WTO Law and Prices of Pharmaceutical Products: Rule of Law Gaps and the Unclear Balance between Trade Protection, Human Rights, and IP Protection

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Abstract

Price of medicine is subject to discussions from ethical, legal, political, and economic perspectives. This Article takes a rule of law perspective. Rule of law gaps in political systems cause legal uncertainties for investors and increase transaction costs for pharmaceutical producers. That can cause prices of pharmaceutical products to go up. This Article discusses rule of law gaps in World Trade Organization ("WTO") law. First, this Article provides a brief discussion of the conceptual challenges with the rule of law, in particular when it is applied at international level. Next, it highlights rule of law problems for pharmaceutical producers concerning access to justice and administration of WTO law. This Article gives examples of unclear law in the relationship between the Trade-Related Aspects of Intellectual Property Rights ("TRIPS") and competition law; between health protection and TRIPS; and between WTO law and human rights.

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I. INTRODUCTION

Access to medicine is a human right and is derived from Art. 12.1 of the International Covenant on Economic, Social and Cultural Rights ("ICESCR"):

"The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health."

Access to medicine and health are fundamental rights in public international law. However, even though the ICESCR imposes obligations on states to provide the means to achieve the highest attainable standard of health, there is an economic reality of high prices of pharmaceutical products. High prices are subject to discussions from legal, political, ethical, and economic perspectives, and some states interfere into the market by regulating prices of medicine. With only a few exceptions, companies have no direct liability under public international law.[1] However, they have *moral* responsibilities and accountabilities concerning human rights. Some pharmaceutical companies create legal and moral expectations through their corporate social responsibilities ("CSR"). For example, by following the UN Global Compact and the Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines.[2] On top of national regulation and pharmaceutical companies' CSRs is the regulation of international trade and intellectual property ("IP") rights in the World Trade Organization ("WTO"). This Article engages in the pricing debate with a focus on WTO law and the rule of law.

WTO law is part of public international law. It aims to reduce tariffs and eliminate trade barriers, which is materialized in the principles of non-discrimination; *Most Favored Nation* ("MFN"), i.e. states must not discriminate between their trading partners; and *National treatment* ("NT"), i.e. states must not discriminate between national and foreign producers and their products once the product has crossed the custom zone. The other WTO principles of law are *market access*, *transparency*, and *fair trade on the markets*. Some WTO Members have eliminated tariffs on pharmaceutical products in the Pharmaceutical Tariff Elimination Agreement, but it is not a global elimination of such tariffs.[3]

Multilevel rule of law gaps cause legal uncertainties that can generate higher prices of pharmaceutical products. That is not to suggest that companies have a *moral right* to raise the prices. Although ethical questions concerning the

1. *See e.g.*, International Convention on Civil Liability for Oil Pollution Damage (1969); UN Convention on the Law of the Sea, 71 (1982).

2. U.N. Secretary-General, *Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health*, ¶ 25, U.N. Doc. A/63/263, 2, 7 (Aug. 11, 2008).

3. Sir Robert Atkins, *Subject: The Pharmaceutical Tariff Elimination Agreement (Zero for Zero)* (Jan. 21, 2004), http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+WQ+E-2004-0213+0+DOC+XML+V0//EN&language=bg (on file with *The University of the Pacific Law Review*).

problem with access to medicine in developing countries are politically vital and need legal attention,[4] they are outside the scope of this Article.[5] Rather, rule of law gaps provide a legitimate basis for economic considerations related to the risks associated with unclear law, problems of enforcement, cross-sectorial problems, lack of due process, etc. Furthermore, rule of law gaps give openings to higher prices beyond the law through corrupt practices. This Article will illustrate some rule of law gaps concerning access to justice and administration of law. However, this Article will also show that political interference and case law have reduced some rule of law gaps.

II. MARKETS AND THE INTERNATIONAL RULE OF LAW

This part concerns the concept of the rule of law and its relevance in an economic context. It will also identify some of the challenges when the rule of law is applied in an international context.

A. Introduction: Overall Rule of Law Elements

A society based on the rule of law implies that all actors, public and private must comply with the law. The law is supreme and no legal or physical person is above the law. However, that does not imply that there is no space for political decisions. For example, all statutory acts have underlying policies behind them. Nevertheless, constitutional law provides *procedures* for turning the policies into law. The concept of the rule of law has transplanted beyond a national level into international law. Thus, an overall definition encompasses not only national governments, but also states and international organizations, which have a mandate, *de jure* or *de facto*, to administer and enforce the law. However, importing the rule of law into international legal and political systems is not without challenges, which this Article addresses below.

The concept of the rule of law is subject to discussions about content and values. The divide is usually between the rule of law as formal or substantive.[6] The formal version, which claims to be value-neutral, provides a political-legal infrastructure of elements that are required to ensure the law's supremacy. According to Raz, who is a proponent of a formal rule of law, the elements of the

4. *See generally Communities at the Centre: Defending Rights, Breaking Barriers, and Reaching People with HIV Services*, GLOBAL AIDS UPDATE 2019, 2–307 (2019), *available at* https://www.unaids.org/sites/default/files/media_asset/2019-global-AIDS-update_en.pdf (on file with *The University of the Pacific Law Review*).

5. *See e.g.*, Göran Collste, *Specifying Rights: the Case of TRIPS*, 4 (1) PUBLIC HEALTH ETHICS, 63 (2011).

6. Paul Craig, *Formal and Substantive Conceptions of the Rule of Law: An Analytical Framework,* Autumn, PUBLIC LAW 467, 467 (1997); Randall Peerenboom, *Varieties of Rule of Law: An Introduction and Provisional Conclusion, in* ASIAN DISCOURSES OF RULE OF LAW: THEORIES AND IMPLEMENTATION OF RULE OF LAW IN TWELVE ASIAN COUNTRIES, FRANCE AND THE U.S., 2–3 (Randall Peerenboom ed., 2004) (distinguishing between *thin* and *thick* versions of the rule of law).

rule of law are: All laws should be prospective, open, and clear; laws should be relatively stable; the making of particular laws (particular legal orders) should be guided by open, stable, clear, and general rules; the independence of the judiciary must be guaranteed; the principles of due process must be observed; the courts should have review powers over the implementation of the other principles; the courts should be easily accessible; and, the discretion of the crime-preventing agencies should not be allowed to pervert the law.[7]

The list of formal elements are non-exhaustive and there is no claim of specific weight between the elements. The substantive versions of the rule of law generally accept the formal elements. The difference is that the substantive versions include value-oriented elements, like human rights and democracy. The law is not legitimate if it violates these values. Thus, a substantive rule of law evaluates the law. For example, Rawls' rule of law has its base in liberal values, where a rule of law cannot be successful in an authoritarian society.[8] It is not the aim to engage in a discussion between different conceptions and value discussions of the rule of law. As this writer has argued elsewhere, the rule of law has a normative function. Some inherent values, including some human rights, compose the rule of law and offer the following: a system of *transparency* in the political, legal and judicial procedures; protection of all private and public agents by offering *access to justice*;[9] and, it ensures *equality* between all members and institutions of society in the legal procedures.[10]

B. Rule of Law and Economics

If a rule of law serves economic aims, i.e. efficiency on the market,[11] it is not value neutral as it assesses the legal and political institutions' ability to provide efficient markets. Although it is a substantive rule of law, it seems too narrow to confine the rule of law to solely economic aims; the rule of law should mainly aim at protecting citizens, et cetera against governmental and/or private abuses of the law, regardless of the law's economic relevance. However, using the rule of law in an economic context can illustrate its relevance for economic behavior. For example, Hoff and Stiglitz use a rule of law which provides "well-defined and enforced property rights, broad access to those rights, and predictable rules,

7. JOSEPH RAZ, THE RULE OF LAW AND ITS VIRTUE (1977), *reprinted in* THE AUTHORITY OF LAW: ESSAYS ON LAW AND MORALITY, 210, 214–218 (Oxford University Press, 2d ed. 2009).

