

An Elementary Consideration of Humanity? Linking Trade-Related Intellectual Property Rights to the Human Right to Health in International Law

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This paper explores methods of achieving linkage in international law between the human right to health and the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). It explores the relevance to this question of international law's accepted hierarchies, namely *jus cogens* (peremptory norms), *ergo omnes* duties (duties "owed to all") and section 103 of the United Nations (UN) Charter. It argues that these rules collectively prohibit gross violations of any rights including health, and place reasonable limits on all human conduct (including trade) to protect human health and life. It turns to historical support for these assertions, including recent *de facto* recognition that access to AIDS medicines in Sub-Saharan Africa presents a legitimate exception to TRIPS rights. The paper further explores interpretive methods in international law for recognizing the prioritized value of human life and health within existing WTO law and dispute settlement processes, including from the *Vienna Convention on the Law of Treaties*. It concludes that raising health's priority requires a substantive reordering of the normative priorities that drive trade rules. It suggests that a practical strategy for raising the priority of health within decision making by WTO dispute settlement panels and domestic governments is to advance legal argument about health's appropriate location within international law's existing hierarchies.

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In this paper, I explore methods of achieving linkages between the right to the highest attainable standard of health ("the right to health") in international law and the World Trade Organization (WTO) Agreement on Trade-Related Intellectual Property Rights (TRIPS). I argue that linkage between trade and human rights law is inherent within international law, which prescribes universal interpretive methods for treaties in the *Vienna Convention on the Law of Treaties*. I also explore the idea that international law places a universal minimum duty on all states to abstain from gross violations of human rights to life and health, including through a set of prioritized duties including *jus cogens* (peremptory norms), obligations *ergo omnes* (state duties owed "to all") and duties in the *Charter of the United Nations*. The implication of these duties is that trade (like all human conduct) is subject to reasonable limitations in protection of health and life, including in relation to medicines, a key health care intervention. I do not suggest that health is explicitly recognized within international law's prioritized norms, but rather that health as an interest could appropriately fall within their conceptual domain. I suggest that the absence of explicit recognition of health in these norms is more reflective of the *de facto* neglect of health as a social right within international legal theory and practice, than of any categorical or substantive basis for its exclusion. Moreover, while international human rights law does not currently recognize the right to health within these prioritized norms, it does prohibit gross violations of any human right, a prohibition that arguably extends to the right to health. I argue that this legal duty not to grossly violate human rights to health and life is implicitly reflected in provisions

throughout WTO agreements that limit trade where doing so is necessary in order to protect human life and health.

This paper therefore advances arguments grounded in international legal theory and praxis, about what international law should be. The aim of these arguments is to raise the priority of health both within and outside the human rights domain. This intent is particularly apposite given that existing interpretations of TRIPS by WTO dispute settlement panels have tended to prioritize trade and intellectual property rights at the expense of collective health needs. I suggest that raising the comparable or enforceable priority of health in these rules requires a substantive reordering of the normative priorities that drive trade rules and that argumentation for the elevated priority of health within international law's existing hierarchies provides a practical strategy for achieving this goal, including within decision making by WTO dispute settlement panels and domestic governments.

The paper proceeds by first, exploring the conflict between human rights and trade related to pharmaceutical patents; second, examining the location of health within the established superior norms within international law contained in peremptory norms, *ergo omnes* duties (duties "owed to all") and section 103 of the United Nations (UN) Charter; third, exploring TRIPS and its jurisprudence in light of international law on treaty interpretation, important changes in state agreement and practice relating to medicines; and finally, exploring the implications of the foregoing legal analysis for rights-based reforms of TRIPS.

Conflicts Between the Right to Health and Trade-Related Intellectual Property Rights

Legal protections of the right to health and trade-related intellectual property rights converge in relation to medicines, imposing obligations that appear to point to incompatible choices (Hestermeyer, 2007, p. 175; ILC, 1996, paragraph 2). TRIPS requires all WTO members to provide 20 year exclusive patent protection on pharmaceuticals (TRIPS, article 28.1.a and b), which in addition to providing incentives to produce medicines, also allow patent holders to charge monopoly pricing for patented drugs. Yet under the international human right to health, states are required to create conditions that would assure to all medical service and medical attention in the event of sickness (ICESCR, 1976, article 12.1 and 12.2.d). These provisions have been interpreted by the UN Committee on Economic, Social and Cultural Rights to require states to provide accessible and affordable medicines as a minimum core duty under the international human right to health (United Nations Committee on Economic, Social and Cultural Rights (CESCR), 2000, paragraph 47).

This contrasting duties appear to create a legal conflict faced by a majority of countries globally: Approximately 84% of all WTO members (128 countries) have ratified the ICESCR (United Nations Office of the High Commissioner for Human Rights, 2008), and are therefore bound by both TRIPS and ICESCR duties. The remaining WTO members who are not parties to the ICESCR will certainly be bound under health rights in article 24.1 of the *Convention on the Rights of the Child*, which with 193 ratifications holds an effective universality (albeit that its rights and duties only apply to children). Thus, almost all WTO members must balance treaty or legislative right to health duties with TRIPS duties, and this has practical implications for how government policy makers and legal adjudicators of either treaty should interpret and implement these duties.

The problem of conflicting treaty duties is not novel to TRIPS and the right to health. Since 1945, the field of international law has exploded, with specialized regimes emerging in multiple issue areas, each with separate rules, institutions and practices (International Law Commission

(ILC), 2006, paragraph 8). Similarly, international treaties have proliferated: 6,000 multilateral treaties were concluded in the twentieth century, around 1,800 of which are general treaties that all states can participate in (ILC, 2006, paragraph 7, footnote 10). The proliferation of treaties and specialized legal regimes that appear to be siloed from each other and international law has led to growing concerns about the fragmentation and increasing incoherence of international law (Benvenisti and Downs, 2007; ILC, 2006; Koskeniemi and Leino, 2002; Pauwelyn, 2003).

