RAISING THE RIGHT TO HEALTH CONCERNS WITHIN THE FRAMEWORK OF INTERNATIONAL INTELLECTUAL PROPERTY LAW[*]

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ABSTRACT

Balancing the trade-off between the pursuits for economic interests (from the protection of the intellectual property rights) and public health (from promotion of human rights to health) is always a complicated issue and sometimes a tragic choice. Even though international trade laws afford member countries the flexibility to impose restrictions on intellectual property rights to protect public health, individuals' rights to health (especially the right to access affordable medicines) are still frequently sacrificed. This article proposes that applying the human rights approach to the international intellectual property regime would provide the state an objective and monitorable standard to balance the conflicts between the intellectual property right and the right to health. Furthermore, by defining the scope of the right to health protection, this article develops an independent assessment mechanism (the right to health impact assessment for intellectual property policies) to provide both developing and developed

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countries legal grounds to refuse unjustified intellectual property protection (when fundamental rights to health are at stake) and to prevent the TRIPS-exemptions from being misused (when only some vague notion of public health is at stake).

KEYWORDS: *right to health, human rights impact assessment, intellectual property rights, pharmaceutical patents, TRIPS Agreement*

I. INTRODUCTION

Access to medicines is very important to the control of epidemics and diseases. For example, World Health Organization (WHO) studies have shown that approximately three million people die from HIV/AIDS, two million from tuberculosis, and one million from malaria in developing countries each year.[1] These epidemics are treatable diseases that could have been prevented, treated or even cured by existing medications. But people in poor countries have little chance to recover from these epidemics because they have no resources to access essential medicines. Therefore, international human rights documents have recognized that the right to health in all its forms and at all levels contains economic accessibility (affordability) as an important element, meaning health facilities, goods (including medicines) and services have to be accessible and affordable to everyone without discrimination.[2]

However, the World Trade Organization (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights [hereinafter TRIPS Agreement] brought about very important changes in international standards relating to intellectual property rights and posed a direct conflict with the international human rights to health, established by the International Covenant on Social, Economic and Cultural Rights (ICESCR). This has notably been the case in relation to pharmaceuticals[3] because the consumption of medicines is sensitive to price.[4] More specifically, the framework of stringent intellectual property rights established by the TRIPS Agreement enables pharmaceutical manufacturers to charge prices

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[1] WHO, *Deaths by Age, Sex and Cause for the Year 2002*, *available at* http://www.who.int/healthinfo/global_burden_disease/estimates_regional_2002_revised/en/ (last visited Mar. 3, 2010); JOINT UNITED NATIONS PROGRAMME ON HIV/AIDS & WORLD HEALTH ORGANIZATION, AIDS EPIDEMIC UPDATE 2 (2005), *available at* http://www.who.int/hiv/epi-update2005_en.pdf (last visited Mar. 4, 2010); WORLD HEALTH ORGANIZATION, PUBLIC HEALTH, INNOVATION AND INTELLECTUAL PROPERTY RIGHTS: REPORT OF THE COMMISSION ON INTELLECTUAL PROPERTY RIGHTS, INNOVATION AND PUBLIC HEALTH – REPORT OF THE COMMISSION ON INTELLECTUAL PROPERTY RIGHTS, INNOVATION AND PUBLIC HEALTH 2-3 (2006), *available at* http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf (last visited Mar. 4, 2010); WORLD HEALTH ORGANIZATION, TOWARDS UNIVERSAL ACCESS: SCALING UP PRIORITY HIV/AIDS INTERVENTIONS IN THE HEALTH SECTOR: PROGRESS REPORT 5 (2009), *available at* http://www.who.int/entity/hiv/pub/tuapr_2009_en.pdf (last visited Mar. 6, 2010).

[2] *See generally* U.N. Econ. & Soc. Council [ECOSOC], Comm. On Econ., Soc. & Cultural Rts. [CESCR], *General Comment No. 14: Substantive Issues Arising in the Implementation of the International Covenant on Economic, Social and Cultural Rights – The Right to the Highest Standard of Health*, U.N. Doc. E/C. 12/2000/4 (Aug. 11, 2000) [hereinafter *CESCR General Comment 14*].

[3] Carlos M. Correa, *TRIPS Agreement and Access to Drugs in Developing Countries*, 2(3) INT'L J. HUM. RTS. 25, 25 (2004).

[4] COMMISSION ON INTELLECTUAL PROPERTY RIGHTS, INTEGRATING INTELLECTUAL PROPERTY RIGHTS AND DEVELOPMENT POLICY 37 (2002).

above marginal costs,[5] which transforms the ability of governments to monitor and protect public health by restricting their capacity to ensure affordable access to medications and to regulate health conditions.[6] Even though the Doha Declaration on the TRIPS Agreement and Public Health[7] [hereinafter Doha Declaration] and the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health[8] [hereinafter 2003 Decision] recognize the "gravity" of the public health problems and reflect concerns regarding the implications of the TRIPS Agreement,[9] these documents left a number of technical legal problems unresolved.[10] For example, because the term "epidemics" in the Doha Declaration[11] has been left undefined, governments may face challenges from pharmaceutical manufacturers on whether the issuing of compulsory licenses over certain medications (e.g. chronic disease medications) surpasses the "national emergency" provision[12] (see more discussion in section (III)(A)). There are also concerns that the administrative burden associated with the procedural arrangement for notifying the WTO[13] will

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[5] Correa, *supra* note 3, at 25.

[6] Ellen R. Shaffer et al., *Global Trade and Public Health*, 95(1) AM. J. PUB. HEALTH 23, 23 (2005).

[7] World Trade Organization [hereinafter WTO], Ministerial Conference of 14 November 2001, WT/MIN(01)/DEC/W/2 (Nov. 14, 2001).

[8] WTO, Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, WT/L/540, (Sept. 2, 2003) [hereinafter 2003 Decision].

[9] Correa, *supra* note 3, at 26.

[10] John H. Barton, *TRIPS and the Global Pharmaceutical Market*, 23(3) HEALTH AFF. 146, 149-52 (2004).

[11] Declaration on the TRIPS Agreement and Public Health, ¶ 5(c), WT/MIN(01)/DEC/2 (Nov. 20, 2001) [hereinafter Doha Declaration]: ("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 and other epidemics, can represent a national emergency or other circumstances of extreme urgency.")

[12] For example, when the Thailand government issued a compulsory license over Plavix (a heart disease medication), its action represents the first time a compulsory license was authorized for a chronic disease medication, as opposed to being issued over an infectious disease medication. Pharmaceutical manufacturers therefore argued that it demonstrates "how the world is rapidly approaching a slippery slope of accepting any nation's arbitrary issuance of a compulsory license over any type of drug available on the market." Jamie Feldman, *Compulsory Licenses: The Dangers Behind the Current Practice*, 8 J. INT'L BUS. & L. 137, 151-52 (2009). Press Release, Ambika Ahuja, Associated Press, Thailand: Abbott Laboratories Won't Introduce New Drugs in Thailand Due to Breaking of Patent (Mar. 14, 2007), *available at* http://www.aegis.com/news/ads/2007/AD070549.html (last visited Mar. 4, 2010) [hereinafter Abbott Laboratories Press Release].

[13] 2003 Decision, *supra* note 8, ¶ 2(a): ("[T]he eligible importing Member(s) has made a notification to the Council for TRIPS, that:
(i) specifies the names and expected quantities of the product(s) needed;
(ii) confirms that the eligible importing Member in question, other than a least-developed country Member, has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question in one of the ways set out in the Annex to this Decision; and;
(iii) confirms that, where a pharmaceutical product is patented in its territory, it has granted or intends to grant a compulsory licence in accordance with Article 31 of the TRIPS Agreement and

be costly for developing countries.[14]

The disarray in protecting public health stems partly from the fact that the international intellectual property framework has been regarded as a complicated and important component of the international trade regime and thus health concerns have been moved out from its traditional arena. In contrast to the importance it places on economic globalization, the international society has shown less concern over trade-related threats to global health.[15] In addition, the pursuits of opposing goals by international intellectual property rights and human rights (the right to health) suggest the possibility of legal conflicts between these two regimes. Resolving the legal, policy, and normative conflicts between international intellectual property rights and the right to health is therefore an important issue.

In this article I focus on exploring what the engagement of the right to health actors and languages has brought to the debate about international intellectual property systems, and on developing a human rights impact assessment to build the state's capacity to understand the implications of international intellectual property rights agreements for health.[16]

II. TENSIONS BETWEEN INTELLECTUAL PROPERTY RIGHTS AND THE RIGHT TO HEALTH

Balancing the trade-off between the pursuits for economic interests (from the protection of the intellectual property rights) and the promotion of human rights to health is a complicated issue and sometimes a tragic choice.[17] The debate mainly concerns issues of justice, fairness, and equity that are raised by the adverse impact of trade, particularly among vulnerable countries and communities.[18] There thus is a huge controversy as to the grounds on which developed and developing countries debated regarding an international undertaking of the magnitude in the protection of pharmaceutical patents and concerns for public health.

The problem here is that when it comes to decision-making and

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the provisions of this Decision 6.")

[14] Duncan Matthews, *WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: A Solution to the Access to Essential Medicines Problem?*, 7(1) J. INT'L ECON. L. 73, 97 (2004).

[15] Shaffer et al., *supra* note 6, at 23.

[16] World Health Assembly [hereinafter WHA], Report of an Expert Group Meeting, *Trade and Health: Developing a Toolkit for National Assessment*, at 1-2, (New Delhi, Mar. 6-7, 2007) [hereinafter Report of an Expert Group Meeting].

[17] Tragic choices reflect the regrettable but inevitable tension between the fulfillment of the right to health care and the efficient allocations of scarce resources. GUIDO CALABRESI & PHILIP BOBBITT, TRAGIC CHOICES 15-28 (1978). CLARK C. HAVIGHURST ET AL., HEALTH CARE LAW AND POLICY: READINGS, NOTES, AND QUESTIONS 6-7 (1998).

[18] James Thou Gathii, *International Justice and the Trading Regime*, 19(3) EMORY INT'L L. REV. 1407, 1407 (2005).

priority-setting, the right to health is often lost in a sea of economic considerations. Individuals' rights to health (especially patients' rights to access affordable medicines in developing countries) are often sacrificed under the international intellectual property regime in order to pursue the general economic interests. U.S. policy on HIV/AIDS is illustrative. U.S. policy on this issue tends to prioritize the protection of intellectual property rights because pharmaceutical manufacturers have persuaded society that pharmaceutical patents, which offer the promise of advanced development of medicine and a cure, are crucial drivers of public health initiatives rather than barriers.[19] Similarly, the TRIPS Agreement also establishes a standard of intellectual property protection (including pharmaceutical patents) on the basis of the premise that intellectual property protection is the best means for facilitating later access to affordable medication. However, such a strong commitment to pharmaceutical patents protection might come at the expense of access to drugs for the world's poor.[20]

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[19] Jamie Crook, *Balancing Intellectual Property Protection with the Human Right to Health*, 23(3) BERKELEY J. INT'L L. 524, 532 (2005).

