss and Kenneth Shadlen, "The Politics of Patents: Conditions of Implementation of Public Health Policy in Thailand," in *Politics of Intellectual Property: Contestation Over the Ownership, Use, and Control of Knowledge and Information* (Cheltenham: Edward Elgar Publishing, 2009), 1–249, https://doi.org/10.4337/9781849802062; Shahnawaz, "The Optimal Timing of Compulsory Licensing: A Story of Thailand's Winter of Discontent"; Harris, "TRIPS After Fifteen Years: Success or Failure, as Measured by Compulsory Licensing"; Reichman, "Comment: Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options."

[55] Donald Harris, *Loc.Cit.*

[56] Caio Rodrigues da Silva and Leonor Galvão de Botton, "Compulsory Pharmaceutical Patent Licensing in Brazil: The Controversy of Public Interest," *Pharmaceutical Patent Analyst* 2, no. 6 (November 2013): 1–3, https://doi.org/10.4155/ppa.13.63; Feldman, "Compulsory Licenses : The Dangers Behind the Current Practice."

[57] Vera Zolotaryova, "Are We There Yet ? Taking " TRIPS " to Brazil and Expanding Access to HIV / AIDS Medication," *Brooklyn Journal of International Law* 33, no. 3 (2008): 1099–1126, https://brooklynworks.brooklaw.edu/bjil/vol33/iss3/10.

precedent for the misuse of compulsory licensing by countries that could afford to pay, potentially affecting the introduction of new drugs in Brazil.[58]

Brazil has effectively used the threat of compulsory licensing as a negotiation tool with pharmaceutical companies, as seen in its negotiations with Gilead over the drug *tenofovir*. Gilead agreed to cut the price in half due to Brazil's strong negotiating position, backed by its status as the world's 12th largest economy. This economic power not only strengthens Brazil's bargaining power in the pharmaceutical sector but also enables it to withstand international pressure, including from the United States.[59] Additionally, Brazil leverages a combination of soft power strategies, emphasizing human rights, development, international solidarity, and strategic interests.[60]

However, Brazil experienced negative repercussions from its approach to compulsory licensing, including impacts on patent enforcement and the economy. These consequences led to a policy shift, with Brazil now avoiding the use of compulsory licensing for pharmaceuticals.[61]The country has not pursued any new compulsory licensing actions nor used it as leverage in negotiations since this change.[62]

India's experience with compulsory licensing differs to date.[63] The country has issued a compulsory license for the cancer drug *Sorafenib Tosylate (Nexavar)*, owned by Bayer, on March 12, 2012.[64] This decision allowed Natco Pharma to produce the drug, drastically reducing its price from $5,000 to $170 per month—a 97% cost reduction.[65] The Indian Patent Office approved this license because, under its laws, patents that are unaffordable and inaccessible to the public may be subject to compulsory licensing. In 2011, *Nexavar* was accessible to fewer than 200 Indians, affordable to only 2% of patients needing the drug, prompting the use of compulsory licensing to enhance access and affordability.[66]

A significant factor in Natco Pharma's favor was Bayer's argument that an alternative, cheaper version of *Nexavar*, produced by CIPLA, was already available in India.[67] Bayer was simultaneously suing CIPLA for patent infringement, which inadvertently strengthened the case for compulsory licensing. When Bayer challenged the compulsory licensing decision before the Indian Patent Appellate Board (IPAB), the IPAB upheld the decision but increased the royalty rate from 6% to 7%, aiming to ensure Bayer still benefited from its patent.[68]

The United States expressed strong concerns over India's compulsory licensing decision. The US Commerce Secretary, John Bryson, voiced worries about the weakening of India's

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[58] Jamie Feldman, *Loc.Cit*.
[59] Donald Harris, *Loc.Cit.*
[60] Matthew Flynn, "Brazilian Pharmaceutical Diplomacy: Social Democratic Principles versus Soft Power Interests," *International Journal of Health Services* 43, no. 1 (January 2013): 67–89, https://doi.org/10.2190/HS.43.1.f.
[61] Caio Rodrigues da Silva and Galvão de Botton, *Loc.Cit*."
[62] Medicines Law & Policy, "The TRIPS Flexibilities Database," Medicines Law & Policy, 2018, http://tripsflexibilities.medicineslawandpolicy.org/.
[63] Reuters Staff, "India Defends Right to Issue Drug 'Compulsory Licenses,'" Reuters, 2016, https://www.reuters.com/article/us-india-patents-usa-idUSKCN0WP0T4; Medicines Law & Policy, "The TRIPS Flexibilities Database."
[64] Mansi Sood, "Natco Pharma Ltd. v. Bayer Corporation and the Compulsory Licensing Regime in India," *NUJS Law Review* 6, no. 1 (2013): 99–119, http://nujslawreview.org/2016/12/02/natco-pharma-ltd-v-bayer-corporation-and-the-compulsory-licensing-regime-in-india/.
[65] Bela Gandhi, "India's Compulsory License Model: Increased Pharmaceutical Access and Innovation Coexist," *BYU Prelaw Review* 33, no. 5 (2019): 33–51, https://scholarsarchive.byu.edu/byuplr/vol33/iss1/5/.
[66] Gandhi, "India's Compulsory License Model: Increased Pharmaceutical Access and Innovation Coexist."
[67] Satish Saroha, Deepak Kaushik, and Arun Nanda, "Compulsory Licensing of Drug Products in Developing Countries." *Journal of Generic Medicines*: The Business Journal for the Generic Medicines Sector 12, no. 3-4, (2015). P. 89-94. https://doi.org/10.1177/1741134313503827.
[68] *Ibid*.