As a result, the ILC, a body set up by the UN to codify and develop international law, initiated a 4-year investigation into the issue. In 2007, it released a report, which emphasizes that no specialized regime, including the WTO, operates outside of international law (ILC, 2006, paragraph 13.a). Martti Koskeniemi, the chair of the project and author of the report, argues for application of the principle of systemic integration so as to link functional areas to a deeper normative idea in international law, so that the “common good of humankind [is] not reducible to the good of any particular institution or regime” (ILC, 2006, paragraph 480). Koskeniemi suggests that systemic integration between functional areas of international law can be achieved in two primary ways: first, because all bodies of law must respect hierarchically superior norms in international law, and second, because all international law is linked through treaty interpretation in the *Vienna Convention on the Law of Treaties*, a legal treaty that establishes the framework and interpretive methods that all international treaties are subject to.

The idea of hierarchically superior norms and the interpretative approach provided in the *Vienna Convention* suggest both an analytical framework and strategic approach to addressing the conflict between TRIPS and the right to health. The remainder of the paper will explore both as analytical approaches capable of achieving linkages between human rights and TRIPS.

The Right to Health and International Law's Superior Norms

The primary basis on which to seek the prioritization of health within international law more generally is through the international human right to health. Yet neither human rights in general, nor the right to health in particular, is universally viewed as prioritized norms within international law. International law only recognizes three primary sources of hierarchically superior norms: *jus cogens* or peremptory norms, obligations *ergo omnes* and section 103 of the *Charter of the United Nations*. The following section explores each category and how they may relate to the right to health.

Jus Cogens and Peremptory Norms

Jus cogens are the only norms within international law recognized as superior to all others. Article 53 of the *Vienna Convention on the Law of Treaties* defines peremptory norms as those norms accepted and recognized by the international community of states as a whole as norms from which no derogation is permitted, and which can be modified only by a subsequent norm of general international law having the same character. Few norms are seen in this way, although international consensus has coalesced around a core list, including slavery, genocide, torture and racial discrimination (Brownlie, 1979, p. 513; Dugard, 2001, p. 40; ILC, 2001, pp. 283–4).

Peremptory norms have two primary functions in international law: first, as article 53 goes on to specify, they void any treaty that conflicts with such norms; second, they bind any state to compliance, irrespective of whether they agree with the rule or not. This aspect of the peremptory norms runs contrary to the traditional view of international law as a consensual order, and has generated considerable controversy (Caplan, 2003, p. 741; D'Amato, 1990; Weil, 1983, pp. 430 and 441). The non-consensual nature of these norms is nonetheless somewhat attenuated by the *Vienna Convention's* definitional requirement that peremptory norms be recognized as such by the

international community of states. Yet requiring political consensus to identify peremptory norms also points to the circuitous logic of their definition: Peremptory norms are supposed to be binding irrespective of consent, albeit that their content is determined by consent (Koskeniemmi, 1989, p. 283). The requirement of consent also suggests more inherent limitations, as contestation, *realpolitik* and political or cultural bias may prevent political consensus in identifying new *jus cogens* norms or in classifying existing conduct as falling within the ambit of existing norms (Meron, 1986, p. 4) (the lack of a concerted political response to genocide in Darfur provides a cogent contemporary example of the latter). This is not to suggest that the choice of existing peremptory norms is wrong, but rather that this short list cannot possibly reflect the priority of all human rights norms, nor exhaust international law's prohibitions on similarly wrongful acts. The current absence of health-related prohibitions from the list of accepted peremptory norms does not therefore bar health from inclusion in the future. On the contrary, I argue that the circumscribed list of accepted peremptory norms is itself reflective of normative priorities within international law that could reasonably be interpreted to include health-related interests.

Indeed, as the ILC pointed out in its commentary to the *Vienna Convention's* provisions on peremptory norms, it is not the form but the particular nature of the subject matter that gives norms the character of *jus cogens* (*Reports of the International Law Commission*, 1966). This recognition is evident in the way that the International Court of Justice has recognized that these norms are derived from interests that are "fundamental" or relate to "elementary considerations of humanity" (*Corfu-Channel*, 1949, p. 22) or "intransgressible principles of international law" (*Legality of Nuclear Weapons*, 1996, paragraph 79). The "fundamental" nature of these values is suggested in the prohibitions on slavery, genocide and torture, acts that violate human rights to dignity, life and bodily integrity to such a gross extent that the essential content of all human rights are negated.

These recognized prohibitions hold two primary implications relevant to the present inquiry. The first implication is that the prohibition against gross violations of human rights to life, dignity and bodily integrity reflect prioritized and "fundamental" interests within international law. If this is the case, aspects of the right to health would appropriately fall within the ambit of recognized prioritized international human rights, as the right to health is intimately connected to these (and other) rights. As the UN Committee on Economic, Social and Cultural Rights indicates, "[h]ealth is a fundamental human right indispensable for the exercise of other human rights" (CESCR, 2000, paragraph 1).

Health and life in particular are intimately interlinked, a relationship well recognized within international legal theory and practice. For example, while the right to life in article 6.1 of the *International Covenant on Civil and Political Rights* is formulated as imposing a duty to prohibit arbitrary deprivations, this right has been interpreted as imposing a positive obligation on states to increase life expectancy especially in eliminating epidemics (Human Rights Committee, 1982, paragraph 5). As a result, the Human Rights Committee has required states to include health-related data including in relation to pregnancy and child-related deaths of women in their regular treaty reports (Human Rights Committee, 2000, paragraph 10). Several regional and national judicial fora have similarly been willing to read positive health-related obligations into the right to life (*Glenda Lopez*, 1997; *Paschim Banga Khet*, 1996; *Villagran Morales*, 1999, paragraph 144). Indeed, some academic commentators and courts suggest that the right to life is itself a *jus cogens* (Parker and Neylon, 1989, pp. 431–2; *Street Children Case*, 1999, p. 139).

It seems unlikely, however, that the right to life could be designated as a *jus cogens* in toto. For example, while the arbitrary deprivation of human life is almost universally viewed as unlawful (Finnis, 1980), such acts would likely only rise to the level of *jus cogens* or international crime if

committed on a mass scale or with the requisite intent to constitute genocide or a crime against humanity. This implication is made explicit in the *Rome Statute of the International Criminal Court*, which specifies that killing will only constitute genocide if accompanied with the “intent to destroy, in whole, or in part, a national, ethnical, racial or religious group” (article 6).