[20] *Id.* at 533-34. Some might argue that the TRIPS Agreement does provide less developed countries access to patented medicines by granting them a longer transitional time before providing intellectual property rights with such products. According to Article 66(1) of the TRIPS Agreement, in view of the special needs and requirements of least-developed countries (LDCs) – such as economic, financial and administrative constraints, and needs for flexibility to create a viable technological base, these countries shall not be required to apply the provisions of the TRIPS Agreement (other than Articles 3, 4 and 5) for a period of time. In addition, the Council for TRIPS may accord extensions of the transitional period on the basis of LDCs' requests. In 2002 the WTO council responsible for intellectual property has approved a decision extending the transition period until 2016, during which LDCs do not have to provide patent protection for pharmaceuticals. Therefore, LDCs (if they have enough resources and proper technologies) can still manufacture life-saving medicines without paying any royalties to pharmaceutical manufacturers and sell these medicines for much lower prices. In other words, with the transitional provision, pharmaceutical patent protection in the TRIPS Agreement seems not necessarily accompanied with burdens on individuals' right to access affordable medicines. However, even though the transitional provision is of the utmost importance in terms of access to medicines in the developing world, it can hardly be regarded as a stable international legal framework that can fully protect individuals' right to health (especially those in LDCs). First, the transitional period will expire eventually. The expiry of the transitional period for LDCs is likely to result in an increase in the prices of patented medicines and a corresponding decrease in access. Second, even after the transitional periods, there are strong doubts that LDCs would have the resources to stay abreast of new technology and innovation to produce new medicines. Third, the transitional provision, with its technology focus, seems to overlook LDCs' actual needs for flexibilities in implementing the TRIPS Agreement to protect public health. Press Release, WTO News, Press/301, Council Approves LDC Decision with Additional Waiver (June 28, 2002), *available at* http://www.wto.org/english/news_e/pres02_e/pr301_e.htm (last visited Mar. 4, 2010). Bryan C. Mercurio, *Resolving the Public Health Crisis in the Developing World: Problems and Barriers of Access to Essential Medicines*, 5(1) NW. J. INT'L HUM. RTS. 1, 19 n.61 (2006). Karin Timmermans, *Ensuring Access to Medicines in 2005 and Beyond*, *in* NEGOTIATING HEALTH: INTELLECTUAL PROPERTY AND ACCESS TO MEDICINES 41, 41-42 (Pedro Roffe et al. eds., 2006). Samnang Chea & Hach Sok, *Cambodia's Membership in the WTO and the Implications for Public Health*, 4 YALE J. HEALTH POL'Y, L. & ETHICS 363, 371 (2004). Riadh Quadir, *Patent Stalemate? The WTO's Essential Medicines Impasse Between Pharmas and Least Developed Countries*, 61(2) RUTGERS L. REV. 437, 450 (2009).

The WTO also recognizes that trade liberalization (or globalization) has led to monetary and regulatory changes that have transformed health and disease, and diminished individual control over health status while magnifying the impacts of societal determinants of health. Therefore, international trade institutions have made efforts to allow member states to take actions that restrict trade if they are "necessary to protect human . . . life or health" (see Article 27(2)[21] of the TRIPS Agreement). Furthermore, the WTO appellate body announced that "WTO members have a right to determine the level of protection of health that they consider appropriate in a given situation."[22] In other words, member states may choose their desired level of health protection, and that this is the level of protection to consider when determining whether a measure is "necessary".[23] Read in conjunction with the WTO standard for reviewing such actions, these provisions seem to permit scrutiny by dispute settlement panels leading to objective assessments of claims of health care needs (or health necessity) made in support of trade restrictions.[24] In 2001 after the WTO's Ministerial Conference at Doha, Qatar, the Doha Declaration was issued and confirmed that the TRIPS Agreement "can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and,

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[21] Agreement on Trade-Related Intellectual Property Rights art. 27(2), Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments – Results of the Uruguay Round, 33 I.L.M. 1125 (1994) [hereinafter TRIPS Agreement]: ("Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.")

[22] Appellate Body Report, *European Communities – Measures Affecting Asbestos and Asbestos-Containing Products*, ¶ 168, WT/DS135/AB/R (Apr. 5, 2001) [hereinafter *EC Asbestos AB Report*].

[23] A variant of the least restrictive alternative approach to the "necessary for" formulation is important and has been employed by GATT and WTO panels. For example, the Appellate Body in European Communities – Measures Affecting Asbestos and Asbestos-Containing Products, like the United States - Restrictions on Imports of Tuna panels – read Article XX(b) to incorporate a least GATT-inconsistent requirement: a measure is not "necessary" under Article XX(b) if "an alternative measure which [the party] could reasonably be expected to employ and which is not inconsistent with other GATT provisions is available to it," and if no GATT-consistent measure is reasonably available, the party is "bound to use, among the measures reasonably available to it, that which entails the least degree of inconsistency with other GATT provisions." In Thailand - Restrictions on Importation of and Internal Taxes on Cigarettes, the GATT panel found that the import restrictions imposed by Thailand on cigarettes could be considered to be "necessary" in terms of Article XX(b) only if there were no alternative measure consistent with the General Agreement, or less inconsistent with it, which Thailand could reasonably be expected to employ to achieve its health policy objectives. *Id.* ¶ 171. Panel Report, U*nited States – Restrictions on Imports of Tuna*, ¶ 155, DS21/R – 39S/155 (Sept. 3, 1991). Panel Report, *Thailand – Restrictions on Importation of and Internal Taxes on Cigarettes*, ¶ 75, DS/10/R – 37S/200 (Nov. 7, 1990) [hereinafter *Thailand Cigarettes GATT Panel Report*].

[24] M. Gregg Bloche & Elizabeth R. Jungman, *Health Policy and the World Trade Organization*, *in* GLOBALIZATION AND HEALTH 254 (Ichiro Kawachi & Sarah Wamala eds., 2007).

in particular, to promote access to medications for all."[25] Member states then are allowed to use exceptions in the TRIPS Agreement to the compulsory licensing provision to address "public health crises, including those related to HIV/AIDS, tuberculosis, malaria and other epidemics [that] can represent a national emergency or other circumstances of extreme urgency."[26] They also have the freedom to "determine the grounds upon which such licenses are granted."[27] In 2003, the WTO General Council announced its 2003 Decision authorizing a developed member-state to compel compulsory licenses from its own manufacturers, create generic versions of medications, and export those medications to countries in need.[28] This decision resolved the technical legal problem left by the Doha Declaration of how compulsory licensing should be applied to help countries that lack manufacturing capabilities to make medications themselves. In 2006, the World Health Assembly (WHA) also passed a resolution on "international trade and health" that addressed coordination in the development of trade and health policies and urged WHO Members "to promote multi-stakeholder dialogue at [a] national level to consider the interplay between international trade and health."[29]

III. FAILURE TO PROTECT THE RIGHT TO HEALTH THROUGH THE INTERNATIONAL INTELLECTUAL PROPERTY RIGHTS MECHANISM

No doubt, international trade laws, such as Article 31(b) (compulsory licensing)[30] of the TRIPS Agreement, the Doha Declaration and the 2003

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[25] Doha Declaration, *supra* note 11, ¶ 4: ("We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement 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.")

[26] *Id.* ¶ 5(c).

[27] *Id.* ¶ 5(b).

[28] 2003 Decision, *supra* note 8.

[29] Fifty-Ninth World Health Assembly, *International Trade and Health*, WHA 59.26, *available at* http://www.who.int/gb/ebwha/pdf_files/WHA59/A59_R26-en.pdf (last visited on Mar. 4, 2010).

[30] TRIPS Agreement, art. 31(b): ("Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected: . . . (b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public noncommercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly.")

Decision, afford member countries the flexibility to impose restrictions on international trade to protect human, animal, and plant life or health. These laws also permit trade restrictions in the case of national emergency (such as a health crisis of epidemic proportions). There seems to be no place for public health concerns within the international trade regime since such concerns could be accommodated as special exceptions to the basic obligations of trade liberalization[31]. Yet there are reasons to doubt these provisions will play a critical role in providing affordable health care to fight disease and disabilities.

A. Vague Scope of Exemptions from the TRIPS Agreement

The exemptions provided by the TRIPS Agreement and other international trade documents contain major problems of ambiguity and non-uniformity in application.[32] The vagueness no doubt is necessary because the importance of illness varies with the social circumstances, and the pandemic exception must leave room for such variation. But the vagueness might also cause violations of the right to health.

For example, although the Doha Declaration tries to provide member states with reasonably detailed instructions as to how to interpret those flexibilities,[33] many key terms and issues are still left open to interpretation. According to the Doha Declaration, even though each member state has "the freedom to determine the grounds upon which [compulsory] licences are granted,"[34] the use of the subject matter of a patent without the authorization of the right holder is still limited to "national emergency or other circumstances of extreme urgency or in cases of public noncommercial use,"[35] which includes "those relating to HIV/AIDS, tuberculosis, malaria and other epidemics."[36] Because these provisions do not further explore the content and scope of a "national emergency", the state maintains substantial authority to interpret a public health issue as "not an emergency" and to arbitrarily prioritize economic interests over public health without justification and vice versa.[37] In addition, because

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[31] Gathii, *supra* note 18, at 1422.

[32] Vishal Gupta, *A Mathematical Approach to Benefit-Detriment Analysis as a Solution to Compulsory Licensing of Pharmaceuticals Under the TRIPS Agreement*, 13 CARDOZO J. INT'L & COMP. L. 631, 659 (2005).

[33] For example, according to the Doha Declaration, each member State is entitled to determine suitable grounds for granting compulsory licenses (Paragraph 5(b)), and each member can state what a "national emergency" is, while pandemics (AIDS, tuberculosis, and malaria are clearly stated in the Declaration as cases of pandemics) are automatically proclaimed a national emergency or other circumstances of extreme urgency (Paragraph 5(c)).

[34] Doha Declaration, *supra* note 11, ¶ 5(b).

[35] TRIPS Agreement, art. 31(b).

[36] Doha Declaration, *supra* note 11, ¶ 5(c).

[37] In other words, due to the vagueness there is hardly any legal qualification to prevent the

the term "epidemic" has been left undefined,[38] the Doha Declaration lacks legal validity to expand its scope from "HIV/AIDS, tuberculosis, and malaria" (which are automatically proclaimed as national emergencies) to other serious health care problems.[39] The content of "national emergency" therefore remains ambiguous because one member state still has the authority to define a certain disease (e.g. obesity) as a health crisis while another does not. Due to this vagueness, developed countries and the pharmaceutical industry then argue that it is justified to restrict the scope of "national emergency" such that it refers only to "HIV/AIDS, tuberculosis, and malaria.[40] For example, in the dispute about compulsory licensing for AIDS/HIV drugs between the U.S. and South Africa, the U.S.'s concession on South Africa's compulsory licensing was clearly limited solely to AIDS drugs and not for other needed pharmaceuticals.[41] In other words, even though the U.S. government eventually acknowledged South Africa's authority to grant compulsory licenses for AIDS/HIV drugs and pledged to withdraw the threat of sanctions, scholars believe that the U.S. simply backed down due to harsh political pressure rather than actually recognizing the legality of compulsory licensing.[42]

Article 27(2) of the TRIPS Agreement presents a similar problem. Article 27(2) authorizes member states to exclude from patentability inventions when it is "necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment" without exploring the meaning of "necessity". Developing countries are likely to argue that necessity should fall within the definition of "flexibility" which enables countries to decide when is "necessary to protect ordre public or morality" based upon national standards. But with such a vague standard, developing countries can also

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government from abusing compulsory licensing. Melissa McClellan, Note, *"Tools for Success": The TRIPS Agreement and the Human Right to Essential Medicines*, 12 WASH. & LEE J. CIVIL RTS. & SOC. JUST. 153, 160-61 (2005).