patent system. Subsequently, discussions in the US House of Representatives labeled India's actions as potentially violating the TRIPS Agreement. The situation escalated when, on February 21, 2013, the Global Intellectual Property Center (GIPC) placed India at the bottom of an intellectual property rights strength ranking. Further statements and lobbying intensified US dissatisfaction with Indian patent laws.[69]

The cases of Thailand, Brazil, and India illustrate both the benefits and challenges of compulsory licensing. While each country managed to increase the accessibility and affordability of medicines, they also faced criticism. Compulsory licensing was accused of serving industrial rather than humanitarian goals in Thailand, acting as a geopolitical tool in Brazil, and provoking retaliation from the United States in all three instances. Such actions can indeed place pressure on a country's economy. However, as India's situation shows, countries with strong patent systems and economic foundations can effectively utilize compulsory licensing for public benefit while mitigating negative repercussions.

b. Treaty Performance Regarding Compulsory Licensing Under TRIPS Agreement

After the Doha Declaration, interpreting the TRIPS Agreement in good faith means aligning with the objectives and principles outlined in Articles 7 and 8, with a special focus on Article 7 as embodying the principle of good faith.[70] This understanding of good faith has been elaborated in subsequent cases.

In the Russia-Transit case, it was determined that the General Agreement on Tariffs and Trade (GATT) 1994—and by extension, the TRIPS Agreement—defines acting in good faith as implementing measures that do not avoid treaty obligations.[71] The Saudi Arabia-Intellectual Property case serves as a clarification, where Saudi Arabia's refusal to allow criminal proceedings for intellectual property violations was seen as a circumvention of Article 61 of the TRIPS Agreement, thus breaching the principle of good faith.[72]

Furthermore, for an interpretation to be considered in good faith, it must be effective, meaning it should not render any parts of the treaty meaningless or redundant.[73] This principle, rooted in Article 31 of the Vienna Convention on the Law of Treaties (VCLT) 1969, insists that interpretation be based on the treaty's text. The United States-Section 211 appellate report exemplifies this by stating that relevant provisions must be factored into the interpretation to ensure it is practical.[74] Neglecting or misinterpreting TRIPS provisions suggests a lack of good faith, as demonstrated in the Canada-Pharmaceutical case.[75] Here, the Panel acknowledged the limitations imposed by Article 30 of TRIPS by Articles 7 and 8.1, marking one of the initial recognitions of the scope of Articles 7 and 8 in the TRIPS Agreement prior to the Doha Declaration.[76]

Third, the misuse of the principle of good faith through incorrect interpretation of the TRIPS Agreement must be avoided. Interpretations should not undermine the treaty obligations

[69] Médecins Sans Frontières, "A Timeline of US Attacks on India's Patent Law and Generic Competition" (Geneva, 2015), https://msfaccess.org/sites/default/files/2018-10/IP_Timeline_US pressure on India_Sep 2014_0.pdf.

[70] Alison Slade, "Good Faith and the TRIPS Agreement: Putting Flesh on the Bones of the TRIPS 'Objectives.'" *International and Comparative Law Quarterly* 63, no. 2(2014), pp. 35-83.

[71] Stephanie Hartmann, "Russia – Measures Concerning Traffic in Transit (WTO)," *International Legal Materials* 58, no. 5 (October 2019): 899–1027, https://doi.org/10.1017/ilm.2019.40.

[72] WTO Panel, Saudi Arabia – Measures Concerning the Protection of Intellectual Property Rights (2018).

[73] WTO Appellate Body, Japan - Taxes on Alcoholic Beverages (1996).

[74] *Ibid*.

[75] Alison Slade, *Op.Cit.* p. 4.