This latter provision points to the second major implication of the acts prohibited under *jus cogens*, namely that any gross violations of these and other human rights would be similarly prohibited. International legal doctrine and practice suggest that at a particular scale and intent, all human rights violations become gross and therefore peremptory. This idea is supported in several authoritative legal sources: For example, the American Law Institute, a respected codifier of international law, has identified the broad category of gross violations of internationally recognized human rights as a peremptory norm (American Law Institute, 1987, section 702). This recognition is similarly reflected in the UN “1503” mechanism that allows individual complaints about gross human rights violations to be made against any country, irrespective of any specific treaty duties that a country may hold (ECOSOC Resolution, 1970, paragraph 1.a). This implies a universal prohibition against gross violation not dependent on treaty ratification. What constitutes a gross violation would be factually dependent: a violation could be gross because of its scale or order of magnitude, such as for example, a legally enforced system of apartheid (Crawford, 2002, pp. 245–7). However a violation could also be gross based on “the intensity of the violation or its effects” (Crawford, 2002, pp. 245–7) even if perpetrated against one person. For example, the prohibition on slavery would be violated by enslaving only one person.

Thus, both accepted peremptory norms and the categorical prohibition of any gross human rights violation suggest a hierarchical importance for certain human rights and a prohibition of grossly violatory acts, irrespective of which human rights they violate. This conclusion seems fairly logical within the human rights context—because a person is far more egregiously harmed by being enslaved or tortured than by for instance losing their right to vote.

As a recognized human right and an interest intimately connected to human life, liberty and worth, individual rights to health surely are capable of being grossly violated. The alternative is to suggest impunity for autocrats who intentionally cause large-scale deaths through deprivations of access to medicines. In this regard, it is notable that the definition of crimes against humanity in the *Rome Statute of the International Criminal Court* includes extermination, which is defined as “the intentional infliction of conditions of life, *inter alia* the deprivation of access to food and medicine, calculated to bring about the destruction of part of a population” (article 7). Thus, intentional deprivation of life-prolonging goods, such as medicine, can conceivably constitute an international criminal act. Whether this would extend to acts that deprive populations of access to medicines without being calculated to bring about their destruction is more questionable. The Rome Statute itself provides some guidance by defining intent as including situations where people mean to engage in conduct and are aware that a consequence from such conduct will occur in the ordinary course of events (articles 30.2.a and b). This definition of intent could therefore conceivably cover state action that serves to deprive a population of access to life-saving medicines, and where policy makers are aware that their actions in doing so will result in avoidable and foreseeable death. For example, former South African President Thabo Mbeki’s refusal to provide access to antiretroviral medicines is estimated to have caused over 330,000 deaths (Chigwedere *et al.*, 2008), policies popularly viewed as constituting a crime against humanity (Geffen, 2009; Schoen, 2009). A similar argument is advanced by Thomas Pogge, who argues that those who uphold social rules, such as trade and economic policies, can violate human rights when these rules “foreseeably and avoidably deprive human beings of secure access to the objects of their human rights” (Pogge, 2005, p. 194). The implication is that acts that deprive populations of access to medicines and foreseeably

contribute to mass death could sit comfortably within the prohibition on gross human rights violations and the hierarchy of prioritized rights it infers.

Therefore, the fact that the right to health does not appear within accepted peremptory norms does not suggest that this category lacks relevance to health. Indeed, the absence of health-related norms rather reflects the skewed and culturally specific nature of those norms identified as peremptory (Charlesworth and Chinkin, 1993, p. 68; Simma and Alston, 1992, p. 94). As Simma and Alston suggest

it must be asked whether any theory of human rights law which singles out race but not gender discrimination . . . and which finds no place for a right of access to primary health care, is not flawed in terms both of the theory of human rights and of United Nations doctrine (Simma and Alston, 1992, p. 95).

The lack of doctrinal and jurisprudential development of the right to health within domestic and international law has certainly contributed to the *de facto* inferior status of social rights despite international human rights law's rhetorical commitment to the indivisibility of all human rights. In recent years this neglect has considerably abated, with moves to delineate the scope and content of the right to health (CESCR, 2000). The legal and political significance of this right has also been elevated through the creation of a permanent post for a UN Special Rapporteur on the Right to Health (United Commission on Human Rights, 2003). At the same time, there has been a considerable increase in domestic enforcement of the right to health (Forman, 2008; Hogerzeil *et al.*, 2006), and in June 2008, a long awaited individual complaints procedure for violations of rights under the International Covenant on Economic, Social and Cultural Rights was adopted by the Human Rights Council and was opened for state signature in March 2009 (Human Rights Council, 2008).

This growth in the legal definition and enforceability of the right to health creates greater clarity about when this right is being violated, thereby contradicting earlier contentions that social rights cannot be grossly violated to rise to the level of *jus cogens* (Sinclair, 1984, p. 217). The legal development of the right to health (and social rights in general) may therefore contribute to a more coherent integration of these rights into other aspects of international human rights theory, including over time *jus cogens*. Moreover, while state consensus is required for the emergence of new *jus cogens*, popular opinion and "the dictates of public conscience" can influence and help to form state opinion (Meron, 2000, p. 83). Advancing arguments that the right to health could appropriately fall within the category of a peremptory norm may therefore assist this process by coalescing popular opinion and thereby influencing state practice. Even in the absence of these kinds of developments, the *jus cogens* category remains relevant as it suggests that the right to life (and ergo, related aspects of the right to health) could be viewed as prioritized interests within international law that should be favored when balanced against competing legal interests.

Obligations Ergo Omnes (Duties "Owed to All")

The idea of prioritized interests is similarly reflected in the legal doctrine of obligations *ergo omnes*, in other words state duties owed to the "international community as a whole". This concept was created by the International Court of Justice in the *Barcelona Traction Case*, where the court suggested that certain rights are so important that all states can be held to have a legal interest in protecting them, and that these include duties arising from the "basic rights of the human person" (*Barcelona Traction Case*, 1970, paragraphs 33–34). The idea of obligations *ergo omnes* is functionally related to peremptory norms, as both concepts refer to prioritized human interests. The difference, however, is that peremptory norms prohibit the violation of these interests, whereas

obligations *ergo omnes* speak only of duties regarding the interests themselves. Thus rather than constituting non-derogable norms like *jus cogens*, obligations *ergo omnes* confer a general standing on all states to make claims in the event of a violation (Beyers, 1997, p. 230).