[38] Since any epidemic can potentially affect public health, restricting the definition of "epidemic" will violate the Doha commitment to public health. In addition, different countries have their own public health problems to face. As a result, the term "epidemic" then should be left undefined in the Doha Declaration, enabling nations to decide what an epidemic is based on national standards. Srividhya Ragavan, *The Jekyll and Hyde Story of International Trade: The Supreme Court in PhRMA v. Walsh and the TRIPS Agreement*, 38(4) U. RICH. L. REV. 777, 831 (2004).

[39] Even though the Doha Declaration's statement regarding the term "national emergency" aids in its interpretation of "epidemics", it still falls short of providing a concrete definition. *Id.* George Tsai, Note, *Canada's Access to Medicines Regime: Lessons for Compulsory Licensing Schemes Under the WTO Doha Declaration*, 49(4) VA. J. INT'L L. 1063, 1074 (2009).

[40] The U.S. insisted that an exemption be limited to HIV/AIDS, tuberculosis, and malaria with no scope for "other epidemics" to be included. Matthews, *supra* note 14, at 86 (2004)

[41] J.M. Spectar, *Patent Necessity: Intellectual Property Dilemma in the Biotech Domain and Treatment Equality for Developing Countries*, 24(2) HOUS. J. INT'L L. 227, 265 (2002).

[42] Sara M. Ford, *Compulsory Licensing Provisions Under the TRIPS Agreement: Balancing Pills and Patents*, 15(4) AM. U. INT'L L. REV. 941, 955-56 (2000).

easily decide that exclusions to patentability are not necessary and thereby restrict their citizens' right to health in exchange for greater economic interests, especially when they are required to set stricter standards for intellectual property protection to attract foreign investments. For example, after Thailand issued a compulsory license for a patented heart disease medicine, one leading pharmaceutical company stopped introducing new medicines in Thailand[43] and the U.S. signaled its displeasure by placing Thailand on its "priority watch list" of countries that do not adequately protect intellectual property.[44] Since economic coercion (such as the use of the U.S. Trade Act's Super 301) plays an important factor behind developing countries' ultimate decisions when they face conflicts between intellectual property rights and public health, the flexibility provided by the TRIPS Agreement then might backfire by granting the state substantial authority to interpret "necessity" such that it can arbitrarily prioritize intellectual property rights over the right to health without assessing the impact on human rights in a way that can be enforced and monitored.

Due to the vagueness of the pandemic exception in the TRIPS Agreement and other multilateral trade and intellectual property agreements, the scope of diseases to be covered by any exception to pharmaceutical patent rights therefore has become the major issue in balancing intellectual property rights and human rights to health. On the one hand, developed countries want the scope of diseases, which are regarded as public health problems (related to human life or health protection) or national emergency, limited to those constituting a true "public health crisis."[45] On the other hand, developing countries argued that there should be no defined list of eligible diseases for any exception to pharmaceutical patent rights[46] because such a list cannot adequately address the actual public health concerns that developing countries face. The difference is understandable because developed countries want to interpret most provisions narrowly to maximize economic interests from intellectual property while developing countries prefer a broader interpretation to improve accessibility of health

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[43] Abbott Laboratories, the manufacturers of Kaletra (the heart disease medicine), reacted to Thailand's actions by stating, "Thailand has revoked the patent on our medicine, ignoring the patent system. Under these circumstances we have elected not to introduce new medicines there." Abbott then withdrew seven registration applications for new pharmaceutical products in Thailand. Feldman, *supra* note 12, 153. *See also* Abbott Laboratories Press Release, *supra* note 12.

[44] Even thought the U.S. agreed that Thailand did not violate any world trade rules, it nonetheless placed Thailand on its priority watch list of the Special 301 Report. This list is reserved for countries that don't "provide an adequate level of intellectual property rights protection or enforcement." Ed Silverman, *US Trade Rep: Thailand on Watch List*, http://www.pharmalot.com/2007/04/us_trade_rep_thailand_on_watch/ (last visited Mar. 4, 2010).

[45] Bryan C. Mercurio, *TRIPS, Patents, and Access to Life-Saving Drugs in the Developing World*, 8(2) MARQ. INTELL. PROP. L. REV. 211, 237 (2004).

[46] *Id.*

care.[47] But the different, sometimes even contradictory and inconsistent, approaches applied to interpret exceptions of international trade laws operate at cross proposes and leave rooms for states to prioritize intellectual property rights over the right to health arbitrarily without justification. Furthermore, ambiguous and non-uniform provisions of international intellectual property laws lend themselves to the possibility of abuse and potentially destabilize the balance between intellectual property rights and the right to health.[48]

However, here I do not suggest that the international trade institutions should provide an explicit disease list of "other epidemics." A list-of-epidemics approach would not only violate countries' "sovereign commitment not to reduce the line between important and necessary drugs" [49] but also commit countries with different socio-economic conditions to one universal criterion. Nonetheless the absence of a theoretical framework (to clarify the vagueness) also obscures the Doha Declaration's commitment to the substantial protections of public health. In order to balance the "flexibility" required in the international intellectual property rights regime and the protection of the right to health, I suggest that there should be theoretical foundations and justifications to define national emergencies related to public health. Furthermore, since it is hard to derive such a basis from the international intellectual property regime, further explication of the right to health can help international institutions to create a theoretical framework. More specifically, in addition to a general notion of "public health",[50] interpreting international intellectual property laws in light of a defined right to health can help international institutions to explore the content and scope of the pandemic exception, to assess developed countries' claims to intellectual property and developing countries' claims regarding public health, and to identify the significance of the fundamental diversity of different epidemics. For example, defining "the right to decent minimum of health care"[51] (or "the right to the highest attainable standard of health")[52] and identifying the state's core obligation

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[47] *Id.*

[48] *Id. at* 236-37.

[49] Ragavan, *supra* note 38, at 831.

[50] Generally speaking, even though the trade agreements are promising steps toward making access to HIV/AIDS, tuberculosis, and malaria, the WTO negotiations and agreements noticeably avoid any over recognition of human rights. McClellan, *supra* note 37, at 160.

[51] Allen Buchanan argued that the notion of minimum should be applied to both to health and health care in the international human rights regime to avoid the excesses of the strong equal access principle, which would exhaust available resources. Allen E. Buchanan, *The Right to a Decent Minimum of Health Care*, 13(1) PHIL. & PUB. AFF. 55, 55-56 (1984).

[52] According to the CESCR General Comment No. 14, the right to the highest attainable standard of health should not to be understood as a right to be healthy and is subject to progressive realization and resource availability. However, even though the right to health is subject to resource constraints, it still gives rise to some core obligations of immediate effect, which can help the

"to ensure the satisfaction of, at the very least, minimum essential levels"[53] would offer more guidance than the current "public health" language of the agreements, which leaves too much to discretion.[54] In addition, because the human rights approach only points out a functional relationship between diverse health care needs and the various institutions responsible for fulfilling them, after a proper assessment the state can still grant the authority to decide the exact nature of a "national emergency" related to public health (see more discussion in section IV).

B. TRIPS Agreement as a Minimum Standard of Intellectual Property Rights Protection

In the ongoing development of the international intellectual property rights regime, developed countries tend to take positions more restrictive than the TRIPS Agreement because they see the TRIPS Agreement as a minimum standard of protection. But such provisions governing pharmaceutical patent protection that far exceed the protections offered by the TRIPS Agreement further threaten least developed countries' ability to realize the right to health.

According to Article 1(1) of the TRIPS Agreement, "[m]embers may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement." Because the TRIPS Agreement merely sets minimum standards of intellectual property rights, and countries are free to negotiate and bind themselves to more stringent intellectual property rights protections, developed countries then pursue bilateral free trade agreements (FTAs) that require intellectual property rights protection far in excess of standards set by the TRIPS Agreement. These enhanced protections are termed "TRIPS-plus."[55]

Therefore, in addition to enforcing different legal actions through the WTO, developed countries (such as the U.S.) pursue the proliferation of bilateral investment and intellectual property agreements that incorporate TRIPS-plus standards of intellectual property protection to enforce various TRIPS provisions against developing countries.[56] As a result,

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society to prioritize different health care needs. *CESCR General Comment No. 14*, *supra* note 2, ¶¶ 8, 43-45.

[53] See Paragraphs 43-45 of the CESCR General Comment No. 14 and more discussion in section (IV)(B).

[54] McClellan, *supra* note 37, at 160.

[55] Charles T. Collins-Chase, Comment, *The Case Against TRIPS-Plus Protection in Developing Countries Facing AIDS Epidemics*, 29(3) U. PA. J. INT'L L. 763, 765 (2008).

[56] For example, the U.S. has threatened Brazil, South Africa, and Thailand with trade sanctions for making efforts to pursue generic pharmaceutical manufacturing. Even though the U.S. has dropped its WTO complaint against Brazil in 2001, which followed the removal of unilateral threats of

pharmaceutical patents have been included in the definition of "investment" to be encouraged and reciprocally protected in bilateral treaties on the basis of developed countries' requests.[57] Europe has consistently pushed developing countries to establish longer periods of data exclusivity.[58] The U.S. Trade Representative (USTR) has also pushed for increased levels of intellectual property rights and required including data exclusivity and patent linkage in every U.S. FTA to date. For example, Article 16.8 of the U.S.-Singapore FTA contains a standard data exclusivity provision[59] which is not part of a traditional patent regime but rather a parallel form of intellectual property protection that can exist even when a pharmaceutical product is not patented.[60] According to Article 39(3) of the TRIPS Agreement, the states are required "only" to protect undisclosed test or other data against unfair commercial use.[61] Therefore, such a strong protection of undisclosed test data provided in the U.S.-Singapore FTA obviously is not secured through the TRIPS Agreement. However, due to the minimum standards of intellectual property rights protection specified in the TRIPS Agreement, it is justified for the U.S. and other developed countries which favor stronger data protection to impose these terms on nations through bilateral agreements. These bilateral trade treaties with TRIPS-plus provisions thus reflect the view of developed countries that the TRIPS Agreement is merely a minimum and inadequate baseline for pharmaceutical patent protection.[62]

Patent linkage is another example. Article 19.5 of the U.S.-Korea FTA provides a patent-registration linkage provision, which requires the party

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sanctions against South Africa and Thailand in 1999 and 2000 due to the local and global outcry against the U.S. actions, the U.S. still tries to push for increased levels of pharmaceutical patents through bilateral trade agreements. For example, the United States Trade Representative (USTR) required including data exclusivity and patent linkage, which will significantly delay generic product's entry into the market, in every U.S. free-trade agreement (FTA) to date. Sarah Joseph, *Pharmaceutical Corporations and Access to Drugs: The "Fourth Wave" of Corporate Human Rights Scrutiny*, 25(2) HUM. RTS. Q. 425, 445-46 (2003). Robert Galantucci, *Data Protection in a U.S.-Malaysia Free Trade Agreement: New Barriers to Market Access for Generic Drug Manufacturers*, 17(4) FORDHAM INTELL. PROP. MEDIA & ENT. L. J. 1083, 1091 (2007).