[76] World Trade Organization, "Canada - Patent Protection of Pharmaceutical Products (WT/DS114) Report of the Panel," in *Dispute Settlement Reports 2000* (Cambridge: Cambridge University Press, 2002), 2289–2582, https://doi.org/10.1017/9781108378840.002.

or diminish the rights of other members.[77]This principle was underscored in the US-Shrimp case, illustrating that the abuse of rights could invalidate the treaty rights of others. Consequently, the verdict in the US-Shrimp case established that Article 7 objectives serve as a mechanism for balancing the rights and obligations under the TRIPS Agreement.[78]

Fourth, the principle of legitimate expectations is paramount. The India-Patents case highlighted the expectation of protection concerning security and predictability within the multilateral trading system. However, India's failure to fulfill this expectation, due to the inadequacies of its mailbox system in ensuring equal competition between foreign and domestic enterprises, underscored a crucial aspect.[79] This ruling emphasized the TRIPS Agreement's recognition of the legitimate expectation for market access and reciprocal trade benefits as integral to good faith compliance.[80]

From these cases, four key elements of good faith in the context of the TRIPS Agreement emerge: (1) Actions or interpretations must not bypass treaty obligations; (2) Actions or interpretations must effectively respect and incorporate other relevant clauses; (3) Interpretations or actions should not constitute abuse, in the sense of diminishing the treaty rights of other members; (4) Interpretations and actions must safeguard equal competition between foreign and domestic entities.

The debate surrounding compulsory licensing, especially under Article 31 of the TRIPS Agreement, has led to varied legal interpretations concerning its scope. Notably, Article 31 lacks specific provisions to prevent retaliatory actions against weaker states for utilizing compulsory licensing, which has occasionally turned compulsory licensing into a tool of coercion to negotiate better drug prices. This section aims to assess whether Thailand, Brazil, India, and the United States have adhered to the principles of *pacta sunt servanda* and good faith in accordance with the TRIPS Agreement.

Article 26 of the Vienna Convention on the Law of Treaties (VCLT) integrates the ancient principle of pacta sunt servanda from private law into treaty law, which signifies that agreements must be honored. This principle is encapsulated in the statement, "Every treaty in force is binding upon the parties to it and must be performed by them in good faith," from which five key elements can be discerned: (1) Applicability to every treaty; (2) The treaty's legal force; (3) Binding legal obligation; (4) The duty of performance; and (5) Adherence to compliance.[81]

His analysis begins with Thailand's approach to compulsory licensing and its commitment to performing in good faith. The situation in Thailand presents a complex picture. On one hand, the Government Pharmaceutical Organization's (GPO) monopoly and profit-driven motives raise questions about the genuine intent behind compulsory licensing, especially since Thailand restricts procurement contracts for the private pharmaceutical sector, arguing that government control ensures broader access. However, one could argue that the GPO's exclusive production circumvents distribution issues present within the private pharmaceutical sector and that profits from the GPO support public health initiatives, aligning with the public non-commercial purposes clause. Regarding the faithful interpretation and application of the TRIPS Agreement,

[77] World Trade Organization Appellate Body, "United States - Import Prohibition of Certain Shrimp and Shrimp Products (WT/DS58): Report of the Appellate Body," in *Dispute Settlement Reports 1998*, ed. World Trade Organization (Cambridge: Cambridge University Press, 2001), 2755–2820, https://doi.org/10.1017/9781108378703.001.

[78] Alison Slade, *Loc.Cit.*

[79] World Trade Organization, "India - Patent Protection for Pharmaceutical and Agricultural Chemical Products (WT/DS79/R): Report of the Panel," in *Dispute Settlement Reports 1998* (Cambridge: Cambridge University Press, 2001), 2661–2752, https://doi.org/10.1017/9781108378697.002.

[80] Alison Slade, *Loc.Cit.*

[81] Oliver Dörr and Kirsten Schmalenbach, "Article 26 Pacta Sunt Servanda," in *Vienna Convention on the Law of Treaties: A Commentary*, ed. Oliver Dörr and Kirsten Schmalenbach (Berlin, Heidelberg: Springer Berlin Heidelberg, 2012), 1–1423, https://doi.org/10.1007/978-3-642-19291-3.

Thailand's actions appear to be in compliance. Specifically, Thailand has adhered to Article 31(b) regarding the public non-commercial use clause by duly notifying the patent holders, a fact undisputed by both Abbott and Merck. Furthermore, there have been no complaints from these patent holders regarding adequate remuneration, reinforcing Thailand's compliance with its treaty obligations and commitment to acting in good faith.

In understanding the TRIPS Agreement's objectives and principles, Article 7 "Objectives" and Article 8 "Principles" play pivotal roles, further emphasized by the Doha Declaration's Article 5(a). This provision mandates that all TRIPS Agreement provisions be interpreted in light of the treaty's objectives and principles, particularly highlighting public health as a legitimate concern within the TRIPS framework.[82] Thus, interpreting the Agreement without considering these elements would be incomplete and potentially misleading.