While the Barcelona dictum suggests that *ergo omnes* duties arise from “basic” human rights, academic commentary has shifted to view human rights in totality as imposing *ergo omnes* obligations (Institut de Droit International Annuaire, 1989, p. 338; Meron, 1986, p. 13; Seiderman, 2001, p. 133). Nonetheless as the discussion around *jus cogens* suggests, the extension of universal duties of protection with regard to human rights is likely to extend not to all violations, but rather only to those considered serious or gross, or which relate to “basic”, elementary or fundamental human interests.

Henry Shue’s notion of “basic rights” provides a workable definition of what could be considered to fall within this realm. He suggests that basic rights would include rights to security, liberty and subsistence—in other words, those rights we consider to constitute “everyone’s minimum reasonable demands upon the rest of humanity” (Shue, 1980, pp. 18–22). This idea is well reflected in human rights theory, which designates certain rights in total and aspects of others as non-derogable (Shelton, 2002, p. 330). The UN Economic, Social and Cultural Rights Committee applies a similar concept to the right to health, which is viewed as having an essential minimum core that cannot be limited without very stringent justification, and which includes available, accessible and affordable medicines (CESCR, 2000, paragraphs 43–44). To the extent that human life in toto may depend on accessing medicines, the priority of this right within human rights more generally is implied.

Section 103: Charter Duties Regarding Global Health

The final area of international law where one could locate a prioritized value for the right to health is in the *Charter of the United Nations*, which established the UN and which all UN member states ratify as a binding treaty. In the Charter, states pledge to meet the UN’s primary objectives of maintaining peace and security, solving international problems of an economic, social, cultural or humanitarian nature and promoting human rights (articles 1.1, 1.3, 55 and 56). Section 103 states that Charter duties take precedence over all other treaty duties, a primacy reiterated in decisions of the International Court of Justice (see e.g. *Military and Paramilitary Activities in and against Nicaragua (Nicaragua v U.S.)*, *Jurisdiction and Admissibility*, 1986). This section has been viewed as prioritizing human rights duties over other treaty obligations, because under the Charter, UN member states pledge to take action to achieve universal respect for human rights. This is however a point that academics are divided on, as references to human rights in the Charter are sparse, and the general understanding of human rights in 1945 might not have incorporated all human rights subsequently protected. The inclusion of human rights duties within the Charter nonetheless suggests that states have undertaken some kind of duty regarding human rights, and the quibble can therefore only be about the nature of that duty rather than its existence. Thus all that can be said with any precision is that this uncertain duty holds a priority status over other treaty duties and would likely extend to health as an indivisible part of human rights.

The Charter is far more explicit about state duties regarding health. For example, in article 55.b of the Charter, UN member states explicitly pledge to take action to achieve solutions of international health problems, and it seems clear that such duties will set aside other treaty rules to the extent that they conflict with article 103. The identification of these duties might depend however on what is defined as an international health problem. These duties are almost certain to cover disease threats with international dimensions (such as pandemic disease threats or the spread of resistant strains of extensively drug resistant tuberculosis). In this context, access to certain

medicines would fall within the ambit of section 103 duties to the extent that resolving these threats may require the provision of medical treatments.

The other point to emphasize is that the explicit purpose of the UN Charter is to maintain peace and security, suggesting that the reason that Charter duties are prioritized over others is because of their importance to collective wellbeing (ILC, paragraph 36). The implication of Charter duties for the present inquiry is therefore twofold: first they indicate that international health problems are prioritized within international law because of the global harm of not doing so; second, they explicitly indicate that states hold international responsibilities to protect against global health problems. This latter idea is reflected in the UN Security Council's resolution in 2000 recognizing AIDS as a threat to global security (Hindmarsh, 2008). The recognition of HIV/AIDS as a threat to security gives currency to the idea that health (including access to medicines for global health threats) is a prioritized collective interest that implicates powerful Charter duties capable of subordinating competing obligations under other treaties.

Section Conclusion

The demarcation of prioritized rights and core elements of rights does not simply denote their *a priori* importance, but also suggests an approach to how they should be balanced with competing interests. International human rights treaties such as the *International Covenant on Civil and Political Rights* provide for the justifiable limitation of certain human rights to protect collective interests such as national security, public health or the rights of others. International law has further developed the criteria for such restrictions, indicating that they must be both necessary and proportional, meaning that restrictions should be the least restrictive alternative for achieving a particular aim (United Nations Economic and Social Council, 1984).

Thus international law prioritizes certain human interests by peremptorily prohibiting their gross violation, and by placing reasonable limits on political, economic or social conduct that renders human rights meaningless. This idea is practically animated in the emergence of an international law prohibition of slavery, a legal system of property in which human life was subordinated to the commercial interests of private slave owners and the countries that supported and benefited from the slave trade. The emergence of the prohibition of slavery not only suggests that human life and equal worth are prioritized values of international law, but also implies that international law limits trade and commerce to the extent that they grossly violate the worth and existence of human health and life. This basic principle is reflected within the WTO's founding document, most notably in article XX of the *General Agreement on Trade and Tariffs (GATT)* that allows states to limit GATT duties to ensure open markets when doing so is necessary to protect human health and life. The inclusion of this provision within both the 1948 and current trading regime suggests recognition therein that health and life interests should place reasonable limits on trade. Nonetheless, as I discuss below, this clause does not necessarily provide effective protection against trade restrictions affecting human life, given that health impacts are viewed as externalities to trade policies, rather than as their primary objectives.

TRIPS and Rights: Achieving Linkage through an Interpretative Approach

Bearing in mind the foregoing argument about the hierarchical location of health within international law, what potential is there for the interpretive approach proposed in the *Vienna Convention on the Law of Treaties* to achieve linkages between TRIPS and the right to health? This possibility is explored in the following section, by first, overviewing the *Vienna Convention's* provisions on treaty interpretation; second, exploring the implications of these provisions for interpreting trade-related intellectual property rights at the WTO; third, overviewing WTO

jurisprudence on TRIPS in light of this provision; and fourth, identifying subsequent state agreements and practice related to TRIPS that could affect its interpretation.