[57] *Id.*

[58] Brook K. Baker, *Ending Drug Registration Apartheid: Taming Data Exclusivity and Patent/Registration Linkage*, 34(2) AM. J. L. & MED. 303, 307 (2008).

[59] United States - Singapore Free Trade Agreement, U.S.-Sing., May 6, 2003, at 196, *available at* http://www.ustr.gov/trade-agreements/free-trade-agreements/singapore-fta/final-text (last visited Mar. 4, 2010).

[60] Galantucci, *supra* note 56, at 1096-97.

[61] TRIPS Agreement, art. 39(3): ("Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.")

[62] Susan K. Sell, *Trade Issues and HIV/AIDS*, 17(2) EMORY INT'L L. REV. 933, 946 (2003).

"to implement measures in its marketing approval process to prevent such other persons from marketing a product without the consent or acquiescence of the patent owner."[63] Article 17.10(5) of the U.S.-Australia FTA has similar provisions which not only require that "[the] drug regulatory authority may not approve a generic drug for marketing while the brand name drug is under patent unless the patent holder permits it," but also obligate generic manufacturers to notify patent owners when seeking marketing approval of a generic version of a drug. In other words, patent linkage provisions put the burden on the second applicant (generic manufacturers) to prove that the originator's patent is invalid, and require the national regulatory agency to act as "patent police" and assess the validity of the patent.[64] However, despite their presence in several U.S. FTAs (See Table 1), it is important to be aware that these patent linkage requirements are entirely unprecedented in the TRIPS Agreement.[65]

[63] United States - Korea Free Trade Agreement, U.S. – Korea, June 30, 2007, *available at* http://www.ustr.gov/trade-agreements/free-trade-agreements/korus-fta/final-text (last visited Mar. 6, 2010).

[64] Galantucci, *supra* note 56, at 1098.

[65] Carlos M. Correa, *Bilateralism in Intellectual Property: Defeating the WTO System for Access to Medicines*, 36(1) CASE W. RES. J. INT'L L. 79, 90-91 (2004).

Table 1 U.S. Free Trade Agreements about Pharmaceutical Patents Protection

Central American Free Trade Agreement (CAFTA)	A country's drug regulatory authority may not approve a generic drug for marketing while the brand name drug is under patent (unless the patent holder permits it). A patent owner must be notified if another party seeks marketing approval of a generic version of a drug while it is still under patent (Article 15.10(2))
U.S.-Jordan FTA	A patent owner must be notified if another party seeks marketing approval for a generic version of a drug while it is still under patent.(Article 4(23))
U.S.-Singapore FTA	A country's drug regulatory authority may not approve a generic drug for marketing while the brand name drug is under patent, unless the patent holder permits it-essentially giving the regulatory authority the role of another layer of IP enforcement. (Article 16.8(4)(c))
U.S.-Chile FTA	A country's drug regulatory authority may not approve a generic drug for marketing while the brand name drug is under patent (unless the patent holder permits it). A patent owner must be notified if another party seeks marketing approval of a generic version of a drug while it is still under patent. (Article 17.10(2)(b-c))
U.S.-Australia FTA	A country's drug regulatory authority may not approve a generic drug for marketing while the brand name drug is under patent (unless the patent holder permits it). A patent owner must be notified if another party seeks marketing approval of a generic version of a drug while it is still under patent. (Article 17.10(5))
U.S.-Morocco FTA	A country's drug regulatory authority may not approve a generic drug for marketing while the brand name drug is under patent (unless the patent holder permits it). A patent owner must be notified if another party seeks marketing approval of a generic version of a drug while it is still under patent. (Article 15.10(4))
U.S.-Korea FTA	Where a Party permits, as a condition of

	approving the marketing of a pharmaceutical product, persons, other than the person originally submitting safety or efficacy information, to rely on that information or on evidence of safety or efficacy information of a product that was previously approved, such as evidence of prior marketing approval in the territory of the Party or in another territory, that Party shall: (a) provide that the patent owner shall be notified of the identity of any such other person that requests marketing approval to enter the market during the term of a patent notified to the approving authority as covering that product or its approved method of use; and (b) implement measures in its marketing approval process to prevent such other persons from marketing a product without the consent or acquiescence of the patent owner during the term of a patent notified to the approving authority as covering that product or its approved method of use. (Article 19.5)

These TRIPS-plus provisions then enforce patent-like barriers to the accessibility of affordable generic medication and cause serious violations on the right to health. First, data exclusivity in the FTAs would prevent a generic pharmaceutical company from getting its competing drugs to the market in a timely manner[66] because generic manufacturers can no longer use the earlier test data that was submitted in the original drug manufacturer's application to apply for marketing approval.[67] Data exclusivity may also impact the ability of a government to issue a compulsory license, which is considered a valuable mechanism for reducing drug prices.[68] Second, the practice of patent linkage, which prevents a drug manufacturer from obtaining market approval for a drug while the original version is still under patent unless by consent of the patent owner, would prevent the generic drug from immediately entering the market upon expiration of the patent.[69] In the negotiation of the U.S.-Malaysia FTA, the U.S. further required Malaysian regulatory agencies to make patent infringement decisions, ignoring that the

[66] Galantucci, *supra* note 56, at 1102.
[67] *Id.* at 1098.
[68] *Id.*
[69] *Id.* at 1102-03.

Malaysian government is incapable of assessing patent rights.[70] Such a requirement then would significantly extend the effective length of a patent owner's market exclusivity and delay the entrance of cheaper generic drugs on the market. Furthermore, because many FTAs preclude the use of intellectual property flexibilities that are crucial policy options in the TRIPS Agreement for combating the disease,[71] they effectively restrict individuals' right to access affordable medicines. Therefore, applying both the minimum levels of global intellectual property standards in the TRIPS Agreement and stronger intellectual protections for pharmaceuticals in the FTAs, the U.S. may have succeeded in euthanizing both Article 31 (compulsory licensing) of the TRIPS Agreement and the Doha Declaration.[72]

However, due to the minimum standard established by the TRIPS Agreement, it is difficult to make TRIPS-plus provisions illegal and to avoid upsetting the balance between the right to health and intellectual property rights struck by the WTO. Furthermore, the vagueness of the TRIPS-compliant flexibilities (see section (III)(A)) strengthen the influence of TRIPS-plus provisions on public health. For example, it is not clear what the TRIPS Agreement means by "necessary measures" which the state may adopt "to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development."[73] Thus, developed countries might argue that "necessary measures" imply that there are no other alternatives possible and that only the least intrusive, disruptive measures will be used"[74] (e.g. U.S. may argue that price discount programs would create a non-infringing alternative to compulsory licenses and abrogation of data exclusivity).[75] By using ambiguity about the meaning of "necessary measures", developed countries can launch backdoor pressure against developing countries to adopt TRIPS-plus provisions. Consequently, even though TRIPS-plus provisions might significantly impair public health, these provisions would still be regarded as justified because the obligations to implement patent linkage or data exclusivity in the FTAs would not affect the state's ability to take "necessary measures" to protect public health by promoting access to medicines for all.[76]

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[70] *Id.* at 1103.
[71] Collins-Chase, *supra* note 55, at 783.
[72] Baker, *supra* note 58, at 330-31.
[73] TRIPS Agreement, art. 8(1).
[74] Aaron Xavier Fellmeth, *Secrecy, Monopoly, and Access to Pharmaceuticals in International Trade Law: Protection of Marketing Approval Data Under the TRIPs Agreement*, 45(2) HARV. INT'L L.J. 443, 450-52 (2004).
[75] Baker, *supra* note 58, at 332-33.
[76] *See, e.g.*, Off. of the U.S. Trade Representative, Understanding Regarding Certain Public Health Measures (side letter of the CAFTA) (Aug. 5, 2004), *available at* http://www.ustr.gov/sites/default/files/uploads/agreements/cafta/asset_upload_file697_3975.pdf.

The TRIPS Agreement's and other international trade documents' intermediate and contradictory position on the protection of public health in the international intellectual property rights regime has created an obstacle for developing countries to stand against developing countries. Due to lack of a consistent theoretical basis, developing countries have no solid legal grounds or pragmatic strategies to resist developed countries' demands that stricter obligations be imposed to protect intellectual property rights through TRIPS-plus provisions. Thus, if international institutions want to persist in balancing intellectual property rights and public health, inconsistency between these conflicting approaches needs to be resolved, and an independent and coherent conceptual logic needs to be established. In addition to the international trade approach, the human rights approach is an option to supplement the TRIPS Agreement with a theoretical basis to balance the costs of epidemics against the benefits of FTAs with developed countries. In addition, a right to health approach could lend greater legal certainty to the provisions regarding pharmaceutical patent laws and health, and thus help developing countries to face and resist TRIPS-plus requirements from developed countries.[77]

C. Effects of Power Asymmetries

Because developing countries need access to large industrialized country markets, their trade dependence on developed countries gives the latter considerable economic leverage over the former.[78] The asymmetric power relationships between developed and developing countries are then reflected in continued threats or use of trade sanctions and the proliferation of bilateral investment.[79] In other words, developed countries can force developing countries to adopt and enforce strict and highly protectionist intellectual property policies (e.g. TRIPS-plus provisions) by threatening trade sanctions against developing countries. Such economic coercion is an important factor in the failure of many developing countries to provide affordable health care.

In order to balance (or to rectify) power asymmetries in international trade relationships, it is then necessary to establish objective criteria regardless of different countries' voluntaristic preferences to evaluate trade-offs between intellectual property rights and public health. However, ambiguous and non-uniform provisions of international intellectual property laws prevent the establishment of an independent assessment mechanism that can be monitored. The lack of such a mechanism combined

(last visited Mar. 4, 2010).

[77] McClellan, *supra* note 37, at 161.

[78] Sell, *supra* note 62, at 944.