8. JOHN RAWLS, A THEORY OF JUSTICE (The Belknap Press of Harvard University Press, Revised ed., 1999).

9. For example, the public is protected against multinational enterprises abuses or corrupt practices.

10. Henrik Andersen, *India – Solar Cells and Mexico – Taxes on Soft Drinks: Multilevel Rule of Law Challenges in the Interpretation of Art. XX (d) of GATT 1994 in WTO Case Law*, 10 INDIAN J. INT'L ECON. L. 60, 64 (2019).

11. *See e.g.*, FRIEDRICH A. HAYEK, THE ROAD TO SERFDOM, 112 (Bruce Caldwell ed., University of Chicago Press 2007). The use of Hayek is also a choice of a rule of law in a liberal and market-based system with only limited governmental interference.

uniformly enforced, for resolving property rights disputes"[12] in their model economy with agents controlling the rights over their enterprises. Hoff and Stiglitz demonstrate that—in post-socialist states—there would be demand for rule of law by beneficiaries of privatization to protect their contract rights. With the exception of asset strippers and criminals, the rule of law is necessary to protect contract rights of investors, property rights, and to handle issues of money laundering.[13]

According to Haggard and Tiede, economic literature on the rule of law divides it into 4 categories: 1) *The rule of law and security of persons*; personal insecurity in civil wars or in systems with high level of crimes have a negative economic impact; 2) *The rule of law and contract and property rights*; strong property rights protection and contract enforcement correlate with better long-run economic performance; 3) *The rule of law and institutional balance;* judicial independence is necessary to secure contract and property rights. There is correlation between institutional checks on governments and economic growth; and, 4) *The rule of law and corruption;* prices will rise as lack of confidence in courts raise the costs of dispute resolutions as the disputing parties must use alternative, private enforcement mechanisms.[14] Furthermore, rent-seeking behavior by participants in corrupt societies raise costs for consumers and producers, and policy distortions cause barriers to long-run growth by protection or creation of monopolies.[15]

Access to justice with independent and neutral courts is necessary for the pharmaceutical companies to protect their intellectual property rights, contract rights, and legitimate expectations under public law. Not only as a matter of protecting the expected revenue from the investments, including the irreversible sunk costs, in the research and development ("R&D") et cetera, but also to protect the consumers from falsified medicines, which might be inferior or even dangerous compared to the products by the patent holder.[16] Furthermore, as pharmaceutical companies are acting on worldwide markets and will be on markets in areas with weak rule of law compliance, the risk is that competing companies can—without any governmental interference—copy products and

12. Karla Hoff & Joseph Stiglitz, *After the Big Bang? – Obstacles to the Emergence of the Rule of Law in Post-Communist Societies,* 94 AM. ECON. REV. 753, 755–56 (2004) (on file with *The University of the Pacific Law Review*).

13. *See id.* (noting that Hoff and Stiglitz do not directly analyze money laundering but instead the possibility of hiding money abroad if the rule of law is weak).

14. *See generally* Stephan Haggard & Lydia Tiede, *The Rule of Law and Economic Growth: Where are We?*, 39 World Dev. 673 (2011) (on file with *The University of the Pacific Law Review*). (categorizing four distinct divisions of economic literature on the rule of law).

15. *Id.* at 674–75.

16. *See generally* O. B. K. Dingake, *The Rule of Law as a Social Determinant of Health,* 19 HEALTH & HUM. RTS. J. 295 (2017) (discussing how the rule of law affects "exernal conditions in which people live that may affect their health."); Yannis Katsoulacos & David Ulph, *Legal Uncertainty, Competition Law Enforcement Procedures and Optimal Penalties*, 41 EUR. J.L. ECON. 255, 285 (2016) (on file with *The University of the Pacific Law Review*).

force the patent holder to lower the prices; thus, companies will raise the prices in markets with strong rule of law compliance. In addition, weak rule of law systems with a high degree of corruption can lead to anti-competitive behavior.[17] That will increase the prices of the products. However, even in areas with high rule of law compliance, the pharmaceutical industry cannot free itself of participating in anti-competitive practices that will raise the prices of products.[18]

Lack of compliance with the rule of law leads to *legal uncertainty*, which Katsoulacos and Ulph loosely have defined as "lack of ability to predict the outcome of a legal dispute."[19] They suggest legal uncertainty may have a positive effect on welfare, as it can have a deterrent effect on companies' conduct if companies cannot predict how enforcement authorities will assess their conduct.[20] Even if that is the case, a weak rule of law might discourage pharmaceutical companies from investing in R&D for new products if the companies cannot protect the investment from, for example, corrupt practices in the judicial or administrative system.[21] Craswell and Calfee suggest that the administration of the rules, rather than the rule itself, can lead to legal uncertainty.[22] They suggest legal uncertainty may deter market agents and lead to over-compliance if the penalties are too severe.[23] However, the rules themselves, or lack of rules, can also lead to legal uncertainty. For example, rules on the right to health and compulsory licenses can limit pharmaceutical companies' IP rights. The international rules do not clearly establish the balance between the right to health and IP rights; without clear authority on how to establish that balance, states and international institutions might administrate and apply the rules differently.[24]

A weak rule of law is an economic risk as companies' investments have only limited legal protection. That increases the transaction costs, such as the costs of using the market,[25] and raises the price of the pharmaceutical products. Companies on world markets might even raise the prices in well-functioning rule of law societies if they have losses on markets with a weak rule of law.

17. Andreas Stephan, *Cartel Laws Undermined: Corruption, Social Norms, and Collectivist Business Cultures*, 37 (2) JOURNAL OF LAW AND SOCIETY 345 (2010).

18. See examples in section E. Unclear Law I: Competition Law and IP Law.

19. Katsoulacos & Ulph, *supra* note 16, at 66 (concluding that legal uncertainty in enforcement procedures may have better deterrence effects).

20. *See id.* (concluding that legal uncertainty in enforcement procedures may have better deterrence effects).

21. *Id.* The theory proposed by Katsoulacos and Ulph does not concern systems with a weak rule of law but it concerns the uncertainties associated with high discretion by authorities in cases about competition law.

22. *See* Richard Craswell & John E. Calfee, *Deterrence and Uncertain Legal Standards*, 2 J.L. ECON. & ORG. 279, 279–80 (1986) (on file with *The University of the Pacific Law Review*) (concerning the uncertainties associated with the application of rules as a mathematical restatement of theories advanced by legal realists).

23. *Id.* at 298–99.

24. *Compare id.*, with Carl J. Dahlman, *The Problem of Externality*, 22 J.L. & ECON. 141 (1979).

25. *See generally* Dahlman, *supra* note 24, at 141–42 (1979) (on file with *The University of the Pacific Law Review*) (detailing how external forces, including company investments, influence the market and create undesirable side effects).

Furthermore, those companies benefitting from societies with a weak rule of law, where corruption and anti-competitive behavior go hand-in-hand, can raise the price of the product. A strong rule of law should narrow down the scope of legal uncertainty and reduce transaction costs. To strengthen the rule of law in societies with a weak rule of law, it is necessary to work towards a stronger rule of law on international level.