Article 7 seeks a balance between the rights of producers and the needs of consumers, aiming to foster innovation and social and economic development while mitigating the negative impacts of intellectual property protection.[83] Article 8.1 empowers member states to enact measures safeguarding public health and interest, allowing for modifying laws and regulations in alignment with the Agreement. Article 8.2 aims to prevent the misuse of intellectual property rights that could unduly restrict trade or adversely affect international commerce.[84]

The contention around Thailand's application of compulsory licensing, as it relates to Article 7 of the TRIPS Agreement, encapsulates a nuanced debate. On one side, critics argue that Thailand, under military governance, which significantly increased defense spending, might have explored alternatives to mitigate the impact on patent holders despite its substantial economy.[85] The concerns are compounded by issues surrounding the Government Pharmaceutical Organization's (GPO) corruption and failure to meet WHO standards, questioning the efficacy and ethics of bypassing patents. However, the context that Thailand's pharmaceutical sector represented less than 0.5% of the global market suggests a minimal impact on patent holders, juxtaposing the urgent public health needs against the strictures of intellectual property rights.[86] This scenario underlines the intricate balance the TRIPS Agreement seeks between fostering innovation and ensuring public health, particularly in crises, framing Thailand's use of compulsory licensing within a broader debate of necessity versus potential abuse of patent holders' rights.

Thailand has laws for compulsory licensing in its Patent Act, specifically Section 51, which allows it to issue licenses for important public services or to address national needs without violating trade practices "service for public consumption or which is of vital importance to the defense of the country, or for the preservation or realization of natural resources or the environment, or to prevent or relieve a severe shortage of food, drugs, or other consumption items, or for any other public service.[87] This has been applied without international complaints,

[82] Alice Maxwell, "Plainly Justifiable? The World Trade Organization's Ruling on the Validity of Australia's 'Plain Packaging' Under Article 20 of the TRIPS Agreement," *Asian Journal of WTO & International Health Law & Policy* 14, no. 1 (2019): 115–45, https://doi.org/10.2139/ssrn.3363052.

[83] Alison Slade, "The Objectives and Principles of the WTO TRIPS Agreement: A Detailed Anatomy," *Osgoode Hall Law Journal* 53, no. 3 (2016): 1–59, https://ssrn.com/abstract=2781664.

[84] Antony Taubman, Hannu Wager, and Jayashree Watal, eds., "Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) (as Amended on 23 January 2017)," in *A Handbook on the WTO TRIPS Agreement* (Cambridge University Press, 2020), 295–337, https://doi.org/10.1017/9781108883511.015.

[85] A military junta is a government led by a committee of military leaders.

[86] Cynthia Ho, "Unveiling Competing Patent Perspectives," *Houston Law Review* 46, no. 4 (2009): 1047–1114, https://houstonlawreview.org/article/4270-unveiling-competing-patent-perspectives; Lybecker and Fowler, "Compulsory Licensing in Canada and Thailand: Comparing Regimes to Ensure Legitimate Use of the WTO Rules"; Shahnawaz, "The Optimal Timing of Compulsory Licensing: A Story of Thailand's Winter of Discontent."

[87] Sakda Thanitcul and Matthew Lim Braslow, "Compulsory Licensing of Chronic Disease Pharmaceuticals in Thailand," *Thai Journal of Pharmaceutical Sciences* 37, no. 2 (2013): 61–83,

particularly due to the high number of HIV patients in the country, demonstrating Thailand's commitment to meeting its people's health needs while respecting international norms.

Brazil's approach to compulsory licensing significantly differs from Thailand's, primarily using the threat of licensing as a tool in price negotiations with patent holders. HIV/AIDS crisis in Brazil from 2002 to 2011 severely impacted the nation, with approximately 530,000 people infected, 253,706 deaths, and an incidence rate of 20.2 cases per 100,000 people, highlighting the country's public health emergency. In a strategic move against the United States, stemming from a dispute over cotton subsidies, Brazil implemented Provisional Measure 482/2010 on February 10, 2010. This measure, aimed at intellectual property rights, served as retaliation within the World Trade Organization's Dispute Settlement Understanding (WTO DSU) framework. Brazil's action here mirrors a strategy later employed by Russia in the Russia-Transit case, with both countries carefully ensuring their measures did not violate treaty obligations.[88]

Whether the pressures of compulsory licensing can be utilized to coerce patent holders into reducing their negotiation prices brings to light the duty of good faith in treaty performance. Brazil possesses greater leverage and purchasing power as the world's 12th largest economy in compulsory licensing than Thailand. Despite this, Brazil negotiated with patent holders, a step not mandated by Article 31(b) of the TRIPS Agreement for public non-commercial use. In contrast to Thailand, Brazil initiated negotiations with patent holders in a sincere effort, indicating both parties' willingness to negotiate prices.[89] This approach by Brazil exemplifies an act of good faith in domestic performance. It extends to good faith in interpreting the TRIPS Agreement, as neither party has accused the other of unreasonable interpretations. By voluntarily adhering to Article 31(b) of the TRIPS Agreement as a precautionary measure, Brazil demonstrates its commitment to respecting relevant legal provisions.