[79] *Id.* at 945.

with structural power asymmetries between developed and developing countries in turn has an adverse impact on the provisions of public health. Because of the ambiguity of the TRIPS-exemptions, they can hardly provide theoretical or legal bases for developing countries, which have little or no bargaining power in negotiations, to reevaluate intellectual property rights policies. Developing countries then are forced to accept developed countries' view that an exemption can be made for HIV/AIDS, tuberculosis and malaria only with no scope for "other epidemics" to be included.[80] As the example described earlier, when Thailand attempted to use TRIPS-exemptions guaranteed and encouraged by the Doha Declaration to issue compulsory licenses on patented drugs for heart disease and cancer, the USTR placed Thailand on the special 301 "priority watch list" for alleged violations of intellectual property law.[81] In addition, because the TRIPS Agreement adopts minimum standards of intellectual property rights protection, developing countries have no legal basis to guard against proposals to introduce TRIPS-plus provisions in FTAs. Laboring under structural power asymmetries, these countries are forced to accept increasingly common bilateral treaties with stricter intellectual property rights provisions.[82]

A monitorable and objective standard based on human rights impact assessment therefore could help to endow the attempts by developing countries to restrict international intellectual property rights with a degree of moral legitimacy, the force of legal obligation, and a sense that they are somehow beyond the possibility of compromise or negotiation.[83] Proper assessment of the trade-offs between pharmaceutical patents and public health interests provided by human rights impact assessment could also help societies to decide the scope of "necessary measures" to protect public health and the definition of "national emergency." Furthermore, with a proper assessment, developing countries would have stronger claims to face critical structural challenges in resisting relentless pressures from developed countries to adopt inappropriate and excessive international trading regimes. In other words, characterizing specific goals (public health concerns, such as access to low-cost antiretroviral medications effective against AIDS) as human rights (the right to health) through an objective criterion then can elevate these goals above the rank and file of competing societal goals (e.g. intellectual property rights), give them a degree of immunity from challenge, and endow them with an aura of absoluteness

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[80] Matthews, *supra* note 14, at 86-87.

[81] OFFICE OF THE U.S. TRADE REPRESENTATIVE, 2007 SPECIAL 301 REPORT 27 (2007).

[82] There were fewer than twenty such bilateral agreements with developing countries in the 1960s. By 1996, more than 400 bilateral treaties had been signed among developing countries and countries of Eastern Europe. *Id.*

[83] Andrew T.F. Lang, *Re-Thinking Trade and Human Rights*, 15(2) TUL. J. INT'L & COMP. L. 335, 395 (2007).

and universal validity.[84]

IV. RE-EVALUATING INTERNATIONAL INTELLECTUAL PROPERTY AND THE RIGHT TO HEALTH RELATIONSHIP

As discussed in section (III), international intellectual property laws and policies significantly influence individuals' right to access affordable medicines. But these laws and policies are seldom evaluated with attention to their impact on the right to health or the norms of international human rights laws. In other words, international intellectual property laws and policies are sometimes formulated without careful consideration of their consequences, whether the means adopted will achieve those proposed policy goals, and whether intended economic interests outweigh the human rights burden.

The human rights approach is one possible solution to resolve conflicts between intellectual property rights and public health, and has the capacity to bolster developing countries' public health responses when facing developed countries' challenges. Because the human rights approach is capable of defining the right to "decent minimum health care"[85] and to add clarity to the scope of public health protection, it can provide specific and explicit grounds "that both require more exceptions to intellectual property rights (e.g. compulsory license) when individual lives are at stake, and limit exceptions when only some vague notion of public health or public good is at stake."[86] Furthermore, since the trade and human rights (the right to health) debate is essentially one about coherence between international regimes, the human rights paradigm can in some sense be a practical approach to ensure that trade rules are developed and applied in ways that promote a fair and equitable trading system and to further establish a just international and social order.[87]

But the development of an international intellectual property rights regime is likely to push the protection and the fulfillment of the right to health out of its independent arena and to make health care merely a component of international trade policy. The ignorance is partly caused by the fact that international trade law, which mostly involves transactions between private actors and inter-linkages of private actors across state boundaries, was for a long time considered part of the "private" rather than

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[84] Philip Alston, *Making Space for New Human Rights: The Case of the Right to Development*, 1 HARV. HUM. RTS. Y.B. 3, 3 (1988).
[85] *See supra* note 53, ¶ 54.
[86] McClellan, *supra* note 37, at 161.
[87] Caroline Dommen, *Human Rights and Trade: Two Practical Suggestions for Promoting Coordination and Coherence*, *in* INTERNATIONAL TRADE AND HUMAN RIGHTS: FOUNDATIONS AND CONCEPTUAL ISSUES 199 (Frederick M. Abbott et al. eds., 2006).

the "public" sphere.[88] It is argued by many of those who negotiate international trade law rules that each of the two legal systems (international trade and international human rights) should take into account only its own rules and regulations.[89] Thus, right-to-health issues are rarely discussed within WTO bodies.[90] For example, the Doha Declaration argued that, while reiterating the commitment to the TRIPS Agreement, the state only needs to "affirm that the Agreement 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"[91] without explicitly referring to human rights.[92]

In addition, some are not convinced that there are tensions between intellectual property protection and the right to health, and propose that it is in the very nature of the existing international intellectual property regime to enhance human rights protection. In their proposal, if every country can respect and protect intellectual property rights of other countries, inventors and creators would have the maximum incentive to create, mutually benefiting the world. Consequently, protecting intellectual property in the international trading system maximizes the overall social interest and further promotes trade liberalization,[93] which most economists view as a means to wealth maximization.[94] If individuals' wealth can be maximized, they can then freely spend their own resources to purchase health care. For example, the WTO Consultative Board believes that "the exposure of governments and citizens to an international institutional framework dedicated to openness will have its effects on much more than commerce" and the WTO will only bring benefits to the promotion of human rights.[95] Therefore, international intellectual property law does not restrict the

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[88] JAMES HARRISON, THE HUMAN RIGHTS IMPACT OF THE WORLD TRADE ORGANISATION 34 (2007).

[89] *See, e.g.*, Joses E. Alvarez, *How Not to Link: Institutional Conundrums of an Expanded Trade Regime*, 7 WIDENER L. SYMP. J. 1, 10 (2001). Lorand Bartels, *Article XX of GATT and the Problem of Extraterritorial Jurisdiction: The Case of Trade Measures for the Protection of Human Rights*, 36(2) J. WORLD TRADE 353, 363 (2002). Robert Howse, *Human Rights in the WTO: Whose Rights, What Humanity? Comments on Petersmann*, 13(3) EUR. J. INT'L L. 651, 656 (2002).

[90] Some argued that taking the right to health into consideration during international trade rules negotiations would make it harder to achieve consensus between negotiating parties and therefore reduce the chances of welfare-increasing liberalization commitments. *See, e.g.*, E-U Petersmann, *The Human Rights Approach Advocated by the UN High Commissioner for Human Rights and by the International Labour Organisation: Is It Relevant for WTO Law and Policy?*, 7 J. INT'L ECON. L. 605, 611 (2004). Veijo Heiskanen, *The Regulatory Philosophy of International Trade Law*, 38(1) J. World Trade 1, 1 (2004),

[91] Doha Declaration, *supra* note 11, ¶ 4.

[92] HARRISON, *supra* note 88, at 36.

[93] AMRITA NARLIKAR, THE WORLD TRADE ORGANIZATION: A VERY SHORT INTRODUCTION 28-29 (2005).

[94] *Id.* at 2.

[95] WTO, THE FUTURE OF THE WTO: ADDRESSING INSTITUTIONAL CHALLENGES IN THE NEW MILLENNIUM 10 (2004).

fulfillment of the right to health and can help to promote individuals' opportunities to pursue their own conceptions of the good about health.

Increasingly, however, criticisms are made that treating the international intellectual property law system as an epitome of trade openness regardless of its impact on human rights is "an over-simplification that fails to take into account the multi-dimensional rationales."[96]

First, the state's obligation to respect, to protect, and to fulfill the right to health should not be totally excluded from the international trade regime. Since all WTO members have ratified at least one international human rights instrument with the vast majority having ratified many more,[97] these states are obliged to respect, to protect, and to fulfill the right to health[98] largely as written in existing international human rights laws[99] if the workings of the international trade regime are to have any legitimacy and ethical force.[100] States must not only respect the right to health when executing WTO intellectual property provisions through national legislation but also evaluate human rights burdens when drafting and implementing domestic patent laws. Furthermore, based on the fact that people and organizations worldwide rank health as one of the greatest goods,[101] many states have gradually recognized an individual's right to health as a basic socio-economic right in national constitutions.[102] Even if some countries,

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[96] *Id.* at 43.

[97] U.N. Econ. & Soc. Council [ECOSOC], Off. of the Comm'r for Human Rights, *Liberalization of Trade in Services and Human Rights – Report of the High Commissioner*, ¶ 5, U.N. Doc. E/CN.4/Sub.2/2002/9 (June 25, 2002).

[98] Lawrence O. Gostin, *The Human Right to Health: A Right to the "Highest Attainable Standard of Health"*, 31(2) HASTINGS CENTER REP. 29, 29 (2001).

[99] Many international human rights documents and organizations have proposed that individuals have the right to maintain the "highest attainable standard" of physical and mental health. *See, e.g.*, Universal Declaration of Human Rights art. 25.1, G.A.Res. 217A, at 71, U.N. GAOR, 3d Sess., 1st plen. mtg. U.N. Doc. A/810 (Dec. 12, 1948) [hereinafter UDHR]; International Covenant on Economic, Social, and Cultural Rights art. 12, G.A. Res. 2200A (XXI), 21 U.N. GAOR Supp. (No. 16), at 49, U.N. Doc. A/6316, 993 U.N.T.S. 3, 6 I.L.M. 368 (Dec. 16, 1966) [hereinafter ICESCR]; World Health Organization, Constitution of the World Health Organization, Pmbl, Off. Rec. Wld. Hlth. Org., 2, 100 (July 22, 1946).

[100] Kenneth Roth, *Defending Economic, Social, and Cultural Rights: Practical Issues Faced by an International Human Rights Organization*, 26(1) HUM. RTS. Q. 63, 64 (2004).

[101] HARVARD LAW SCHOOL HUMAN RIGHTS PROGRAM & FRANCOIS-XAVIER BAGNOUD CENTER FOR HEALTH AND HUMAN RIGHTS, ECONOMIC AND SOCIAL RIGHTS AND THE RIGHT TO HEALTH: AN INTERDISCIPLINARY DISCUSSION HELD AT HARVARD LAW SCHOOL IN SEPTEMBER 1993, at 17 (1995).

[102] For example, Section 27 of South Africa's constitution includes "health care, food, water and social security" as basic human rights. In Section 15(a) of the Finnish Constitution Act of 1995, the right to health is included in a broader provision of welfare rights. In Article 25 of the Japanese constitution, the state is obligated to maintain the minimum standards of wholesome and cultured living, which implies the right to health care of all citizens. FINLAND CONSTITUTION ACT s. 15(a) (1995). Section 157 and Amendment Section 10 of the Taiwan Constitution state that the government should provide adequate and sufficient health care services to support the health of people, especially the elderly, women, children, and the handicapped. TAIWAN CONSTITUTION s.

such as the U.S., do not recognize the right to health in their constitutions,[103] they have developed related but subordinate laws to substantially protect significant aspects of the right to health.[104] In other words, since most states across the globe have recognized the right to health for every citizen and have explicitly supported and accepted international human rights law, they should also be obliged to apply existing norms of the right to health as a primary basis for analysis of international intellectual property law rules because of the far more universal acceptance of the values contained therein.