C. Multilevel Rule of Law Challenges

Theories of the rule of law often use the *state* as the focal point of analysis. The challenge is to import the rule of law to international level. A well-functioning state will have a mature constitutional, institutional, and political infrastructure with checks-and-balance systems in place to ensure law's supremacy. A state is sovereign with an implied vertical power structure between the governing institutions and the citizens. Even in a democratic society, there is an implied vertical power structure, although the legitimacy behind it derives from the people. International law does not have the same type of vertical power structure. The traditional assumption of international law is that states are *equal* and that there is only limited scope of international institutions to take a supreme role over the states. The equality assumption should not be confused with economic, political, and social equality. Rather, the assumption implies *formal equality* where the execution of a state's legislative and jurisdictional scope within its territory must be accepted by other states and there is no higher authority than the state. The limited scope of international institutions' supreme role is also more nuanced in reality. For example, the European Union ("EU") is a good example where EU member states have conferred political and judicial powers to EU institutions. In addition, the UN Security Council is an example where an international institution has specified supreme powers. It can be argued that constitutional principles are developing—although at a less mature level—in the international system.[26] Despite global challenges—like the recent US hegemonic approach to international economic law[27]—law and the international institutions work on cultivating and protecting to some degree the international rule of law. As Cogan suggests, even non-compliance might be an element in the process of developing the international rule of law by "reconciling formal legal prescriptions with changing community policies or by bridging the enforcement gap created by inadequate community mechanisms of control."[28]

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26. Matej Avbelj & Jan Komárek, *Four Visions of Constitutional Pluralism*, 4 EUR. CONST. L. REV. 524, 526 (2008); Neil Walker, *The Idea of Constitutional Pluralism*, 65 MODERN L. REV. 317, 337 (2002); ERNST-ULRICH PETERSMANN, INTERNATIONAL ECONOMIC LAW IN THE 21ST CENTURY – CONSTITUTIONAL PLURALISM AND MULTILEVEL GOVERNANCE OF INTERDEPENDENT PUBLIC GOODS 1–574 (Hart Publishing, UK ed. 2012); Henrik Andersen, *Protection of Non-Trade Values in WTO Appellate Body Jurisprudence: Exceptions, Economic Arguments, and Eluding Questions*, 18 J. INT'L ECON. L. 383, 389 (2015).

27. For example, the attempt to undermine the Appellate Body of the WTO, and through their trade wars.

28. Jacob Katz Cogan, *Noncompliance and the International Rule of Law,* 31 YALE J. INT'L L., 189, 191

On international level, the UN General Assembly has formalized the rule of law:

"We recognize that the rule of law applies to all States equally, and to international Organizations, including the United Nations and its principal organs, and that respect for and promotion of the rule of law and justice should guide all of their activities and accord predictability and legitimacy to their actions. We also recognize that all persons, institutions and entities, public and private, including the State itself, are accountable to just, fair and equitable laws and are entitled without any discrimination to equal protection of the law."[29]

In the WTO Dispute Settlement System,[30] Members of the Appellate Body ("AB") have affirmed the rule of law.[31] AB jurisprudence reflects rule of law developments, like reviews of national law and practices, and through the development of a case law to provide predictability in WTO law.[32] However, the *multilevel* problems concern the relationship between national and international rules of law. It concerns different *coupling* techniques between international law and national law,[33] and the manner national authorities administer international law, in particular in states with corruption in the administrative units. An additional challenge with a rule of law at international level is its *fragmentation.*[34] The question is whether international law offers sufficient instruments to handle norm overlaps between the various sectors of international law. The debate is between legal pluralism and its more political solutions to that question,[35] and its potential "antithesis to the rule of law,"[36] and constitutional pluralism where the development of constitutional principles and hierarchy between international norms provide basis for a solution.[37] This writer takes the

(2006).

29. G.A. Res. 67/1, at 1 (Sept. 24, 2012).

30. When WTO Members have a dispute, they notify the Dispute Settlement Body (DSB), which consist of all the WTO Members. The first step is to solve the case through negotiation and consultation. If that is not possible, the quasi-judiciaries get involved and the DSB establishes a panel whose recommendation can be appealed to the Appellate Body (AB). Both a panel and AB recommendation can be rejected by the DSB if there is full consensus among the WTO Members to reject it. James Bacchus, *Groping Towards Grotius: The WTO and the International Rule of Law*, 44 HARV. INT'L L.J. 533 (2003).

31. *Id.* at 536, 546; Appellate Body Report, *Annual Report for 2011*, 76–78, WTO Doc. WT/AB/17 (adopted June 20, 2012) (on file with *The University of the Pacific Law Review*).

32. Henrik Andersen, *China and the WTO Appellate Body's Rule of Law*, 5 GLOBAL J. COMP. L. 146, 149 (2016).

33. Andersen, *supra* note 10, at 64.

34. Fragmentation of International Law: Difficulties Arising from the Diversification and Expansion of International Law, Rep. of the Study Group of the Int'l Law Comm'n, U.N. Doc. A/CN.4/L.682 (Apr. 13, 2006).

35. See generally Nico Krisch, *The Case for Pluralism in Postnational Law* 4–5 (LSE Law Society and Econ., Working Paper No. 12, 2009); Martti Koskenniemi & Päivi Leino, *Fragmentation of International Law? – Postmodern Anxieties*, 15 LEIDEN J. INT'L L. 553, 578–79 (2002).

36. Brian Z. Tamanaha, *The Rule of Law and Legal Pluralism in Development*, 3 HAGUE J. RULE L. 1, 16 (2011) (on file with *The University of the Pacific Law Review*).

37. See generally Avbelj & Komárek, *supra* note 30, at 525–26 (2008); Walker, *supra* note 30, at 337; PETERSMANN, *supra* note 30; Andersen, *supra* note 30, at 389.

position that there are constitutional principles developing in international law,[38] and international courts are developing a common case law through cross-fertilization by cross-referencing.[39] However, it is immature at this stage, and it is fragile to power-oriented approaches.

III. THE WORLD TRADE ORGANIZATION AND RULE OF LAW ISSUES

The next step is to identify and discuss some of the rule of law gaps in the WTO system of relevance for the pharmaceutical sector. The main issues are access to justice and unclear law. After giving examples of problems accessing justice, the Article uses three examples to illustrate unclear law: 1) the interface between protection of IP and competition law; 2) the relationship between health protection and trade; and, 3) the relationship between WTO law and human rights.

A. Access to Justice and Administration of Law

The WTO legal system limits the access to justice to states. There is no *locus standi* for individuals. Individuals must rely on their national governments' interest in pursuing a potential breach of WTO law. There is the risk that a case can damage a special trade relationship between the states. That risk can deter the state from pursuing the case in the DSB to the detriment of the pharmaceutical company.[40] In such situations, companies must rely on national courts. The direct applicability and direct effect of WTO law depends on the WTO Members' own judicial systems. Some states follow a strong monist approach with direct effect of WTO law, whereas others require a more dualist-oriented approach. For example, although the EU does not have a strict dualist approach, WTO law is only applicable for companies in the EU judicial system if the EU intends to implement a specific WTO obligation, or if there are secondary acts that expressly reference specific provisions of WTO law.[41] The Court of Justice has used political, instead of legal, arguments in its contention for this complex application of WTO law.[42] However, the Court of Justice has accepted direct effect in other sectors of international law.[43] This example illustrates some of the

38. Andersen, *supra* note 30, at 389.

39. Chester Brown, *The Cross-Fertilization of Principles Relating to Procedure and Remedies in the Jurisprudence of International Courts and Tribunals*, 30 Loy. L.A. INT'L & COMP. L. REV. 219, 231 (2008) (on file with *The University of the Pacific Law Review*).

40. Sara M. Ford, *Compulsory Licensing Provisions Under the TRIPs Agreement: Balancing Pills and Patents,* 15 Am. U. INT'L L. REV. 941, 944 (2000) (on file with *The University of the Pacific Law Review*).

41. Case C-93/02, Biret Int'l v. Council 2003 E.C.R. I-497, ¶ 63.

42. *See* Case C-149/96, Portugal v. Council 1999 E.C.R. I-8425, ¶ 42–46 (emphasizing the principle of reciprocity. The differences in the respective judicial systems would give an advantage in other states if the Court reviewed EU law in light of WTO law and "would deprive the legislative or executive organs of the Community of the scope for manoeuvre enjoyed by their counterparts in the Community's trading partners.").

43. Case C-104/81, Mainz v. Kupferberg 1982 E.C.R. 3644, 3663–64.

multilevel rule of law problems. WTO Members have different coupling techniques between WTO law and national law, and these techniques can be complex and difficult to see through; thus, making the access to justice costly if not impossible.