Regarding the obligation not to undermine the object and purpose of a treaty, one could contend that Brazil ought not to exploit the threat of compulsory licensing as a bargaining tool despite the efficacy of such a strategy in yielding results. Nonetheless, one must question whether Brazil would have secured similarly advantageous terms and effectively addressed the HIV pandemic had it adopted a more conciliatory strategy. Given Brazil's economic stature and its different domestic conditions compared to Thailand, it is conceivable that Brazil's use of compulsory licensing threats in negotiations could be interpreted as an abuse of rights.

Yet, there has been no decisive criticism regarding Brazil's ability to strike a balance between the rights of patent holders and the accessibility of medicines for consumers. Brazil has experienced economic and patent enforcement repercussions as a result of its policies, and it has shown restraint in resorting to compulsory licensing as a negotiating tool subsequently. Moreover, Brazil has established a legal framework for compulsory licensing through Law No. 9.279 of May 14, 1996, amended in 2001 (Law on Industrial Property), specifically addressing pharmaceutical products. This legal basis underscores Brazil's adherence to the objectives and principles of the TRIPS Agreement, thereby fulfilling its duty not to frustrate the treaty's purpose.[90] Given the absence of complaints from patent holders regarding this legislation, Brazil has met legitimate expectations of fostering fair competition.

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https://www.researchgate.net/publication/289551723_Compulsory_licensing_of_chronic_disease_pharmaceuticals_in_Thailand.

[88] Stephanie Hartmann, "Russia – Measures Concerning Traffic in Transit (WTO)," *International Legal Materials* 58, no. 5 (October 2019): 899–1027, https://doi.org/10.1017/ilm.2019.40.

[89] Hilary Wong, "The Case for Compulsory Licensing during COVID-19," *Journal of Global Health* 10, no. 1 (June 2020): 1–5, https://doi.org/10.7189/jogh.10.010358.

[90] Viviane Yumy Mitsuuchi Kunisawa, "Analyzing the Brazil Case," in *The TRIPS Agreement Implementation in Brazil*, ed. Christoph Ann et al., 1st ed. (Baden-Baden: Nomos Verlagsgesellschaft mbH, 2015), 151–78.

In the context of India, the country's adherence to the principles of good faith in both treaty performance and interpretation is unequivocal. This is evidenced by the stringent nature of Indian patent courts and the robust intellectual property regime embedded within India's domestic patent legislation. The necessity of the treaty's objectives and purposes is further underscored by the historically limited access to cancer medications in India, where only 2% of the population can afford them. Additionally, the process for obtaining compulsory licensing in India is notably rigorous, as demonstrated by the duration required to reach a final decision in the case of Bayer, from 2011 to 2013. The increased royalty rate of 7%, as determined by the IPAB, further attests to India's balanced approach in this matter.

India ensures a fair entitlement to royalties for patent holders, promoting equitable competition between domestic and foreign enterprises. The uniform access to compulsory licensing remedies for domestic and foreign entities aligns with India's commitment to good faith under the TRIPS Agreement provisions. India's approach, characterized by adherence to treaty obligations without circumventing, neglecting, or misrepresenting relevant clauses or engaging in actions that degrade other members' treaty rights, exemplifies its commitment to the principles of the TRIPS Agreement.

Turning to the actions of the United States, it could be contended that its pressure tactics on countries implementing compulsory licensing contradict the obligations to perform under the TRIPS Agreement in good faith. Specifically, the United States has employed aggressive measures against Thailand, Brazil, and India, actions which are at odds with Article 23 of Annex 2 of the TRIPS Agreement. According to this provision, the United States would be expected to pursue claims against such parties through formal dispute mechanisms rather than resorting to unilateral reprisals deemed inappropriate in compulsory licensing.[91] Regarding the interpretation of the TRIPS Agreement, the United States has not been accused of asserting baseless or unreasonable interpretations; therefore, this aspect remains unchallenged.

Concerning the objectives and purposes of the TRIPS Agreement, the retaliatory measures employed by the United States do not fully embody the spirit of Article 7. Such actions undermine the ability and legitimacy of foreign governments to devise pharmaceutical policies that strike a balance between the interests of patent holders and consumers. Nonetheless, it might be argued that the United States seeks to protect patent holders from potential abuse under Article 8.2 of the TRIPS Agreement despite the questionable nature of its methods.