Second, trade liberalization, which international intellectual property laws intend to achieve, does not necessarily enhance the right to health protection in all situations. The hypothesis – trade liberalization can promote the right to health – is that trade promotes economic growth and reduces poverty, so that citizens can have more resources to pursue their own good ends (including health).[105] However, it is difficult to justify trade liberalization on economic grounds alone because "the correlation between trade openness, poverty reduction, and development is a complex one."[106] Empirical studies have shown that the average price of brand name drugs in South Africa is about 230% as much as generic drugs.[107] The price of

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157 (The Constitution of the Republic of China, 1947); TAIWAN CONSTITUTION AMENDMENT s. 10 (Additional Articles of the Constitution of the Republic of China, 2005). Even when some countries, such as the United States, do not recognize the right to health in their constitutions, the related but subordinate issues of the right to health care are present in statutes and common laws. For example, the Social Security Act of 1935 first supported grants for maternal/infant care. The Economic Bill of Rights introduced "the right to adequate care and the opportunity to achieve and enjoy good health." The Patients' Bill of Rights of 2005 also mentioned "access to [health] care" and "nondiscrimination". *See generally* Social Security Act, ch. 531, 49 Stat. 620 (1935) (codified as amended in scattered sections of 42 U.S.C.); Economic Bill of Rights of 1944, 90 Cong. Rec. 55-57 (1944); Patients' Bill of Rights Act of 2005 (S. 1012, 109th Congress) (2005), *available at* http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=109_cong_bills&docid=f:s1012is.txt.pdf (last visited Mar. 6, 2010). In conclusion, the fact that the right to health care is codified in a substantial number of national constitutions implies that states generally recognize their responsibility regarding the health of their citizens, and support the existence of an international right to health care in "delivery of services", "quality assurance," "promoting good medical practice," etc.

[103] Kenneth R. Wing, *The Right to Health Care in the United States*, 2 ANNALS HEALTH L. 161, 163 (1993).

[104] For example, in the U.S., President Franklin D. Roosevelt's proposed Economic Bill of Rights of 1944 first introduced the idea of the right to adequate medical care and the opportunity to achieve and enjoy good health. The National Health Planning and Resources Development Act of 1974 required federal policy to provide "equal access to quality care at a reasonable cost." Carolynne Shinn, *The Right to the Highest Attainable Standard of Health: Public Health's Opportunity to Reframe a Human Rights Debate in the United States*, 4(1) HEALTH AND HUM. RTS. 114, 115 (1999). Economic Bill of Rights, 90 Cong. Rec. 55-57 (1944). National Health Planning and Resources Development Act, 42 U.S.C. § 300K (1974).

[105] HARRISON, *supra* note 88, at 42.

[106] *Id.* at 43.

[107] Hazel Tau et al. v. GlaxoSmithKline and Boehringer Ingelheim et al., Competition Commission of South Africa (Sept. 2002), *available at*

drugs in India also went up to 200%-750% after the implementation of intellectual property laws.[108] Therefore, even if trade liberalization (accompanying with intellectual property protection) can help individuals to earn more money, it does not necessarily mean that they can afford more expensive drugs. In addition to intellectual property protection, more mechanisms need to be established to guarantee individuals' access to affordable medicines.

In addition, poverty reduction does not reveal exact levels of health in vulnerable populations and thus is only a crude signifier of the right to health. For example, Amartya Sen argued that even though poverty can be sensibly identified in terms of capability deprivation, there are factors other than low income that cause capability deprivation.[109] Without basic capabilities (meaning decent minimal health, which is what the right to health guarantees)[110], individuals can hardly develop their own conceptions of the good[111] regarding how to use their external resources (income) to pursue the good ends of their life (including health care decisions). Therefore, an overall net gain in income through global trade policies is not, and should not be, equivalent to the right to health compliance because the latter puts more emphasis on ensuring an individual's life, health, and dignity.[112] In other words, in addition to economic efficiency, it is important to bring an added dimension (the right to health) and to measure

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http://www.tac.org.za/Documents/DrugCompaniesCC/HazelTauAndOthersVGlaxoSmithKlineAndOthersStatementOfComplaint.doc (last visited Mar. 6, 2010). BELINDA BERESFORD, THE PRICE OF LIFE: HAZEL TAU AND OTHERS V. GLAXOSMITHKLINE AND BOEHRINGER INGELHEIM – A REPORT ON THE EXCESSIVE PRICING COMPLAINT TO SOUTH AFRICA'S COMPETITION COMMISSION (2003).

[108] Shubham Chaudhuri et al., *The Effects of Extending Intellectual Property Rights Protection to Developing Countries: A Case Study of the Indian Pharmaceutical Market*, Columbia University Economics Department Discussion Paper No.: 0304-08, 31 (2003) (estimating price increases for India of in-between 200% and 750%). Carsten Fink, *How Stronger Patent Protection in India Might Affect the Behavior of Transnational Pharmaceutical Industries* 42 (World Bank Dev. Research Group, Policy Research Working Paper No. 2352 May 2000) (suggesting price increases for India of well over 200%).

[109] AMARTYA SEN, DEVELOPMENT AS FREEDOM 87-88 (1999).

[110] For example, Buchanan argued that common features are widely associated with the right to a decent minimum of health care. First, it is reasonably assumed that a decent minimum of health care, which allows individuals in a society to adjust the level of health care services to be provided as a matter of a right to relevant social conditions, is to be understood in a society-relative sense. Second, the idea of a decent minimum standard of health care avoids the excess of what has been called the strong equal access principle, which acknowledges a substantial universal right. Third, since the right to health must be limited in scope (to avoid the unfavorable consequences of a strong equal access right), it should be limited to the most basic services. Buchanan, *supra* note 51, at 57-59.

[111] According to John Rawls, the ability to have, to receive, and to rationally pursue a conception of good (the capability for a conception of the good) is what an individual needs to be a free, equal, and fully cooperating member of the society. Another one is the ability to understand, to apply, and to act based on the principles of political justice that specify the fair terms of social cooperation (the capability for a sense of justice). JOHN RAWLS, POLITICAL LIBERALISM 315-16 (1993). JOHN RAWLS, JUSTICE AS FAIRNESS: A RESTATEMENT 18-19 (2001).

[112] HARRISON, *supra* note 88, at 45.

the justice of the world trading system in considering and evaluating the impact of international trade regulations.

Third, the human rights approach "can provide an institutional space for the development of norms about [international intellectual property] policy which are different from, and contrary to, those circulating within the trade regime."[113] The elaboration of international human rights law relating to international intellectual property policy "may provide an impetus for the use of domestic human rights enforcement mechanisms to influence governments' [international intellectual property] policy positions."[114] The human rights approach then can not only offer a variety of policy technologies which may be used to achieve desirable international intellectual property policy outcomes but also make available a variety of strategies that can be used to exert considerable political pressure.[115]

I propose that an enforceable and monitorable human rights impact assessment should be established in order to evaluate restrictions on human rights to health under the international intellectual property regime. Generally speaking, human rights impact assessment, which focuses on careful gathering of relevant information, provided through perspectives of various disciplines, can provide society with credible arguments based upon "hard evidence" to justify or to condemn international intellectual property strategies.[116] Within a well-defined framework for human rights impact assessment for international intellectual property policies (see more discussion in section V), the human rights approach then can be adopted to supplement or interpret the flexibilities of international trade laws, to improve the implementation of international trade policies, and to provide reasonable and practical initiatives to evaluate trade-offs between economic interests and public health. For example, the list-of-services approach adopted by the Committee on Economic, Social and Cultural Rights [hereinafter CESCR] to prioritize the state's core obligations to fulfill certain rights to health care (e.g., rights to maternal and child health care, to immunization, to essential drugs, and to medical treatments for

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[113] Lang, *supra* note 83, at 397.

[114] *Id.*

[115] *Id.* at 396.

[116] According to Lawrence O. Gostin and Jonathan Mann, the protection of the right to health requires proper fact-finding because "a set of "facts" presented by the government may be incomplete or biased". In order to find out "hard evidence" when assessing human right impacts, broad-based consultation with experts in different fields, who can provide invaluable perspective regarding how policies affect human rights in their communities (such as international agencies, public health associations, advocacy groups, and community leaders), then is necessary. Lawrence O. Gostin & Jonathan M. Mann, *Towards the Development of a Human Rights Impact Assessment for the Formulation and Evaluation of Public Health Policies*, *in* HEALTH AND HUMAN RIGHTS: A READER 54, 55 (Jonathan M. Mann et al. eds., 1999).

epidemics)[117] can be applied as a criterion to interpret national emergency stated in Article 31(b) of the TRIPS Agreement. Thus, by applying human rights impact assessment to evaluate trade-offs between trade and public health, relationships between international trade laws and human rights to health institutions would become mutually supportive rather than competitive.[118]

However, I do not suggest that the human rights paradigm must be engaged at the level of ideas and knowledge in re-making the international economic order about intellectual property rights. I do not propose to establish a hierarchy of international intellectual property laws and human rights laws, or to interpret the provisions of international intellectual property laws in light of existing right to health obligations either.[119] It is illusory and represents an oversimplified account of how human rights language works to suggest that human rights can provide a set of

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[117] According to CESCR General Comment No. 14 art 43 and 44, state parties have the following core obligations (which directly relate to health care services): (1) to ensure access to the minimum essential food which is nutritionally adequate and safe; (2) to ensure access to basic shelter, housing and sanitation; (3) to ensure access to adequate supply of safe and potable water; (4) to provide essential drugs; to ensure reproductive, maternal (pre-natal as well as post-natal) and child health care; (5) to provide immunization against the major infectious diseases occurring in the community; (6) to take measures to prevent, treat and control epidemic and endemic diseases. *CESCR General Comment 14*, *supra* note 2, ¶¶ 43-44.

[118] However, when developing the right to health impact assessment in the international intellectual property regime, the fact that developing countries (especially LDCs) face the dilemma in prioritizing health care should not be ignored. Governments on the one hand must fulfill citizens' entitlements to a "decent minimum of health care", on the other hand governments also need to commit to improving economic efficiency and to reducing cost within the system. However, in order to avoid a great drain on resources, in most cases governments put more emphasis on the growth of gross national product (GNP), the rise in personal incomes, industrialization, technological advancement, and the reduction of economic cost (narrow views of development) than on health. Governments' unwillingness to devote resources into improving citizens' health would weaken the right to health impact assessment. In an attempt at revising the decline, scholars have tried to develop different strategies. For example, Bryan Mercurio also argued that government policies initiated to increase access to essential medicines "can rarely succeed without the support and understanding of all levels of government and community involvement". Therefore, in order to encourage developing countries to re-orientate their priorities of health care, Mercurio then proposed that all actors (including government ministries, academics, professionals, consumers, and NGOs) should be consulted and involved in the process of policy formulation and implementation. In addition, he also proposed a model of funding and assistance through the creation of a new agency to assist in developing and implementing a health framework in developing countries. In this model, a nation will be rewarded with additional funding and support if it is willing to participate and can demonstrate its continued commitment to improve health. On the contrary, the agency should not support a country that is unwilling to participate or does not desire to meaningfully prioritize health care. PAUL DOLAN & JAN ABEL OLSEN, DISTRIBUTING HEALTH CARE: ECONOMIC AND HEALTH ISSUES 32 (2002). Sen, *supra* note 109, at 3. Bryan C. Mercurio, *Health in the Developing World: The Case for a New International Funding and Support Agency*, 4(1) ASIAN J. WTO & INT'L HEALTH L. & POL'Y 27, 32-35 (2009).