WTO law is not immune to concerns over companies' access to a minimum level of administrative and judicial protection. Besides due process for states in the dispute settlement proceedings, the Appellate Body ("AB") has developed a jurisprudence protecting due process for companies in the national systems.[44] Furthermore, the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS") contains rules on access to courts and administrative procedures. That includes the right to access the courts to review final administrative decisions.[45] Article 42 of TRIPS imposes an obligation on the WTO Members to provide due process in their administrative procedures. In *US – Section 211 Appropriations Act*, the AB stated:

"From all this, we understand that the rights which Article 42 obliges Members to make available to right holders are procedural in nature. These procedural rights guarantee an international minimum standard for nationals of other Members within the meaning of Article 1.3 of the TRIPS Agreement"[46]

These due process requirements are only *minimum guarantees* as TRIPS takes into account differences in the national legal and administrative systems.[47] Companies must take a comparative law approach to assess the level of due process protected in the respective countries where they are doing business. However, TRIPS contains the NT and MFN principles. Thus, a WTO Member must provide equal treatment to foreign companies in the administrative and judicial system as it provides to national companies and to companies from other trading partners.[48] The due process requirements are also part of the bigger picture of WTO law in providing general transparency in administrative procedures. The various WTO Councils monitor the level of transparency and administration of law in the WTO Members' administrative systems. Ala'i has suggested that this potential transparency improvement can help reduce corrupt practices and improve the rule of law.[49]

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44. Appellate Body Report, *European Communities – Definitive Anti-Dumping Measures on Certain Iron or Steel Fasteners from China*, ¶ 541, WTO Doc. WT/DS397/AB/R (adopted July 28, 2011).

45. Agreement on Trade-Related Aspects of Intellectual Property Rights art. 41.4, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Org., Annex 1C, 1869 U.N.T.S. 299 (1994) [hereinafter TRIPS].

46. Appellate Body Report, *US – Section 211 Omnibus Appropriations Act of 1998*, ¶ 221, WTO Doc. WT/DS176/AB/R (adopted Jan. 2, 2002).

47. *Id.* at ¶ 216. It follows also from the preamble of TRIPS that the multilateral trading system takes "into account differences in national legal systems." TRIPS, *supra* note 49.

48. Appellate Body Report, *supra* note 50; Panel Report, *European Communities – Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs*, ¶ 7.271–7.272, WTO Doc. WT/DS174/R (adopted Apr. 20, 2005).

49. Padideh Ala'I, *The WTO and the Anti-Corruption Movement*, 6 LOY. U. CHI. INT'L L. REV. 259 (2008) (on file with *The University of the Pacific Law Review*).

Nevertheless, the administrative handling of imported pharmaceutical goods can still cause problems. Where tariffs are relatively easy to measure, non-tariff barriers can be more difficult to predict. A non-tariff barrier can be any measure, or practice other than a tariff, that restricts import or export like import-licensing, valuation of goods for custom purposes, pre-shipment inspection, rules of origin, labelling requirements, or investment measures. The WTO treaties regulate these areas. What they all have in common is the reliance on local authorities' discretion to allow the pharmaceutical product to enter the country, and the length of time it takes the authorities to inspect the products. The WTO Members have succeeded with a new Trade Facilitation Agreement, which aims at "further expediting the movement, release and clearance of goods, including goods in transit," and is a complement and clarification of the vague trade facilitation rules of GATT 1994. Although it is a step in the right direction, the pharmaceutical companies still need to know in advance the different cultures underlying the inspection and custom authorities. That includes knowledge of the use—or abuse—of discretion taken by the authorities to the detriment of the rule of law. A discriminatory handling of import of pharmaceutical products can be part of the importing state's strategy to protect their own pharmaceutical companies. For example, the US and EU pharmaceutical companies have complained about the treatment in Russia. According to the Russian *Pharmaceutical Industry Development Plan 2020*, Russian producers should account for a minimum 50% of all sales of pharmaceutical products in Russia. According to the US and EU companies, they feel discriminatory treatment in violation of the NT principle.[50] The case has not materialized in the DSB, but the Council of Goods of the WTO has discussed the case behind closed doors.

The case illustrates the problem of access to justice. The pharmaceutical companies in the US and the EU do not have standing in the DSB. They can only get a case tried if the US government and the EU Commission decide to make a case. Before that, the pharmaceutical companies will be behind the curtain of diplomacy and political operations, which are not clear for the companies.[51] Naturally, some industries, like the pharmaceutical industry, have lobbying power to influence the decision makers in the US and the EU whether to make a case. That is not a given right by law. The alternative is to make a case in the national Russian judicial system if it allows a direct effect of WTO law.[52]

50. John Zarocostas, *EU and US Criticise Russia over Protectionist Measures for its Pharmaceutical Industry*, PHARMACEUTICAL JOURNAL (Nov. 21, 2014), https://www.pharmaceutical-journal.com/news-and-analysis/eu-and-us-criticise-russia-over-protectionist-measures-for-its-pharmaceutical-industry/20067231.fullarticle?firstPass=false (on file with *The University of the Pacific Law Review*).

51. *See* PAUL MEERTS, DIPLOMATIC NEGOTIATION ESSENCE AND EVOLUTION 65 (Clingendael Institute, 2d ed. 2015) (reasoning that diplomats have a role to provide predictability for the benefit of the international relations).

52. Elena A. Wilson, *Russia in the WTO: Will It Give Full Direct Effect to WTO Law?*, 27 GLOBAL BUS. & DEV. L.J. 325, 327–28 (2014) (on file with *The University of the Pacific Law Review*).

B. Unclear Law I: Competition Law and IP Law

Competition law balances companies' access to protect their IP with economic theory of consumer welfare. A patent holder gets monopoly-type status on a market with the right, among other things, to exclude competing companies' use of the patented good. Competition law provides rules against abuse of a dominant position on the market and against anti-competitive agreements and concerted practices to safeguard consumer welfare and society.[53] Anti-competitive practices by pharmaceutical producers can raise prices of the products and be incompatible with the human right to access medicine.

A strong rule of law can provide a healthy balance between private interests to innovate and protect the investments through IP law while restraining anticompetitive conduct and securing the public interest through competition law.[54] For example, there have been several cases in the EU system where pharmaceutical companies tried to eliminate competition in violation of EU and/or national competition laws through anti-competitive practices. For example, the anti-competitive conduct could be the abuse of the patent system and the procedures for marketing pharmaceutical products to prevent the arrival of competing products on the market and impede parallel trade,[55] and it could be anti-competitive agreements and concerted practices to create barriers to entry for other competitors.[56] The result was heavy fines for anti-competitive behavior.[57] In all cases, the companies had access to try the administrative decisions before the courts.

While EU laws, national laws, and national authorities' practices demonstrate the balance between competition law and IP, it is more problematic in WTO law. WTO law does not have a competition law.[58] The relationship between trade and competition law was part of the WTO Doha Development Agenda, but the WTO

53. Ioannis Lianos, *Some Reflections on the Question of the Goals of EU Competition Law* 16 (Centre for Law Econ. & Soc'y, Working Paper No. 3, 2013).

54. *See generally* Ariel Katz, *Intellectual Property, Antitrust, and the Rule of Law: Between Private Power and State Power*, 17 THEORETICAL INQUIRIES L. 633 (2016) (on file with *The University of the Pacific Law Review*) (exploring the rule of law relating to intellectual property); *Competition Enforcement in the Pharmaceutical Sector (2009-2017) - European Competition Authorities Working Together for Affordable and Innovative Medicines*, at 3 COM (2019) 17 final (Jan. 28, 2019).

55. Case C-457/10, AstraZenec'a v. European Commission 2012 E.C.R. 770, ¶ 1.

56. Case T-472/13, Lundbeck v. European Commission 2016 E.C.R. 449, ¶ 380.

57. *Competition Enforcement in the Pharmaceutical Sector*, *supra* note 58.