In the context of treaty performance, as interpreted by the Vienna Convention on the Law of Treaties (VCLT) 1969, Thailand, Brazil, and the United States' actions reveal instances of non-compliance with the principles of good faith. This observation suggests that similar challenges may arise, particularly with the entry of patented COVID-19 drugs into the pharmaceutical market.[92]

3. Possible International and Local Remedies Against Compulsory Licensing

a. International Remedies

In prior instances, patent owners have contested compulsory licensing through various means. This analysis will outline the strategies patent holders have for seeking international remedies, beginning with litigation before exploring alternative avenues. Beyond the Dispute Settlement Understanding (DSU) framework, multinational patent owners often favor international investment arbitration via bilateral investment treaties. This preference exploits a

[91] Jerome H. Reichman, "Comment: Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options.," *The Journal of Law, Medicine & Ethics : A Journal of the American Society of Law, Medicine & Ethics* 37, no. 2 (January 2009): 247–63, https://doi.org/10.1111/j.1748-720X.2009.00369.x."

[92] Hilary Wong, "The Case for Compulsory Licensing during COVID-19," *Journal of Global Health* 10, no. 1 (June 2020): 1–5, https://doi.org/10.7189/jogh.10.010358.

loophole where the DSU lacks exclusive jurisdiction over disputes involving states and non-state actors, leaving a gap for arbitration. Moreover, the potential of international investment arbitration to deter governments from issuing compulsory licenses due to the threat of substantial compensation claims through the Investor-State Dispute Settlement (ISDS) mechanism is notable.[93]

To date, compulsory licensing disputes have not seen a resolution within international forums, at least in publicly known cases. Notable instances such as Brazil — Patent Protection (2001) and Argentina — Certain Measures on the Protection of Patents and Test Data (2002) were resolved through mutual agreement rather than formal proceedings.[94] The ISDS mechanism's applicability, however, presents a contrasting scenario.

Certain Investment Agreements (IAs), including the India-Singapore Free Trade Agreement (FTA) and the Australia-Uruguay Bilateral Investment Treaty (BIT), explicitly exempt compulsory licensing from being considered expropriation. Nevertheless, investors can challenge compulsory licensing by invoking the Fair and Equitable Treatment (FET) clause or the national treatment clause, alleging that compulsory licensing decisions were based on unstable regulations prompted by COVID-19 trends,[95] or that they disproportionately target foreign companies.[96]Additionally, the ISDS mechanism could be leveraged to pressure states into opposing compulsory licensing, a tactic fraught with ethical considerations.[97]

On the non-litigation front, patent holders may utilize the flag state mechanism, such as the U.S. Trade Representative (USTR) Section 301 Report, which assesses the intellectual property regimes of the United States' trade partners and categorizes problematic jurisdictions into watch lists.[98] Countries designated as "Priority Foreign Country" may face sanctions initiated by the USTR, a controversial approach under Article 23.2 of Annex 2.[99] This strategy primarily impacts economically weaker nations and offers limited consolation due to the lack of guaranteed compensation. Another non-litigation strategy involves pursuing settlements after initiating WTO DSU proceedings, as seen in the Brazil and Argentina cases, where the threat of litigation encouraged parties to seek a negotiated settlement rather than proceed with formal legal action.

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[93] Katarzyna Kaszubska, "Compulsory Licensing under India's New Model Bilateral Investment Treaty," *Review of Market Integration* 9, no. 3 (December 2017): 139–54, https://doi.org/10.1177/0974929217744466.

[94] Emmanuel Kolawole Oke, "The Incorporation of a Right to Health Perspective into Brazil's Patent Law Reform Process," in *Law and Policy in Latin America*, ed. Pedro Fortes et al. (London: Palgrave Macmillan UK, 2017), 311–26, https://doi.org/10.1057/978-1-137-56694-2; Letícia Frazão Leme, "Flexibilities Under Article 39.3 of the TRIPS Agreement: Protection of Pharmaceutical Test Data and the Case of Brazil," in *The WTO Dispute Settlement Mechanism*, ed. Alberto do Amaral Júnior, Luciana Maria de Oliveira Sá Pires, and Cristiane Lucena Carneiro (Cham: Springer International Publishing, 2019), 339–55, https://doi.org/10.1007/978-3-030-03263-0_22.

[95] Federico Ortino, "The Obligation of Regulatory Stability in the Fair and Equitable Treatment Standard: How Far Have We Come?," *Journal of International Economic Law* 21, no. 4 (December 2018): 845–65, https://doi.org/10.1093/jiel/jgy039.