[119] One of the problems is that the vagueness and the absence of theoretical foundations of the right to health might lead the interpretation to ambiguous or manifestly absurd result. Prabhash Ranjan, *Internaitonal Trade and Human Rights: Conflicting Obligations?*, *in* HUMAN RIGHTS AND INTERNATIONAL TRADE 311, 319 (Thomas Cottier & Joost Pauwelyn eds., 2005).

substantive values and rules to guide international intellectual property policy choices.[120] I merely suggest that the human rights (the right to health) paradigm might provide a variety of potentially effective policy tools – human rights impact assessment – for achieving desirable international intellectual property rights policy outcomes. These policy tools can help to provide a "trigger" for policy learning and to facilitate and enable the production of new ideas about desirable international intellectual property policy.[121] Without these policy tools provided by the human rights approach and some changes in ideas, a fair and just transformation of the international trading order is considerably less likely. Here, the human rights approach to international intellectual property protection is applied to "cooperate" with international trade regulations to enhance the state's capacity to understand the implications of international intellectual property laws for the right to health of the populations.[122]

V. THE FRAMEWORK OF THE RIGHT TO HEALTH

However, the difficulty most states face in balancing intellectual property rights and the right to health is that they have trouble distinguishing the fundamental and non-fundamental elements of the right to health (hereinafter "fundamental rights to health" and "non-fundamental rights to health"). Therefore, in order to further apply the right to health impact assessment in the international intellectual property regime, it is necessary to explore the contents of the right to health.

A. The Traditional Definition of the Right to Health

The U.N. Universal Declaration of Human Rights (UDHR) first recognized two sets of human rights: (1) civil and political rights, and (2) economic, social, and cultural rights, with the right to health included in the latter. Article 25.1 of the UDHR further affirms that "[e]veryone has the right to a standard of living adequate for the health of himself and of his family, including food, clothing, housing and medical care and necessary social services." In accordance with Article 12.1 of the International Covenant on Economic, Social, and Cultural Rights (ICESCR), state parties recognize "the right of everyone to the enjoyment of the highest attainable standard of physical and mental health," while Article 12.2 of the ICESCR enumerates, by way of illustration, a number of "steps to be taken by the States' parties . . . to achieve the full realization of this right." The preamble of the World Health Organization (WHO) Constitution asserts

[120] Lang, *supra* note 83, at 376-77.
[121] *Id.* at 377.
[122] Report of an Expert Group Meeting, *supra* note 16.

that "health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity," and that "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." Additionally, the right to health is recognized in Article 5(e)(iv) of the International Convention on the Elimination of All Forms of Racial Discrimination of 1965, in Articles 11.1(f) and 12 of the Convention on the Elimination of All Forms of Discrimination against Women (CEDAW) of 1979, and in Article 24 of the Convention on the Rights of the Child (CRC) of 1989. Several regional human rights instruments also recognize the right to health, such as Article 11 of the European Social Charter of 1961, Article 16 of the African Charter on Human and Peoples' Rights of 1981, and Article 10 of the Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights of 1988. In addition to international human rights documents, national constitutions [123] and non-governmental organizations (NGOs) [124] also have proposed that individuals should have the right to maintain the "highest attainable standard" of physical and mental health, and have gradually recognized an

[123] For example, Section 27 of South Africa's constitution includes "health care, food, water and social security" as basic human rights. In Section 15(a) of the Finnish Constitution Act of 1995, the right to health is included in a broader provision of welfare rights. In Article 25 of Japanese constitution, the state is obligated to maintain the minimum standards of wholesome and cultured living, which implies the right to health of all citizens. Section 157 and Amendment Section 10 of the Taiwan Constitution states that the government should provide adequate and sufficient health care services to support the health of people, especially the elderly, women, children, and the handicapped. TAIWAN CONSTITUTION s. 157; TAIWAN CONSTITUTION AMENDMENT s. 10.Even when some countries, such as the United States, do not recognize the right to health in their constitutions, the related but subordinate issues of the right to health are present in statutes and common laws. For example, the Social Security Act of 1935 first supported grants for maternal/infant care. The Economic Bill of Rights introduced "the right to adequate care and the opportunity to achieve and enjoy good health." The Patients' Bill of Rights of 2005 also mentioned "access to [health] care" and "nondiscrimination." In conclusion, the fact that the right to health is codified in a substantial number of national constitutions implies that states generally recognize their responsibility regarding the health of their citizens, and support the existence of an international right to health in "delivery of services," "quality assurance," "promoting good medical practice," etc.

[124] In addition to international documents, domestic constitutions and laws, NGOs also provide comprehensive articles on the right to health. For example, the World Medical Association's (WMA) "Declaration of the Rights of the Patients" of 1995 presents important concepts about the right to health, such as the right to medical care of good quality, the right to health education, and the right to dignity in receiving health care, etc. In 1980, the Japanese Bar Association also declared that health rights are basic human rights based upon constitutional rights, and that the state is obligated to equally fulfill citizens' health care needs, and that people have "active" rights to ask the state, public hospitals and physicians to provide adequate health care services, and to educate and empower patients in health care policy. The American Hospital Association's "Patient's Bill of Rights" of 1973, and the Japanese "Patients' Bill of Rights" declared by the "Drafting Committee of Patients' Bill of Rights" in 1984 also contain similar rights to health care concepts.

individual's right to health as a basic socio-economic right. Countries not recognizing the right to health also have developed related but subordinate laws to substantially protect significant contents of the right to health[125] (although these contents are more precisely characterized as political rights or entitlements than constitutional rights)[126].

Based on the fact that people and organizations worldwide rank health as one of the greatest goods,[127] the right to health should include both (1) the right to access health care (including medical care, preventive and primary health care, pre- and post-natal health care, mental health care), and (2) the right to enjoy underlying preconditions for health (including clean water, decent housing, and proper clothing).

B. The Current Debate on How to Prioritize the Right to Health Care

However, the right to health is traditionally regarded as one undifferentiated, universal positive right, even though the right bundles a variety of contents with different functions and these contents are not all positive rights.[128] If the right to health is simply an undifferentiated right to positive health,[129] under the precept of the right to health a society is obligated to "equally" fulfill all health care needs with no basis on which to differentiate them. But international human rights documents show the opposite. According to paragraphs 43-45 of the CESCR General Comment No. 14, state parties are obliged with core obligations of immediate effect to fulfill certain contents of the right to health (e.g. providing essential drugs, ensuring reproductive and maternal health care, providing immunization against the major infectious diseases occurring in the community, and providing education and access to information concerning the main health problems in the community).[130] Therefore these contents of the right to health obviously have priority over others.[131] Since the right to health contains various contents with different functions, and these contents are not all positive rights,[132] it is then not appropriate to treat all these contents the same in the assessment of the trade-off relationships

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[125] Wing, *supra* note 103, at 163.

[126] *See* Shinn, *supra* note 104, at 115. *See also* Janet O'Keeffe, *The Right to Health Care and Health Care Reform*, *in* HEALTH CARE REFORM: A HUMAN RIGHTS APPROACH 36 (Audrey R. Chapman ed., 1994).

[127] HARVARD LAW SCHOOL HUMAN RIGHTS PROGRAM & FRANÇOIS-XAVIER BAGNOUD CENTER FOR HEALTH AND HUMAN RIGHTS, *supra* note 101, at 17.

[128] UNITED NATIONS DEVELOPMENT PROGRAMME, HUMAN DEVELOPMENT REPORT 2000: HUMAN RIGHTS AND HUMAN DEVELOPEMENT 93 (2000).

[129] Positive health is "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity." WHO, Constitution, Preamble (1946).

[130] *CESCR General Comment No. 14*, *supra* note 2, ¶¶ 43-45.

[131] *See* McClellan, *supra* note 37.

[132] UNITED NATIONS DEVELOPMENT PROGRAMME, *supra* note 128.

between intellectual property and the right to health. Because the traditional undifferentiated right to health cannot address all these miscellaneous aspects of the right to health, a new framework to differentiate the various contents of the right to health is required.

But prioritizing diverse contents of the right to health is no doubt always a critical issue. Scholars and policymakers are engaged in sharp debates about prioritizing the different contents of the right to health.[133] The battle over the right to health keeps going because "[it] is not so much over whether the rights to health care should be incorporated, but over how they should be incorporated: as justiciable rights in the ordinary way, or as mere directives of state policy."[134] International human rights institutions (such as the WHO) have not helped much in this debate, and have failed to provide sufficient detail of their understanding of the right to health in their policies and programs.[135] Therefore, the definition of the right to health remains vague and broad.[136] Due to the vagueness and ambiguity of the conception of the right to health, it then becomes awkward when applying the right to health in assessing international intellectual property laws and policies.

There are three different approaches in trying to help the policymakers, legislators, and judiciary system determine the contents of fundamental and non-fundamental rights to health, and to precisely and objectively evaluate trade-offs between trade and the right to health in international trade policies.

(1) The list-of-services approach adopted by the CESCR to prioritize the state's core obligations to fulfill certain rights to health care (e.g., rights to maternal and child health care, to immunization, to essential drugs, and to medical treatments for epidemics)[137] might provide one possible

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[133] In order to avoid confusion, I need to remind readers that the contents of the right to health care in traditional international human rights institutions, unlike my definition of the right to health care, is generally confined to the right to health care entitlements only regardless of health care freedoms. They apply the term "the right to health care" as health care entitlements in international treaties, documents, and other official papers and reports.

[134] Albie Sachs, *Social and Economic Rights: Can They Be Made Justiciable?*, 53 SMU L. REV. 1381, 1384 (2000).

[135] Philip Alston, *Out of the Abyss: The Challenges Confronting the New U.N. Committee on Economic, Social and Cultural Rights*, 9 HUM. RTS. Q. 332, 336 (1987).

[136] Some international human rights supplements (such as CESCR General Comment No .14) have extensively discussed the right to health care, but these discussions did not provide a clear standard to prioritize varied contents of the right to health care (see section 9.2). *See, e.g.*, *CESCR General Comment No. 14*, *supra* note 2, ¶¶ 7-29.