58. *See generally* GATT 1994: General Agreement on Tariffs and Trade 1994 art. 6, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, 1867 U.N.T.S. 220 (1994) (providing exceptions, such as predatory pricing for goods is to some extent covered by the WTO antidumping rules in Art. VI of GATT 1994 and the Antidumping Agreement. These rules do not concern abusive conduct by a company with a dominant position on the market but only relate to dumped prices, i.e. that the export price is lower than price in the ordinary course of trade on the domestic market. GATS provides more traditional type of competition rules but only in respect of the telecom sector and only for those states that have committed to it in their GATS schedules).

General Council abandoned it in 2004.[59] However, TRIPS provides principles to counter anti-competitive conduct:

"Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology."[60]

Article 40 of TRIPS concerns the *control of anticompetitive practices in contractual licenses.* It provides:

"Nothing in this Agreement shall prevent Members from specifying in their legislation licensing practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market."[61]

Even though there are few competition rules in TRIPS, TRIPS still does not provide a clear balance between IP rights and competition. The TRIPS Council Meeting in June 2018 illustrates the rule of law problems.[62] At the meeting, the US stated:

"[T]he misapplication of competition law is particularly concerning in IP disciplines because it runs the risk of forestalling future innovation. (. . .) Innovative firms pay close attention to both IP and competition laws in foreign markets when determining where to invest and partner. If competition law is misapplied in the IP context it runs the risk of discouraging the high-value R&D and manufacturing that many Members seek to attract and promote."[63]

Although this statement does not imply that the US favors an international competition law, it still demonstrates the problems of "misapplication" of competition law to the detriment of the IP areas. A better balance between IP and competition at WTO level could provide better options to discuss in the WTO fora—and in case of disputes, to settle—the legal issues resulting from the diverse competition policy practices in the respective WTO Members systems. At this stage, there is only limited access to improve that balance in the WTO. For example, the EU representative has deemed the TRIPS provisions concerning the use of compulsory licenses against anti-competitive practices by patent holders superfluous:

"Compulsory licences to pharmaceutical patents as a remedy to excessive pricing would have a negative impact on innovation incentives and appear to be superfluous, because a competition authority, once it has established unlawful market behaviour, has the normal toolbox of competition policy remedies"[64]

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59. Decis General Council Report, *Doha Work Programme*, WTO Doc. WT/L/579 (adopted Aug. 1, 2004).

60. TRIPS, *supra* note 49, at art. 8.2.

61. TRIPS, *supra* note 49, at art. 40.

62. Council for Trade-Related Aspects of Intellectual Property Rights, *Minutes of Meeting*, at 44, IP/C/M/89/Add.1 (June 5–6, 2018).

63. *Id.* at ¶444.

64. Council for Trade-Related Aspects of Intellectual Property Rights, *supra* note 67, at ¶444.

That argument is not persuasive. Where TRIPS provides the overall rules concerning patent protection, there is no equivalent providing an overall frame for anti-competitive conduct of patent holders. There is the risk of an uneven system of IP rights and competition laws that may harm innovation.[65] For example, a patent holder can extend the patent right to block innovation; which, in some systems, is anti-competitive behavior, but not in others. A better balance between IP and competition law in the WTO would provide a minimum level of protection against anti-competitive behavior. Without a better balance, the potential opening to anti-competitive conduct is at odds with the human right to health, at least indirectly. Pharmaceutical companies need to apply comparative law to understand the differences between the complex competition laws of the respective WTO Members. For example, EU competition law provides a rule against unfair pricing,[66] whereas US antitrust law does not have an equivalent to unfair pricing.[67] That implies different approaches to pharmaceutical companies holding a patent.

Scholars debate whether the WTO should enact an international competition law. An international competition law would provide legal expectations to the rules and administration of competition law at a national level and some minimum level of legal certainty for companies. From a rule of law perspective, it would be welcoming; however, the reality is that it might be difficult to achieve due to different competition policy traditions and administration of law, conceptual challenges, and problems with capacity in developing and least-developed countries.[68] The lack of clear and prospective laws on international level means that pharmaceutical companies must carry the transaction costs associated with different competition laws, policies, and practices by national authorities. In addition, lack of clear and prospective competition laws, and/or corrupt practices by competition authorities, can be an incentive to charge excessive prices by pharmaceutical producers.[69]

C. Unclear Law II: Protection of Health and IP Law

The relationship between protection of health and pharmaceutical companies' patent protection has been uneasy in WTO law. On one side, pharmaceutical companies want to protect their investments by claiming high

65. Jens Schovsbo, *Fire and Water Make Steam: Redefining the Role of Competition Law in TRIPS* 1, 41–42 (Feb. 7, 2009), *available at* https://ssrn.com/abstract=1339346h (on file with *The University of the Pacific Law Review*).

66. Treaty on the Functioning of the European Union art. 102(a) [2016] OJ C326/89.

67. Council for Trade-Related Aspects of Intellectual Property Rights, *supra* note 67, at ¶423.

68. *See generally* Elanor M. Fox, *Trade, Competition, and Intellectual Property – TRIPS and Its Antitrust Counterparts*, 29 VAND. J. TRANSNAT'L L. 481 (1996) (on file with *The University of the Pacific Law Review*) (examining antitrust law in relation to trade and intellectual property rights).

69. Loraine Hawkins, *WHO/HAI Project on Medicine Prices and Availability* 7 (Health Action Int'l, Working Paper No. 4, 2011) (on file with *The University of the Pacific Law Review*).

prices as long as the following occur: the patent provides the exclusive rights; competitors have not developed improved medicine; or, due to market failures like high barriers to entry and/or a weak rule of law. On the other side, states want to protect the health of their people by ensuring access to medicine at affordable prices. That can be a problem in some developing and in least-developed countries if these countries cannot afford patented medicine and want to use alternative domestic producers, or if the developing and least-developed countries lack capacities to produce affordable medicine. In the relationship between the general trade rules concerning goods and the exemptions in GATT 1994, it is noticeable that the AB has developed a jurisprudence where health has a special place in a hierarchy of values. If a state violates the trade rules but justifies the measures as "necessary to protect human, animal or plant life and health", which is provided in Article XX(b) of GATT 1994; the AB adopts a softer "necessity test" if the case concerns protection of human health. As the AB stated in *Brazil – Retreaded Tyres*, human health is a *vital value* and the necessity analysis *"begins with an assessment of the 'relative importance' of the interests or values furthered by the challenged measure."*[70] Even though the case concerns trade in goods, the AB has taken similar positions in respect of trade in services,[71] and there seems to be no hindrance in regarding health as a vital value in TRIPS. The political will by the WTO Members and the latest amendments of TRIPS—addressed below—strengthen this view.

TRIPS protects patents and other forms of IP. The balance between patent protection and protection of health has been problematic. Getting widespread agreement on TRIPS was difficult because the developing and least-developed countries objected to the worldwide obligations to protect the IP of Western multinational enterprises.[72] Nevertheless, TRIPS became binding WTO law and requires WTO members to enforce a minimum level of patent rights. A strong patent right is important in the pharmaceutical industry. The R&D is costly with high sunk costs. A protection of the investments and expected high return is an incentive to further R&D to the benefit of consumers. The downside is if consumers cannot afford the medicine, then prices become a barrier to access medicine.

In *Brazil — Patent Protection*,[73] the US filed a complaint against Brazil for

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70. Request for the Establishment of a Panel by the U.S., *Brazil – Measures Affecting Patent Protection*, 1, WTO Doc. WT/DS199/3 (Jan. 8, 2001).

71. Appellate Body Report, *Brazil–Retreaded Tyres*, ¶ 143, WTO Doc. WT/DS332/AB/R (adopted Dec. 17, 2007) (citing Appellate Body Report, *Gambling*, ¶ 306, WTO Doc. WT/DS285/AB/R (adopted Apr. 20, 2005)).