[96] Yamashita Tomoko, "Procedural and Normative Competition between the WTO's Dispute Settlement and the Investor-State Arbitration: Focusing on the National," *Public Policy Review* 16, no. 5 (2020): 1–23, https://www.mof.go.jp/english/pri/publication/pp_review/ppr16_05_09.pdf.

[97] Public Eye, "Compulsory Licensing in Colombia: Leaked Documents Show Aggressive Lobbying by Novartis," Public Eye, 2017, https://www.publiceye.ch/en/media-corner/press-releases/detail/compulsory-licensing-in-colombia-leaked-documents-show-aggressive-lobbying-by-novartis.

[98] Aswathy Asok, "Compulsory Licensing for Public Health and Usa's Special 301 Pressure: An Indian Experience," *Journal of Intellectual Property Rights* 24, no. 5–6 (2019): 125–31, http://nopr.niscair.res.in/handle/123456789/54321.

[99] Reichman, "Comment: Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options."; Asok, "Compulsory Licensing for Public Health and Usa's Special 301 Pressure: An Indian Experience."

b. Domestic Remedies

This section discusses how parties challenge compulsory licensing of patents domestically, focusing on legal and negotiation strategies. It highlights the constitutional review as a potential avenue for affected patent holders to seek redress, primarily through post-implementation review.

A key initial strategy to counteract compulsory licensing involves preventing it through negotiations between patent holders and either governments or generic manufacturers, like Natco in India. While negotiations are not mandatory for public health emergencies or other public non-commercial uses under TRIPS Agreement Article 31(b),[100] the outcome often depends on the negotiating power of the country involved. These negotiations can lead to voluntary licensing agreements, avoiding compulsory licensing,[101] which has had mixed outcomes for countries like Thailand, Brazil, and India.

If negotiations fail, patent owners can challenge the compulsory licensing decision in domestic courts. However, the success of such legal challenges varies depending on the country's specific patent laws. For example, Thailand's Patent Act (Patent Act BE 2522, sections 50 and 51) does not permit patent holders to oppose government-initiated compulsory licensing for public non-commercial use directly. Instead, patent owners can only appeal the terms of the compulsory license, including royalty rates.[102]

Brazil's approach to compulsory licensing is outlined in the Law on Industrial Property (Law No. 9.279 of May 14, 1996, as amended in 2001), specifically in Section III, Articles 68-74.[103] Under this law, a patent holder has the right to challenge a compulsory licensing application filed by a generic manufacturer within sixty days of its publication by the National Institute of Industrial Property (INPI).[104] If a compulsory license is granted, the patent holder can appeal under Article 73(7), although such an appeal does not halt the implementation of the compulsory licensing decision.[105] Further appeals can be made to the Brazil Federal Trial Court, and potentially to the Federal Supreme Court.[106]

India's compulsory licensing regime is notably rigorous, as illustrated by the Bayer case. India manages patent disputes initially through the Controller and then through the Intellectual Property Appellate Board (IPAB) for appeals. Unlike Thailand, India allows patent holders to contest compulsory licensing decisions. The IPAB has been observed to offer a more balanced approach towards patent holders, evidenced by its decision to award Bayer additional royalties, ensuring a reasonable benefit from the compulsory licensing.[107]

Beyond patent or regular court litigation, there exists a theoretical option to challenge compulsory licensing through the constitutional court via ex-post treaty review. This process involves reviewing the constitutionality of a treaty provision against the state constitution after

[100] Taubman, Wager, and Watal, *Loc.Cit.*

[101] Bryony Simmons, Graham S. Cooke, and Marisa Miraldo, "Effect of Voluntary Licences for Hepatitis C Medicines on Access to Treatment: A Difference-in-Differences Analysis," *The Lancet Global Health* 7, no. 9 (2019): 1189–96, https://doi.org/10.1016/S2214-109X(19)30266-9.

[102] Jakkrit Kuanpoth, "Compulsory Licences: Law and Practice in Thailand," in *Compulsory Licensing Practical Experiences and Ways Forward*, ed. Reto M. Hilty and Kung-Chung Liu (Berlin: Springer Berlin Heidelberg, 2015), 61–77, https://doi.org/10.1007/978-3-642-54704-1_4.

[103] Milton Lucídio Leão Barcellos, "Compulsory License in Brazil: Competition Tool or Just a Threat?," *Revista de Propriedade Intelectual - Direito Constitucional e Contemporâneo* 10, no. 3 (October 2016): 141–52, https://doi.org/10.16928/2316-8080.V10N3p.141-152.

[104] Caio Rodrigues da Silva and Leonor Galvão de Botton, *Loc.Cit.*

[105] Licks Attorneys, "Brazilian Patent Statute and Selected Patent Prosecution Rules" (2016), http://static.lickslegal.com/pdf/Licks Attorneys - Brazil - Selected Patent Prosecution Rules.pdf?x54306.