The Vienna Convention on the Law of Treaties

The *Vienna Convention's* primary provision on treaty interpretation is contained in article 31, which specifies that treaties must be interpreted in good faith according to the ordinary meaning of treaty terms in their context and in the light of a treaty's object and purpose (article 31.1). Adjudicators can ascertain this context from the text of a treaty (including its preamble and annexes) as well as any agreements or instruments relating to the treaty made between parties (article 31.2). They can also take into account subsequent state agreement and practice between parties regarding treaty interpretation (article 31.3) as well as "any relevant rules of international law applicable between the parties" (article 31.3.c).

The broader intent of these rules is to give meaning to treaties that accords with that agreed to during the drafting of a treaty and in subsequent practice. The specific relevance of article 31 to WTO adjudication is well established in law and practice: the WTO *Understanding on Rules and Procedures Governing the Settlement of Disputes* mandates that WTO dispute settlement panels interpret trade agreements according to customary rules of interpretation of public international law (article 3.2). WTO dispute settlement panels have interpreted this provision to require reference to article 31 of the *Vienna Convention* (*India—Patents*, 1998, paragraph 45; *US—Carbon Steel*, paragraphs 61–62; *US—Gasoline*, 1996, pp. 15–6). Article 31 of the *Vienna Convention*, therefore, may be read as requiring that TRIPS be interpreted in light of its provisions in their entirety, as well as subsequent agreement and practice and other relevant rules of international law. As the following sections illustrate, subsequent agreement and practice around TRIPS and access to medicines in particular may hold important interpretive value in adjudicating health concerns that arise under the agreement.

However at a normative and practical level, article 31.3.c, which authorizes reference to "any relevant rules of international law applicable between the parties", is most likely to enable recognition of the right to health within TRIPS. This article most obviously links disparate treaties, and is viewed as animating the principle of systemic integration whereby contextual interpretation of treaties takes account of a broader normative environment within international law (ILC, 2007, pp. 420–3; McLachlan, 2005).

International tribunals are using article 31.3.c as a linkage device between disparate bodies of international law, including the International Court of Justice (*Oil Platforms*, 2003, paragraph 41), the European Court of Human Rights (*Al-Adsani*, 2001; *Bosphorus*, 2005; *Fogarty*, 2001; *McElhinney*, 2001), and the Iran–US Claims Tribunal (*Esphahanian*, 1983). Moreover, a WTO tribunal has referred to this section, albeit only in a footnote, as the basis for seeking additional interpretive guidance of article XX of the GATT according to general principles of international law (*US-Shrimp*, 1998, paragraph 181).

Whether this section could be used to take account of the right to health would however depend on whether an adjudicative body considered this right as "a relevant rule applicable between the parties". Nonetheless, it is doubtful whether this article alone provides a solution to systemic fragmentation (Higgins, 2006, p. 804). A recent international case illustrates why the problem of linkage is unlikely to be resolved simply by formal recognition of other rules of international law. In the 2005 *MOX Plant Case* heard by the International Tribunal for the Law of the Sea, the United Kingdom invoked three separate treaties and institutional procedures: the *United Nations Convention on the Law of the Sea* (UNCLOS), the *Convention on the Protection of the Marine Environment of the North-East Atlantic* (OSPAR Convention) and the *European*

Community and Eurotom Treaties within the European Court of Justice (*EC/EURATOM Conventions*). While the case clearly raised questions of which issue area should be determinative in the case, the UNCLOS tribunal addressing this issue also noted that

even if the OSPAR Convention, the EC Treaty and the Euratom treaty contain rights or obligations similar to or identical with the rights set out in [the UNCLOS], the rights and obligations under these agreements have a separate existence from those under [the UNCLOS] (*MOX Plant*, 2005, paragraph 50).

This decision suggests that different institutions applying the same rules could come up with widely varying results, given “differences in the respective context, object and purpose, subsequent practice of parties and *travaux préparatoires*” (ILC, 2006, paragraph 12). The implication therefore, is that “the meaning of legal rules and principles is dependent on the context in which they are applied. If the context, including the normative environment, is different, than even identical provisions may appear differently” (ILC, 2006, paragraph 12). This problem is exemplified in international law, where specialized regimes respond to different functional and technical requirements, providing considerably different normative environments for interpreting even ostensibly similar rules (ILC, 2006, paragraph 15.) The *telos* (or ultimate end) of each regime will therefore fundamentally influence how rules are interpreted. Assuring that TRIPS will be interpreted in accordance with the right to health may therefore require more than simple reference to other formal international legal rules, and may instead require achieving a shift in the normative priorities underlying the trade regime, however long-range the achievement of this outcome may be. Nonetheless, the approach to interpretation laid out in the *Vienna Convention* provides an interpretive approach, which may enable the prioritization of health within TRIPS even on its own terms.

Interpreting TRIPS in light of the Vienna Convention

As its title suggests, a primary purpose of an agreement on trade-related intellectual property rights is to protect intellectual property rights within all WTO member states. The agreement achieves this goal succinctly, requiring members to provide patents that confer exclusive rights for 20 year periods. The context of the agreement also is reflective of its purpose: TRIPS is an annex to the *Marrakesh Agreement*, which established the WTO, and this context locates TRIPS firmly within a legal system driven by the *telos* of free trade. This ambition is explicit in the very first lines of the preamble of TRIPS, which indicate that its primary object is to protect intellectual property rights in the context of free trade while ensuring that intellectual property rights enforcement does not itself become a barrier to trade. This recognition reflects the somewhat contradictory inclusion of TRIPS within the WTO, as the WTO aims to reduce market barriers and remove protectionist measures, while TRIPS (and intellectual property) is protectionist and can create barriers to trade by limiting imports and exports (Frankel, 2005, pp. 373–4). This point is somewhat moot because the existence of TRIPS is itself illustrative of an acceptance of intellectual property rights as a reasonable limit on trade. However, this argument does suggest that excessive intellectual property rights protection would fall foul of the agreement to the extent that it interfered with free trade (Frankel, 2006, p. 374).

A third objective is reflected in the preamble, namely the need to balance intellectual property rights protection as private rights with public policy objectives, and the recognition that least developing countries have special needs for maximum flexibility. These provisions were inserted in the agreement at its drafting at the urging of developing countries that feared the negative impacts of TRIPS on public welfare and wished to highlight the importance of the public policy imperatives

underlying national intellectual property rights systems (Adede, 2003, p. 28; Barbosa *et al.*, 2007, pp. 93–4).