72. Jae Sundarama, *Brazil's Implementation of TRIPS Flexibilities: Ambitious Missions, Early Implementation, and the Plans for Reform*, 23 (2) INFO & COMM. TECH. L. 81, 84 (2014) (on file with *The University of the Pacific Law Review*).

73. Request for the Establishment of a Panel by the United States, *Brazil–Measures Affecting Patent Protection*, WTO Doc. WT/DS199 (Jul. 5, 2001). DS199: Brazil – Measures Affecting Patent Protection, WTO (last accessed Nov. 8, 2019), https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds199_e.htm (on file with *The University of the Pacific Law Review*).

its "local worker" requirement for AIDS medicine patent holders. Brazil offered free medicine to AIDS patients. To keep costs low, the government required that local producers without a patent to produce the medicine, unless patent holders could negotiate a sufficiently low price of production themselves. If the government and the patent holder could not reach an agreement, Brazilian authorities would grant compulsory licenses to local producers.[74] The US claimed that Brazil violated its obligations under TRIPS,[75] but they reached a mutual agreement without including the panel/AB. The case illustrates the challenge to find the legal balance between the scope of the patent rights and the protection of access to health. Policies of free medicine comply with human rights to health, but their compatibility with patent rights is not clear. These two rights collide. The political agreement between Brazil and the US does not shed any light on that balance.

During *Brazil – Patent Protection*, the US Trade Representative complained about South Africa's introduction of compulsory licenses and parallel importation of AIDS medicine overriding the US pharmaceutical companies' South African patents. The reason for the compulsory licenses was the national health crisis in South Africa where patients could not afford patented medicine and had to resort to copied medicine. The US and South Africa reached an agreement outside of the WTO DSB. However, the case illustrates the same problems as *Brazil – Patent Protection*; the scope of compulsory licensing is not clear but depends on national discretion. Furthermore, TRIPS provides that if there is a *national emergency* the government may allow another producer than the patent holder to make the pharmaceutical products. However, the scope of such a national emergency is not clear.

The cases did have influence in the WTO. At a Ministerial Conference, the WTO Members adopted the Doha Declaration, which recognizes "the gravity of the public health problems afflicting many developing and least-developed countries," and affirms that TRIPS "can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all."[76] It further provides:

"Each Member has the right to grant compulsory licences [sic] and the freedom to determine the grounds upon which such licences [sic] are granted. (. . .) Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria

74. *See* Paul Champ & Amir Attaran, *Patent Rights and Local Working under the WTO TRIPS Agreement: An Analysis of the U.S.-Brazil Patent Dispute*, 27 YALE J. INT'L L. 365, 380–81 (2002) (on file with *The University of the Pacific Law Review*).

75. TRIPS, *supra* note 49, at art. 41.4; General Agreement on Tariffs and Trade, Apr. 15, 1994, Art.III.4, 1867 U.N.T.S 190 (1994) [hereinafter GATT].

76. Declaration on the TRIPS Agreement and Public Health, WTO Doc. WT/MIN(01)/DEC/2 (Nov. 20, 2001).

and other epidemics, can represent a national emergency or other circumstances of extreme urgency."[77]

The legal status of the Doha Declaration has been the subject of debate.[78] In *Australia – Tobacco Plain Packaging (Cuba)*, the panel stated that the Doha Declaration is a *subsequent agreement* within Art. 31.3(a) of the VCLT—as the WTO Members adopted the Doha Declaration by *consensus decision*[79]—and shall use it to interpret TRIPS.[80] This seems to provide some clarity concerning the balance between TRIPS and health. Pharmaceutical companies must consider a nation's discretion to determine the existence of a national emergency. However, it is a discretion without clearly formulated criteria; this might increase the transaction costs for the pharmaceutical companies. Predicting when and how developing and the least-developed countries will resort to the national emergency rule can be difficult. As that is not clear, it might leave the companies in a situation where they must discriminate in their price policies between states to secure a sufficient return of their investment.[81]

Another issue which the WTO Members recently have clarified concerns developing and least-developed countries' lack of capacity to produce copied medicine. In 2003, the WTO Members waived the rules of TRIPS, which provides that compulsory licenses must *predominantly be used for supply on the domestic market,* and allowed exporting states to make compulsory licenses to export to countries with insufficient production capacities.[82] That waiver became law and took effect in January 2017 as an amendment to TRIPS.[83]

Both politically and judicially, WTO institutions have given some clarity concerning the relationship between patent rights and health. While that reduces the rule of law gap in WTO law and reduces the uncertainty about the legal

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77. *Id.*

78. *See generally* 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, 292 (2002) (on file with *The University of the Pacific Law Review*) (analyzing whether the Doha Declaration resolves divergent interpretations of TRIPS).

79. *See* Panel Report, *Australia–Certain Measures Concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging*, ¶ 7.2410, WTO Doc. WT/DS435/R, WT/DS441/R, WT/DS458/R, WT/DS467/R (adopted Aug. 27, 2018) (discussing that because the Doha *Declaration* was adopted by the Ministerial Conference, the panel considered it as a *decision*. "The terms and contents of the decision adopting the Doha Declaration express, in our view, an agreement between Members on the approach to be followed in interpreting the provisions of the TRIPS Agreement.").

80. *Id.* at ¶ 7.2410-12; Appellate Body Report, *United States–Measures Affecting the Production and Sale of Clove Cigarettes*, ¶ 252-53, 262, WTO Doc. WT/DS406/AB/R (adopted Apr. 24, 2012) (analyzing the legal status of decisions from the Ministerial Conference, finding that such decisions are subsequent agreements within Art. 31(3)(a) of the VCLT, ¶ 262).

81. *See also* THE COUNCIL OF ECONOMIC ADVISERS, EXEC. OFFICE OF THE PRESIDENT, REFORMING BIOPHARMACEUTICAL PRICING AT HOME AND ABROAD (Feb. 2018) (discussing the problems concerning different pricing policies in different states and their impact on the price policies in the US for pharmaceutical companies).

82. General Council Decision, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health,* ¶ 2, WTO Doc. WT/L/540 and Corr. 1 (Sept. 1, 2003).

83. TRIPS, *supra* note 49, at art. 41.4.

relationship between protection of health as a human rights and WTO law, it opens another: a multi-level challenge due to the wide discretion left to the WTO Members. From a health perspective, this is welcoming, but it adds legal uncertainty in the strategic planning for pharmaceutical companies.

D. Unclear Law III: WTO Law and Human Rights

Even though the previous section showed that some WTO institutions have clarified certain aspects between human right to health and WTO law, there are still several gaps. In the *European Union and a Member State — Seizure of Generic Drugs in Transit* cases, India and Brazil claimed that the EU violated GATT 1994 and TRIPS. EU law provided that the transit country could seize generic drugs if they violated patent law in the transit country. Generic drugs, produced in India and destined for Brazil, were in transit in the Netherlands where the Dutch authorities seized it. The case never proceeded to panel stage, so it is not clear what the legal arguments could have been. However, in the TRIPS Council, India referred to the UN Commission on Human Rights and the WHO.[84] The African Group also referred to human rights and stated that protection of patents ran counter to international human rights law.[85] The case illustrates the problems of legal conflict between trade, IP, and human rights.[86]

From a human rights perspective, it is hard to find legitimacy supporting the blocking of pharmaceutical products in transit, even if they violate IP law in that specific country. It also shows the relationship between IP and human rights in international law is not clearly settled. The unclear balance between two sets of laws create legal uncertainties. If national authorities—or, in this case, Dutch authorities acting on EU rules—have discretion to determine that balance, and do so on a global scale unevenly, it creates rule of law gaps between overlapping laws and institutions with a claim of authority to establish the balance between WTO Law and human rights.

The question is how to establish the balance between human rights to health and WTO law from a legal perspective. As mentioned above, states have referred to the Human Rights Council as a basis for claiming the right to health over patent rights. Scholars widely debate the relationship between WTO law and human rights, and this section can only provide a glimpse of some of the rule of law problems associated with that balance.