[106] Viviane Yumy Mitsuuchi Kunisawa, *Loc.Cit.*

[107] Mansi Sood, *Loc.Cit.*

the treaty has been signed.[108] Patent holders might argue that a specific interpretation of the TRIPS Agreement, which requires the issuance of a compulsory license, contradicts the state's constitutional provisions.

Indonesia's Constitutional Court reviewed the ASEAN Charter's constitutionality in Decision No. 33/PUU-IX/2011, following its incorporation into national law via Law No. 38/2008 on the Ratification of the ASEAN Charter. This provided a basis for the Court's authority to examine the Charter. The Court justified its review on the grounds of Indonesia's sovereignty, emphasizing the nation's autonomy in entering and exiting treaties and the right to review its international treaty commitments.[109]

The Court's decision affirmed the ASEAN Charter's alignment with the Indonesian constitution. However, had the Court found otherwise, there were two potential responses: a weak-form review or a strong-form review. A weak-form review, which is legally non-binding, would declare the Charter unconstitutional and leave the issue for the current government to address without legal obligations. A strong-form review would legally mandate the government to renegotiate the treaty or withdraw from it entirely to align with the Court's findings.[110] However, Indonesia lacks explicit legal provisions for compelling the executive to renegotiate or exit treaties, making a weak-form outcome more likely in cases of nonconformity.

Other countries, like Germany, Hungary, and Italy, also have mechanisms for conducting constitutional reviews of treaties,[111] presenting an underutilized avenue for patent holders to challenge compulsory licensing. However, the effectiveness of this strategy varies by country, and it may not guarantee compensation if the compulsory licensing decision remains unaffected during the review process. Consequently, constitutional review could influence future compulsory licensing endeavors rather than those currently under examination.

C. Conclusion

The issue of compulsory licensing has become particularly critical during the COVID-19 pandemic for humanitarian reasons. It is anticipated that pharmaceutical patents for effective COVID-19 treatments might be subjected to compulsory licensing. However, past instances of compulsory licensing reveal that not every country adheres strictly to the TRIPS (Trade-Related Aspects of Intellectual Property Rights) Agreement. Furthermore, under the Vienna Convention on the Law of Treaties (VCLT) of 1969, initiating compulsory licensing could potentially provoke backlash from the patent holder's country, despite a more humanitarian interpretation of the TRIPS Agreement since the Doha Declaration.

The discussion highlights four key principles necessary for implementing the TRIPS Agreement faithfully: (1) Any measures or interpretations must not bypass treaty obligations; (2) They must be effective, acknowledging and giving due weight to other relevant clauses; (3) They should not be abusive or diminish the treaty rights of other member states; (4) They must promote fair competition between foreign and domestic companies.

Consequently, patent holders are required to have access to remedies against compulsory licensing. These remedies can be sought through both international and domestic channels. Internationally, the Dispute Settlement Understanding (DSU) mechanism is often preferred for

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resolving disputes related to compulsory licensing. However, states frequently use it to compel a negotiated settlement rather than pursue a resolution through DSU proceedings. Therefore, assessments of good faith in applying and interpreting the TRIPS Agreement concerning compulsory licensing often rely on decisions that are only loosely relevant. The same approach is adopted in Investor-State Dispute Settlement (ISDS) proceedings. Alternatively, patent holders can negotiate with countries that enact compulsory licensing or leverage mechanisms like the USTR Section 301, especially if the United States is the patent holder's country. A significant challenge of international litigation, however, is its high cost. As a result, parties involved in compulsory licensing disputes generally prefer negotiation.

In domestic scenarios, plaintiffs seeking remedies for patent issues typically file lawsuits, effective in countries with strong patent laws. Before moving to litigation, parties often try to negotiate, aiming for a voluntary licensing agreement that gives the patent holder more control, unlike compulsory licensing, where the state sets the price.

However, the idea of using constitutional review to examine treaties related to compulsory licensing remains largely unexplored. This approach is expected to gain relevance following the development of effective COVID-19 treatments but is currently theoretical. There's a clear need to improve the compulsory licensing framework within countries. Engaging in constitutional treaty reviews could bridge the gap between constitutional and international law, especially in intellectual property rights.

India shows the importance of having a strong patent system as it managed to avoid significant backlash from the United States over its patent policies, thanks to its robust legal framework for patents and economic strength. This situation contrasts with the experiences of Brazil and Thailand, illustrating that a solid patent regime not only prevents retaliation but also boosts foreign investors' confidence, even when their interests are challenged. This lesson is crucial for other countries, including Indonesia.

This research is limited as it mainly considers the United States to be the patent holder's country. Future studies should examine compulsory licensing cases involving patent holders from other powerful countries to understand the dynamics at playfully.

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