The need to balance intellectual property rights protection with public policy is iterated most explicitly in articles 7 and 8. Article 7 indicates that the objective of TRIPS is that intellectual property rights promote innovation to the mutual advantage of end users and producers of intellectual property, in a manner conducive to social and economic welfare and a balance of rights and obligations. Article 8 is explicit that as governments implement TRIPS they “may adopt measures necessary to protect public health and nutrition”. The language of mutual advantage, public health and social welfare provide explicit links for right-consistent interpretations cognizant of the public welfare implications of intellectual property restrictions on drug access. However, the provisions are silent on what this entitles governments to do, and only indicate the proviso that these measures should be consistent with TRIPS. Yet the implication is that these measures should include the provisions TRIPS itself famously provides in exclusions, exceptions and limitations that implicitly recognize the need to balance intellectual property rights with social welfare interests. For example, members can exclude certain inventions from patentability to protect life or health, make limited exceptions to exclusive rights, authorize use without consent (through compulsory licensing), limit rights to prevent anti-competitive measures, and parallel import cheaper patented medicines (TRIPS articles 27.1, 30, 31, 40 and 6). These provisions, therefore, seem to reflect the balance sought within the agreements: namely, to protect intellectual property rights without unduly restricting either free trade or public welfare. From the perspective of the *Vienna Convention on the Law of Treaties*, these are the objects and purpose that must be balanced by treaty interpreters.

TRIPS and the WTO Dispute Settlement Procedure

Since 1995, 28 TRIPS-related complaints have been lodged at the WTO dispute settlement units. Fourteen of these cases (50%) were settled, while nine went to panel reports, and three to the appellate body. Two other complaints are still in consultation and relate directly to pharmaceutical patents. These nine cases comprise the entire body of the WTO dispute settlement body’s jurisprudence on TRIPS, four of which addressed pharmaceutical patents (see Table 1). These TRIPS cases have been criticized as largely interpreting the object, purpose and context of TRIPS in favor of protecting intellectual property rights, and giving little weight to arguments about public welfare (Barbosa *et al.*, 2007, p. 99; Frankel, 2005; pp. 373–4; Howse, 2002; Shanker, 2002). This approach is evident in the first two cases decided on TRIPS, where WTO panels upheld

Table 1: TRIPS Jurisprudence

<i>India—Patent Protection</i> , 1997
<i>India—Patent Protection</i> , 1998
<i>Canada—Patent Protection of Pharmaceutical Products Case</i> , 2000
<i>US—Section 110(5) of the US Copyright Act</i> , 2000
<i>Canada—Term of Patent Protection</i> , 2000
<i>United States—Section 211 Omnibus Appropriations Act of 1998</i> , 2002
<i>European Communities—Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs</i> , 2005
<i>European Communities—Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs</i> , 2005
<i>China—Measures Affecting the Protection and Enforcement of Intellectual Property Rights</i> , 2009

challenges by the United States and European Union against what they alleged was India's insufficient protection for patents during its transition period to full implementation of TRIPS. In the first *India—Patents Case*, which dealt with the US complaint, the Appellate Body upheld the panel's finding that India's failure to provide mailbox protection and exclusive marketing rights during its transition period violated articles 70.8 and 9 of TRIPS. Despite explicit reference to article 31 of the *Vienna Convention*, the Appellate Body found that TRIPS' primary object and purpose as deduced from the preamble were "to take into account, *inter alia*, "the need to promote effective and adequate protection of intellectual property rights"" (*India—Patent Protection for Pharmaceutical and Agricultural Chemical Products*, 1997, paragraph 57).

This emphasis on intellectual property rights to the exclusion of other interests is repeated in the 2000 *Canada—Pharmaceuticals* case, where a WTO panel interpreted the limited exception provision in such a narrow way that intellectual property rights were protected as a primary objective, and public interest arguments made under articles 30, 7 and 8 were effectively ignored. This decision has been criticized as reflecting a one-sided and narrow interpretation of the object and purpose of TRIPS, and interpreting TRIPS "largely from the perspective of intellectual property rights holders, abstracting from competing social interests, and reducing considerably the range of regulatory diversity permitted under TRIPS" (Howse, 2002, p. 494). As other commentators have suggested, this approach is in conflict with international law's approach to treaty interpretation as it focuses on a single provision rather than reading the whole treaty together (Barbosa *et al.*, 2007, p. 102).

The Doha Declaration, TRIPS Amendment and State Practice on AIDS

It is doubtful in light of subsequent legal and political events whether WTO panels today would take a similarly restrictive approach to interpreting TRIPS. A primary intervening variable is the *Doha Declaration on TRIPS and Public Health*, passed at the urging of developing countries at the Doha round of WTO trade negotiations in November 2001 (WTO, 2001). These countries sought legal clarification of their right to use TRIPS flexibilities given political limitations of previous efforts to do so (World Health Organization, 2002). The Doha Declaration recognizes the agreement of member states that TRIPS does not and should not prevent members from taking measures to protect public health, and that TRIPS should be interpreted and implemented in a manner supportive of WTO member's right to protect public health and, in particular, to promote access to medicines for all, including through using TRIPS flexibilities to the full (WTO, 2001, paragraph 4). The Doha Declaration explicitly seeks to raise the priority of articles 7 and 8, indicating that customary rules of interpretation require reading TRIPS provisions in light of its object and purpose, particularly its objectives and principles (the official titles of articles 7 and 8) (WTO, 2001, paragraph 5.a). The declaration also notes the need to revise the compulsory licensing provision to allow production for export (WTO, 2001, paragraph 6). A decision to do so was made by the WTO in 2003 and will become a formal amendment to TRIPS itself when two thirds of all WTO members have accepted the change (the deadline for which has been extended to 31 December 2011).