First, a distinction between human rights and WTO law should be made: human rights protect the *individual*, whereas WTO law protects the *state's right*

84. Minutes of Meeting, *Council for Trade-Related Aspects of Intellectual Property Rights*, ¶254, 262, WTO Doc. IP/C/M/61 (Feb. 12, 2010).

85. *Id.* at ¶278.

86. *See* Bryan Mercurio, *Seizing Pharmaceuticals in Transit: Analysing the WTO Dispute that Wasn't*, 61 (2) INTERNATIONAL AND COMPARATIVE LAW QUARTERLY 389, 394, 396 (2012) (on file with *The University of the Pacific Law Review*) (analyzing the case more thoroughly).

to trade. The application of a human rights argument in a WTO context seems problematic, as human rights do not give states rights. Nevertheless, there can be situations where the population in a state resents another state's human rights violations and rejects any trade with the state.[87] WTO law accepts measures "necessary to protect *public morals,"*[88] which may include a state's *human rights moral* if national laws and policies reflect it.[89] Despite its potential extra-territorial aspects, WTO law accepts such trade restrictions if the state can provide a sufficient *nexus* between its own public moral and the product concerned.[90]

Certain human rights, however, do not need any defense under WTO law if they qualify as *jus cogens*—i.e., peremptory norms of public international law.[91] Protection against slavery is an example of such a norm of international law.[92] Pharmaceutical producers are aware of slavery in the supply chain. Some pharmaceutical producers introduce barriers to trade in goods produced by slaves regardless of the state position. For example, Novo Nordisk A/S has taken steps to understand and identify the risk of slavery and manage these risks in its CSR in accordance with the UK Modern Slavery Act 2015.[93] Taking that to the state level and rejecting imports and exports from or to such states is not a violation of

87. *See* Adam Gabbatt & David Batty, *Danish Firm Lundbeck to Stop US Jails Using Drug for Lethal Injections*, THE GUARDIAN (Jul. 1, 2011), https://www.theguardian.com/world/2011/jul/01/lundbeck-us-pentobarbital-death-row (on file with *The University of the Pacific Law Review*) (If a state makes an export ban on pharmaceuticals to another state if the pharmaceutical products were used for capital punishment as a drug in lethal injection. That could be against the *ordré public* of the exporting state. Although the situation did not reach an export ban, it was widely debated, also by the pharmaceutical producer itself, when medicine produced by the Danish company, Lundbeck, was used as lethal injection in the US. Lundbeck responded by making contractual limits on US distributors by banning sales of Lundbeck's products to prisons.).

88. GATT, *supra* note 82; General Agreement on Trade in Services, Apr. 15, 1994, Art. XIV(a), 1869 U.N.T.S. 183, 33 I.L.M. 1167 (1994) [hereinafter GATS].

89. Andersen, *supra* note 30, at 394.

90. Public morals is a legitimate policy objective under WTO law. See case law concerning extra-territorial jurisdiction and the practice of *nexus. See* Appellate Body Report, *European Communities–Measures Prohibiting the Importation and Marketing of Seal Products*, ¶ 5.12, 5.173, WTO Doc. WT/DS400/AB/R, WT/DS401/AB/R (adopted June 18, 2014) (concerning inhuman hunting methods in seal hunting); DS400: European Communities — Measures Prohibiting the Importation and Marketing of Seal Products, WTO (last visited Nov. 8, 2019), *available at* https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds400_e.htm (on file with *The University of the Pacific Law Review*); s*ee also* Appellate Body Report, *United States–Import Prohibition of Certain Shrimp and Shrimp Products*, ¶ 134-35, WTO Doc. WT/DS58/AB/R (adopted Nov. 6, 1998) (discussing protection of turtles as exhaustible resources and extra-territorial jurisdiction).

91. *See* Vienna Convention on the Law of Treaties art. 53, 64, 27 January 1980, 1155 U.N.T.S. 18232 (in respect of peremptory norms and treaties).

92. Barcelona Traction, Light and Power Company, Limited, (Belgium v. Spain), Judgment, 1970 I.C.J. Rep. 3 at 32 ¶ 33–34.

93. *See Modern Slavery Statement 2018*, NOVO NORDISK (Jan. 2019), https://www.novonordisk.com/content/dam/Denmark/HQ/AnnualReport/2018/PDF/Modern-Slavery-Act-Statement-2018.pdf (on file with *The University of the Pacific Law Review*); *see also Responsible Sourcing Standards for Business Partners,* NOVO NORDISK (last visited July 16, 2019), https://www.novonordisk.com/content/dam/Denmark/HQ/sustainablebusiness/performance-on-tbl/Responsible%20business%20practices/Responsible%20sourcing/ResponsibleSourcing/ResponsibleSourcingStandards-2016-ENG.pdf (on file with *The University of the Pacific Law Review*).

WTO trade principles. A state that complies with its primary obligations under peremptory norms cannot be held responsible for wrongful acts under public international law.[94]

Apart from the principles of *jus cogens*, international law does not formally recognize a hierarchy between treaties. Where *jus cogens* does not allow any derogations, the next step are those situations where a state can depart from its international obligations if there are legitimate reasons that do not qualify under *jus cogens*. Scholars debate about the scope of "necessity," which the International Court of Justice has recognized as a customary rule of international law,[95] to protect a state's *essential interest* as a legitimate excuse for violation of obligations under public international law.[96] Protection of health is an essential interest of states.[97] However, the ILC Draft Articles on State Responsibility provides its constraints, as *"necessity may not be invoked by a State as a ground for precluding wrongfulness of an act . . . unless . . . the international obligation in question excludes the possibility of invoking necessity."*[98] The general trade rules of WTO law seem to exclude necessity. However, WTO law refers to *necessity* in its exemptions in GATT 1994. For example, Article XX(b) of GATT 1994 provides that states may impose trade restricting or discriminatory measures if they are "necessary to protect human, animal or plant life or health."[99] In that respect, AB case law has developed a three-step assessment of necessity: 1) an assessment of the relative importance furthered by the measure (as mentioned above, the AB considers health as a vital value);[100] 2) weighing and balancing other factors is a holistic exercise;[101] and, 3) a comparison between the challenged measure and potential alternatives.[102]

The AB must not only weight exceptions under Article XX of GATT 1994 against essential interests, like health, but it must also consider the context of the state's other obligations under international law. Article 12 of the ICESCR enshrines health as a human right, and WTO law should balance these

94. Int'l Law Comm'n, Rep. On the International Law Commission on the Work of its Fifty-Third Session, U.N. Doc. A/56/10, at 84 (2002).

95. The Gabčikovo-Nagymaros Project (Hungary/Slovakia), Judgment, 1. C. J. Reports 1997, ¶ 50-51.

96. Jorge E. Vinuales, *State of Necessity and Peremptory Norms in International Investment Law*, 14 Law & Bus. Rev. 79, 82 (2008) (on file with *The University of the Pacific Law Review*).

97. Jorge E. Vinuales, *State of Necessity and Peremptory Norms in International Investment Law*, 14 Law & Bus. Rev. 79, 91 (2008) (on file with *The University of the Pacific Law Review*).

98. Int'l Law Comm'n, Rep. On the International Law Commission on the Work of its Fifty-Third Session, *supra* note 101, at 80.

99. GATT, *supra* note 82; GATS, *supra* note 95.

100. Appellate Body Report, *Brazil–Retreaded Tyres*, *supra* note 78.

101. Appellate Body Report, *Colombia–Measures Relating to the Importation of Textiles*, *Apparel and Footwear*, ¶ 5.75, WTO Doc. WS/DS461/AB/R (adopted June 22, 2016).