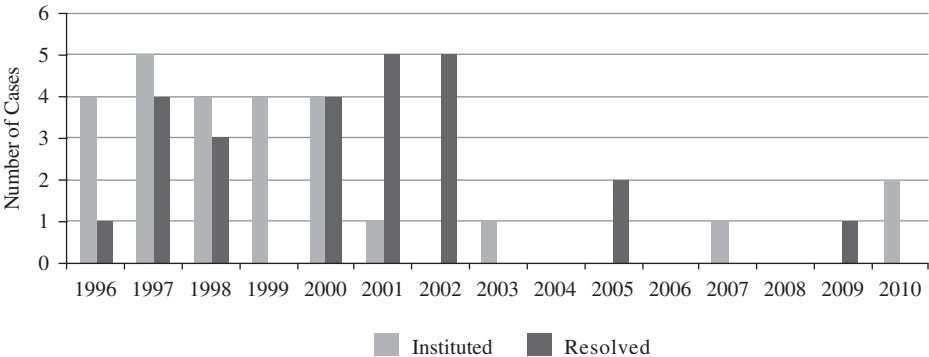
The Doha Declaration is not a formal amendment of TRIPS, and has no specific legal status within WTO law (WTO, 2001, p. 43). However, it could be construed as a subsequent agreement that should guide the interpretation of a treaty as envisaged in article 31.3.a of the *Vienna Convention* (Frankel, 2005, p. 400). If so, this would certainly found arguments that state intentions require panels to recognize health as an interest within TRIPS at least of equal weight to intellectual property rights. The Doha Declaration's use of the terms "right to protect health and promote access to medicines" also provides a framework to support references to similar rights

in international law. This suggestion has precedent in WTO law: in the *Shrimp case*, a WTO panel used several international environmental treaties and non-binding instruments to interpret a key term in article XX (*US—Import Prohibition of Certain Shrimp and Shrimp Products*, 1998). Yet as indicated above, panels interpreting TRIPS have not been particularly welcoming of social welfare concerns, and it is unclear from the jurisprudence what approach they would take to recognizing the right to health.

What is clear is that a panel's approach today is likely be quite different given political and legal developments with regard to TRIPS. In addition to the Doha Declaration, there have been very important changes in state practice around AIDS treatment under TRIPS, which has become broadly accepted as a legitimate reason for limiting intellectual property rights. This acceptance is reflecting in growing issuances of compulsory licenses for AIDS medicines, including by Malaysia, Indonesia, Zambia, Zimbabwe, Mozambique, Brazil and most recently Thailand (Love, 2007). However, it remains unclear whether these gains can be expanded out of the HIV/AIDS or pandemic context to apply to public health needs more generally, as disputes over Thailand's compulsory licensing of cancer drugs suggest. These changes in state practice around the use of TRIPS flexibilities are also legally significant as the *Vienna Convention* indicates that treaties can be interpreted by reference to subsequent state practice to assess agreements regarding interpretation. Such practices will be relevant to adjudication should another case on TRIPS reach the WTO's dispute settlement panels.

For much of the past decade, this outcome seemed unlikely. In the first place, the dispute settlement process (including in relation to TRIPS) had primarily been used by developed countries (Leitner and Lester, 2007, p. 165). In the first 10 years of dispute resolution, less developed countries had brought only one case and had never been the respondents in WTO disputes (Leitner and Lester, 2007, pp. 167–8). These trends likely reflect structural barriers for developing countries to using the mechanism as a strategic venue, and to this extent may also suggest the limitations of this venue for developing countries to protect health needs affected by trade. At the same time, until fairly recently, there had been a significant drop in the use of WTO dispute settlement for TRIPS cases: The majority of TRIPS cases were instituted between 1996 and 2000, with only three cases instituted between 2000 and 2008, none of which related to pharmaceutical patents (see Table 2). This lacuna is likely to have resulted from the fact that instead of relying on dispute settlement at the

Table 2: TRIPS Cases 1996–2010



WTO to protect against lenient application of intellectual property rights, the United States uses its own unilateral sanctions (the Special 301 mechanism) to enforce these rights. Moreover, developed countries are directly negotiating bilateral and regional free trade agreements with developing countries that impose even stricter intellectual property rights than contained in TRIPS. For example, around 60 countries are currently bound by bilateral or regional free trade agreements negotiated by the United States (Forman, 2006). These stricter intellectual property rights have the strategic effect of ratcheting these standards globally, as the non-discrimination requirement of WTO law requires that standards given to one country be given to all (Drahos, 2005, p. 7).

In 2010, two complaints were lodged at the WTO, which reveal a reversal of the trend of low use of the dispute settlement mechanism by developing countries, and which are highly relevant to this paper's core inquiries. In May 2010, India and Brazil lodged complaints against the European Union and the Netherlands for their seizure of generic drugs in transit, claiming that this seizure violated *inter alia*, article 28, 2, 41, 42 and 31 of TRIPS read with the 30 August 2003 decision (WTO, 2010a; 2010b). In its request for consultations, India argued further that "the measures at issue also have a serious adverse impact on the ability of developing and least-developed country members of the World Trade Organization to protect public health and to provide access to medicines for all" (WTO, 2010a, p. 3). India adopted a line of reasoning similar to the interpretive approach explored in this article, arguing that

the provisions of the TRIPS Agreement referred to above must be interpreted and implemented in light of the objectives and principles set forth in Articles 7 and 9 of the TRIPS Agreement, the Doha Ministerial Declaration on the TRIPS Agreement and Public Health adopted on 14 November 2001 and in the light of Article 12(1) of the International Covenant on Economic, Social and Cultural Rights, which recognizes the right of all persons to the enjoyment of the highest attainable standard of physical and mental health.

Should these cases proceed to WTO panels, they will provide an important testing ground for the interpretation of TRIPS provisions in the context of the agreement as a whole, and in relation to article 12 of the International Covenant on Economic, Social and Cultural Rights. Moreover, the outcomes of these complaints may illustrate the extent to which the WTO dispute settlement process could provide protection to developing countries to access affordable medicines with the framework of TRIPS and subsequent amendments and agreements.

Implications for Reform

What then are the implications of the legal analysis on hierarchy and interpretation for effectively raising the primacy of health in the interpretation of TRIPS provisions and for assuring reference to rights standards at the WTO? Certainly the Doha Declaration and the *de facto* carve out of AIDS medicines from the application of TRIPS provisions seem to animate the priority of life and health interests within international politics and law. The promotion of these interests by social actors and governments ensured that TRIPS provisions were curtailed in practice and (minimally) in law, to the extent that they conflicted with these interests. These gains were not achieved through adjudication but through social action, and this suggests that legal strategies alone are insufficient approaches for achieving linkages between rights and trade.

Thus, efforts to achieve linkage may be equally effectively aimed by social actors at domestic policy making. Achieving a pragmatic linkage between health and pharmaceutical patents in the minds of policy makers may acculturate a policy response where intellectual property rights are not implemented or negotiated without reference to their health impacts or the legal flexibilities.

Prominent human rights experts propose that a right to health impact assessment of trade-related intellectual property rights may serve to create this kind of pragmatic linkage (United Nations Commission on Human Rights, 2004). This outcome is surely a lesson that can be drawn from the very title of TRIPS itself, which is an agreement to relate trade and intellectual property rights, essentially forcing a marriage between the two despite the fact that they have no natural association. Certainly a primary implication of the legal analysis is that it should directly influence how TRIPS is applied, and support the most expansive use of TRIPS flexibilities possible.

However, this approach has important limitations beyond the clear difficulties that still persist in using flexibilities. The first is that using the legal flexibilities will never resolve the systemic impact of TRIPS on global production and export of generic medicines, which have become strictly confined to licensing and export authorized under TRIPS. Much depends on the extent to which major generic producers like India can maintain the policy space they have carved out to ensure generic production. Nonetheless expanded use of legal flexibilities will never fully contain the global impact of this agreement on access to generic medicines. A more insidious danger is that relying on exceptions effectively proves the rule, and reinforces the legitimacy of TRIPS itself. In other words, arguing that exceptions should be made for AIDS, diabetes or other narrowly defined exceptions simply reinforces the general rule that drug patents in poor countries should be respected and extended for all other cases. This is not ground that should be ceded, and indeed arguments that TRIPS should be excised from WTO are forthcoming not simply from treatment advocates, but from prominent economists like Joseph Stiglitz and Jagdish Bhagwati (Bhagwati, 2004, p. 182; Stiglitz and Charlton, 2005, pp. 141–6). Bhagwati, an ardent supporter of free markets, describes the inclusion of TRIPS at the WTO as a result of “pharmaceutical and software companies muscling their way into the WTO to turn it into a royalty-collection agency simply because the WTO can apply trade sanctions” (Bhagwati, 2004, p. 182). This is an important arena in which human rights and economic arguments can cohere and suggest more broadly that efforts to achieve reform should not simply aim for the lenient application of TRIPS but should rather argue that for some and perhaps even all countries, it should not apply at all.

Another danger of the interpretive approach is that little is achieved by inserting formal rules into a system if those rules continue to be seen as foreign to that system. Legal systems cohere to their internal logics and priorities and trend toward compliance with those logics and priorities. Achieving counter-systemic objectives is not impossible, but will be exceptional. This certainly seems to be the case in the WTO cases which trend, as they should, toward achieving the WTO’s systemic objectives of free trade. The implication is that formal linkages to rights through interpretation are unlikely to achieve public health objectives, and that inserting rights into TRIPS will be ineffective without a normative recognition of health as a comparable or superior interest. Formal rules will always be deprioritized in service of deeper normative priorities unless they can be seen to be relevant to them, and the confluence of rights and trade toward avoiding excess intellectual property rights seems to provide important framing for this outcome. However, achieving this outcome requires advancing toward a new *telos* for the global trading system in which trade and social values can be upheld as synergistic rather than competing aims (Cho, 2005, p. 674).

Assuring a more appropriate balancing of health and trade interests is not dependent, however, on establishing the legal priority of health over trade within international law’s hierarchically superior norms. As Koskeniemi suggests in the Fragmentation Report in relation to section 103 duties, “the importance of the notion – like the importance of *ergo omnes* obligations – may lie less in the way the concepts are actually “applied” than as signals of argumentative possibilities and boundaries for institutional decision-making”. The drawback to arguing that health is a prioritized value based on its putative hierarchical status within international law is of

course that if these arguments fail, then so does the argument for the priority of health. Engaging in analytic distinction regarding the hierarchical status of health as a human right within international law may therefore unnecessarily raise the bar for protecting the right to health (and ergo all human rights), by pinning its priority to the putative legality of the right to health within *jus cogens*, obligations *ergo omnes* or article 103 of the UN Charter. The inquiry into hierarchy cannot therefore be the sole strategy for raising the priority of health within trade. Instead these rules suggest the importance of shifting adjudicative interpretation of trade rules toward recognition of the broader international law framework.

Ultimately these arguments may most effectively be used to promote a political agenda regarding health as a value that seeks to influence the state interests, preferences and practices that lead to the creation of new international legal rules. The argument regarding superiority should therefore be seen as a normative and pragmatic exercise in shifting *lex lata* (the law as it should be) to *lex ferenda* (the law as it is). Achieving this goal requires re-conceiving human rights as providing a normative framework for resolving trade-offs between trade and health interests in light of the normative importance of human rights values and pre-existing approaches to balancing rights within human rights law and theory according to principles of necessity and proportionality (Lang, 2007, p. 379).

Conclusion

This article overviews strategic methods of achieving linkage between the right to health and trade rules within international law. However, these approaches to linkage do not propose the integration of human rights into trade rules. This implies the one-way insertion of rights into TRIPS or the WTO, a strategic approach that is not simply overly narrow but potentially counterproductive. A formal recognition of rights at the WTO is unlikely to raise their priority unless they are linked to the deeper normative priorities of international law, of which the right to health forms an integral part. The integration therefore should be not of rights into TRIPS but of TRIPS into the broader normative system of international law. This argument holds important implications for the formulation and interpretation of the substantive provisions of TRIPS and for its enforcement.

This argument finds important support in international law, as this paper seeks to illustrate. Yet, the legal exegesis necessary to support this claim is itself illustrative of the moral imbalance within international politics: There is something absurd in having to go to such great lengths to establish that human life should be worth more than property or trading interests. Having to do so defies common sense. Yet, this is not the common sense encoded into TRIPS, which relegates health protection to a non-essential exception to a property right. Historical shifts around slavery, women's suffrage and colonialism suggest that systemic changes are possible, and that we should not restrict ourselves to pragmatism at the expense of transformation. The aim of reform should therefore be to achieve the integration of the priority of health into the very fabric of economic and political life, not simply because it serves important instrumental ends, which it does, but because we do not choose to live in a world where elementary considerations of humanity can be so easily and pragmatically ignored.

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