102. Appellate Body Report, *China–Measures Affecting Trading Rights and Distribution Services for Certain Publications and Audiovisual Entertainment Products,* ¶ 239, 242, WTO Doc. WT/DS363/AB/R (adopted Jan. 19, 2010), WTO (last visited Nov. 1, 2019), *available at* https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds363_e.htm (on file with *The University of the Pacific Law Review*).

obligations accordingly. However, such balance in WTO law is not clear. The WTO Members, the panels, and the AB generally avert human rights arguments. So far, there has only been *one* case in the WTO, *US – Procurement,* which directly concerned human rights. The parties settled the case before it reached the panel stage; therefore, the case gave no guidance on the relationship between WTO law and international human rights law.[103] Only recently did a panel refer to the European Convention of Human Rights in support of its argument that the contested measures, criminal charges for sales of cigarettes, could be reviewed under WTO law.[104]

Where there is little guidance concerning the scope of human rights in WTO law and the WTO is not the right forum to define the scope and contents of human rights, other institutions—like the Human Rights Council, the International Labour Organization ("ILO"), and the WHO[105]—are more appropriate. However, the problem is that the spatial claim of authority to interpret the scope of human rights can interfere with WTO law. This leads to potential overlap and conflict between different sectors of law and their institutions. For example, only rarely have WTO forums used resolutions from the Human Rights Council.[106] The relationship between the WTO and the WHO seems closer as the WHO has *ad hoc* observer status in the TRIPS Council and the GATS Council. The WHO provides the overall evidence to define the international standards concerning protection of human health, which WTO law *per se* considers compatible and legitimate barriers to trade in goods.[107] The panel and the AB also refer to WHO reports and other WHO documents as evidence for health-related issues,[108] although it is not a requirement to consult

103. Lapse of Authority for Establishment of the Panel, *United States–Measures Affecting Government Procurement*, WTO Doc. WT/DS88, WT/DS95 (Feb. 11, 2000) (This case concerns the Burma law of Massachusetts, which implied a rejection of procurement of products from companies which did business in Burma. The reason underlying the rejection was the human rights problems in Burma. The contested Burma law was found by the US Supreme Court to be inconsistent with the US Constitution.); *see* Crosby v. National Foreign Trade Council, 530 U.S. 363, 363–64 (2000).

104. Panel Report, *Thailand–Custroms and Fiscal Measures on Cigarettes from the Philippines*, ¶ 7.583, WTO Doc. WT/DS371/RW (Nov. 12, 2018).

105. *See* WORLD HEALTH ORGANIZATION CONST. pmbl. (July 22, 1946) ("The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition.").

106. *See* Minutes of Meeting, *Council for Trade-Related Aspects of Intellectual Property Rights*, ¶ 363, WTO Doc. IP/C/M/79/Add.1 (June 9–10, 2015) (explaining an example where it has been used as a legal argument in the political discussions concerning the rights of LDCs in the Council for Trade-Related Aspects of Intellectual Property Rights); *see also* Report by the Secretariat, *Trade Policy Review*, ¶ 2.7, WTO Doc. WT/TPR/S/362 (Sept. 14, 2017) (using country reports to establish facts concerning the judicial systems and the independence of the courts).

107. Joint Study by the WHO and WTO Secretariat, *WTO Agreements & Public Health,* at 15, 32, WTO Doc. VII-2002-6,000 (2002), *available at* https://www.wto.org/english/res_e/booksp_e/who_wto_e.pdf (on file with *The University of the Pacific Law Review*).

108. *E.g.,* Appellate Body Report, *India–Measures Concerning the Importation of Certain Agricultural Products*, ¶ 2.6, WTO Doc. WT/DS430/AB/R (June 19, 2015); Appellate Body Report, *European Communities–Measures Affecting Asbestos and Esbestors-Containing Products*, ¶ 162, WTO Doc.

these reports.[109] In respect of the ILO, the 1996 WTO Ministerial Conference adopted a declaration renewing its commitment to 'the observance of internationally recognized core labor standards' when the ILO has the authority to make these standards. Eight fundamental ILO conventions enshrine the core standards.[110] However, the core ILO standards are not binding WTO law.

Overlaps between these sectors of law can cause legal uncertainties for pharmaceutical companies. In particular, it is a challenge for the pharmaceutical companies that have human rights as part of its CSR. Human rights within a company's CSR implies it must take human rights considerations into its contractual relations with suppliers. However, the same companies are uncertain whether a potential conflict between human rights and WTO law can force a change in its contractual discourse and add additional transaction costs to the production or distribution of its products. Even though pharmaceutical companies are not directly subject to WTO law, an association of companies limiting trade to protect human rights is subject to the state's laws and practices, which includes the state's own WTO commitments to provide market access.[111]

As mentioned above, theories of legal pluralism and constitutional pluralism provide different solutions to these potential conflicts. Although this writer in the debate has adopted a constitutional approach, the debate demonstrates that the conflicting issues between different sectors of international law lack clearer authoritative answers, fostering legal uncertainty.

IV. CONCLUSION

High prices of medicine are a barrier to access medicine for consumers and are not compatible with the right to health. This Article has not aimed at targeting the pharmaceutical industry or the states but concerns with WTO law. Rule of law gaps can result in higher prices because pharmaceutical companies can

WT/DS135/AB/R (Apr. 5, 2001).

109. *See* Appellate Body Report, *European Communities–Trade Description of Sardines*, ¶ 302, WTO Doc. WT/DS231/AB/R (Oct. 23, 2002) (the panel did not apply standards for sardine-products from the Codex Commission which was established by the United Nations Food and Agriculture Organization and the WHO).

110. Ministerial Declaration, *Singapore WTO Ministerial 1996*, ¶ 4, WTO Doc. WT/MIN(96)/DEC, (Dec. 18, 1996); *see also* Henrik Andersen, *Core Workers' Rights as Constitutional Principles in the WTO*, in FEJØ, NEERGAARD, TVARNØ, AND ØLYKKE (EDS), FESTSKRIFT LIBER AMERICUM ET AMICORUM IN HONOUR OF RUTH NIELSEN at 39 (COPENHAGEN: JURIST OG ØKONOMFORBUNDETS FORLAG, 2013).

111. For example, Art. 3.4 of the Agreement on Technical Barriers to Trade provides that "[m]embers shall not take measures which require or encourage local government bodies or *non-governmental bodies* within their territories to act in a manner inconsistent with the provisions of Article 2". The question is whether a passive approach by a state towards an association of companies' product requirements can be considered as an indirect encouragement, in particular of such private requirements *da facto* reduce access of foreign products to the domestic market. It is not settled in case law but it cannot be ruled out that private designs can indirectly be subject to WTO law. *E.g.,* Appellate Body Report, *United States–Measures Concerning the Importation, Marketing and Sale of Tuna and Tuna Products*, ¶ 188, WTO Doc. WT/DS381/AB/R, (adopted June 13, 2012); *see also* Panel Report, *United States–Certain Country of Origin Labelling (COOL) Requirements*, ¶7.174, 7.175, 7.176, WTO Doc. WT/DS384//R, WT/DS386//R, (adopted July 23, 2012).

expect higher transaction costs due to legal uncertainty.

This Article has provided some examples of such rule of law gaps. Companies do not have access to justice in the WTO system; therefore, they must use national systems with different approaches to the applicability and effect of WTO law. Furthermore, WTO law provides only a minimum level of due process guarantees; therefore, it is up to the national administrative and judicial systems to find their own level of due process protection beyond the WTO guarantees. Companies also face unclear law in the relation to competition law and TRIPS, human health and patent rights, and human rights and trade law. These examples also show that political interference or panels and AB interpretation of WTO law have reduced some rule of law gaps. However, there are rule of law problems in the interface between different international organizations' claim of authority in overlapping matters. A more settled rule of law on an international level could overcome some of the shortcomings mentioned in this Article.

The pharmaceutical companies might handle the rule of law gaps through their CSR practices, for example, by protecting human rights through preventing distributors or suppliers from engaging in any trade that violates workers' and farmers' human rights. That requires monitoring the suppliers and distributors the companies must account for in their cost analyses, and that might affect the price of pharmaceutical products.