[137] According to CESCR General Comment No. 14 paragraphs 43 and 44, state parties have the following core obligations (which directly relate to health care services): (1) to ensure access to the minimum essential food which is nutritionally adequate and safe; (2) to ensure access to basic shelter, housing and sanitation; (3) to ensure access to adequate supply of safe and potable water; (4) to provide essential drugs; to ensure reproductive, maternal (pre-natal as well as post-natal) and child health care; (5) to provide immunization against the major infectious diseases occurring in the community; (6) to take measures to prevent, treat and control epidemic and endemic diseases.

direction. But this approach fails to explain why these listed health care services are more important than others, and assumes, rather than justifies, the state's "moral" duty to respect individuals' right to health.[138]

(2) On the basis of "autonomy", Campbell argued that priority of rights to health care should be given to individuals who need medical interventions that would "most likely to increase autonomy amongst those least able to exercise it without outside help."[139] On the basis of this criterion, he argued that priority should be given to significant groups such as "children from deprived areas, mentally handicapped, and elderly people without adequate family support"[140] because it would most likely increase their autonomy and because these groups are least able to exercise this without help. Accordingly, he also argued that priority should be given to primary care interventions and health facilities for the chronically sick rather than to acute or maternity hospital services.[141] However, instead of directly applying "autonomy" as a criterion to evaluate the importance of diverse rights to health care, Campbell assumed certain groups are most vulnerable in autonomy protection[142] and argued that these groups have priority for rights to health care. But Campbell's "group classifications" approach neglects the essence of the autonomy principle and the fact that individuals in groups still have diverse conceptions of the good regarding health care rather than a shared ranking of health care needs.

(3) Toebes proposed to distinguish the "scope content" and the "core content" of the right to health by delineating what is "most essential" in human rights and to build a hierarchy of health care needs and the ensuing state obligations.[143] This approach divided rights to health into three elements: core content, scope content, and overlapping content of the right to health (see Figure 2). These elements are similar to the state's "core obligations" listed in CESCR General Comment No. 14. The "core content of the right to health" – the baseline below which no individuals in any

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CESCR *General Comment No. 14*, *supra* note 2, ¶¶ 30-45.

[138] Einer Elhauge, *Allocating Health Care Morally*, 82 CAL. L. REV. 1449, 1470 (1994).

[139] ALASTAIR V. CAMPBELL, MEDICINE, HEALTH AND JUSTICE: THE PROBLEM OF PRIORITIES 48 (1978).

[140] *See id.*

[141] *Id*. at 32.

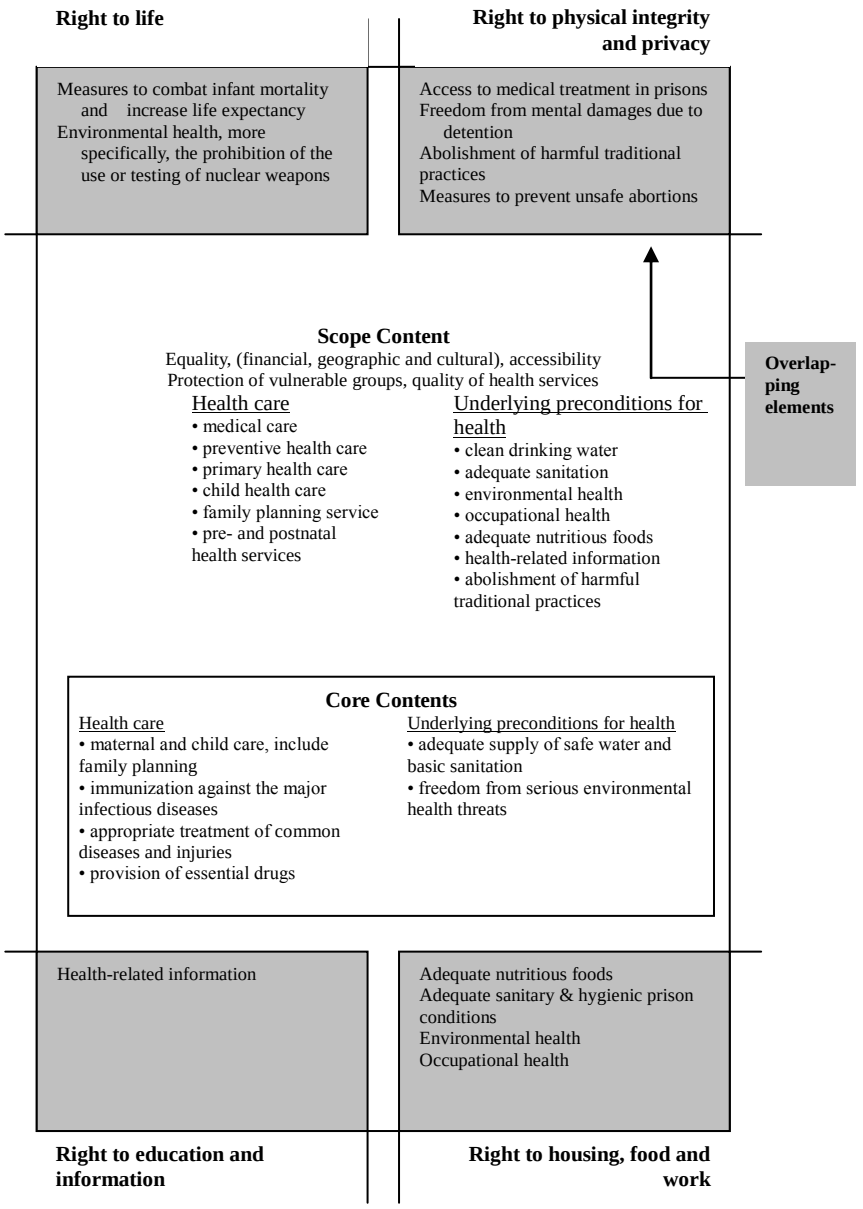
[142] No doubt, people are more or less vulnerable at different stages of their lives because of health problems that force them to turn to others for help. And it is a clear and easy way to directly apply group classifications as a criterion in health care distribution policy. For example, Aday also adopts a similar approach and applies epidemical data to evaluate who is most vulnerable (such as elderly people, low birth weight infants, teenage mothers, persons living with HIV/AIDS, alcohol or substance abusers, people in abusive family situations,, the homeless, immigrants and refugees, and the suicide- or homicide-prone) in health care distribution in the U.S. *See generally* LU ANN ADAY, AT RISK IN AMERICA: THE HEALTH AND HEALTH CARE NEEDS OF VULNERABLE POPULATIONS IN THE UNITED STATES 54-90 (2001).

[143] BRIGIT TOEBES, THE RIGHT TO HEALTH CARE AS A HUMAN RIGHT IN INTERNATIONAL LAW 275-76 (1999).

country should fall[144] – includes the following characteristics (based on various international institutions): (1) Health care should contain maternal and child health care including family planning, immunization against major infectious diseases, appropriate treatment of common diseases and injuries, and provision of essential drugs. (2) Underlying preconditions for health include an adequate supply of safe drinking water and basic sanitation and freedom from serious environmental health threats. The "scope content of the right to health" contains elements that are embedded in various international treaty provisions that stipulate the right to health care, and is accordingly the "general content" of the right to health care, including "health care" such as medical care and preventive care, along with the "underlying preconditions for health" such as clean drinking water and air and adequate sanitation.[145] However, even though this approach provides a detailed criterion to prioritize the state's obligations to fulfill the right to health, it does not provide a valid theoretical basis for setting priorities for the right to health care or set standards for what groups or what services should receive priority. In other words, this approach merely applies the existing structure of human rights to distinguish the core and scope (marginal) contents of the right to health without evaluating different contents' influence on individuals' capabilities.

[144] WORLD HEALTH ORGANIZATION, GLOBAL STRATEGY FOR HEALTH FOR ALL BY THE YEAR 2000 31 (1981).
[145] TOEBES, *supra* note 143, at 243, 245-46.

Figure 1 Core and Scope Contents of the Right to Health Care[146]



[146] *Id*. at 289.

C. Contents of Fundamental and Non-Fundamental Rights to Health

In addition to prior approaches, I propose that the minimal health, which strongly relates to individuals' basic capabilities to pursue their good end of life plans, can help to determine the contents of fundamental and non-fundamental rights to health. Sen[147] and Nussbaum[148] also argue that health is one of the essential capabilities that enhance the substantial freedoms of individuals to choose and to lead the kind of lives they value, in terms of accessibility, affordability, appropriateness, and quality of health care. Therefore, fundamental rights to health should be those that fall within minimal health, and aims to maintain or to restore individuals' basic capabilities, while non-fundamental rights to health are those that are beyond minimal health and are irrelevant to individuals' basic capabilities.

However, what are those basic capabilities, or minimal health, which fundamental rights to health aim to protect? Even though Sen did not explain what the most central capabilities are, based upon his approach Nussbaum argued that, basic capabilities are those that are a necessary basis for developing more advanced capabilities,[149] or are the innate equipment for individuals to develop necessary functions to achieve whatever an individual's specific chosen ends.[150] Nussbaum further argues that basic capabilities which the right to health should guarantee should include[151] (1) life (being able to live to the end of a human life of normal length, not die prematurely, or before one's life is so reduced as to be not worth living), (2) bodily health (being able to have good health, including reproductive health, to be adequately nourished, and to have adequate shelter), (3) bodily integrity (being able to move freely from place to place, to be secure against violent assault, including sexual assault and domestic violence, having opportunities for sexual satisfaction and for choice in matters of reproduction), and (4) senses, imagination, and thought (being able to use the senses, to imagine, to think, and to reason, and to do these

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[147] *See generally* SEN, *supra* note 109, at 87-110 (1998). Amartya Sen, *Human Rights and Development*, *in* DEVELOPMENT AS A HUMAN RIGHT: LEGAL, POLITICAL, AND ECONOMIC DIMENSIONS 1, 1-8 (Bard A. Andreassen & Stephen P. Marks eds., 2006).

[148] Martha C. Nussbaum, *Capabilities and Human Rights*, *in* THE PHILOSOPHY OF HUMAN RIGHTS, 212-40 (Patrick Hayden ed. 2001). Martha C. Nussbaum, *Capabilities, Human Rights, and the Universal Declaration*, *in* THE FUTURE OF INTERNATIONAL HUMAN RIGHTS 25, 34-60 (Burns Weston & Stephen Marks eds, 1999).

[149] For example, Nussbaum proposed the list of basic capabilities by asking an Aristotelian question: What activities characteristically performed by human beings are so central that they seem definitive of the life that is truly human? Two more precise questions are then formulated: (1) Which changes or transitions are compatible with the continued existence of a being as a member of the human kind and which are not? (2) What kinds of activity must be there if we are going to acknowledge that a given life is human? MARTHA NUSSBAUM, SEX AND SOCIAL JUSTICE 39-40 (1999).

[150] *Id.* at 44.

[151] *Id.* at 44-45.

things in a truly human way; being able to use one's imagination and thoughts in connection with experiencing and producing expressive works and events of one's choice, religious, and so forth; being able to use one's mind in ways protected by guarantees of the freedom of expression with respect to both political and artistic speech and freedom of religious exercise).

But Nussbaum's approach is still too broad because it implies an ideal and perfect health condition. Under Nussbaum's framework, the state shall exhaust all resources to protect individuals' physical, mental and social well-being, or its policies would be regarded as violating the right to health. Thus, based upon Nussbaum's approach, I would modify this framework and propose only two domains: (1) physical and mental functions that are directly related to life-saving, and (2) physical and mental functions, which if substantially restricted, preclude individuals from being a free, equal, and fully cooperating member of the society. In other words, only these two conditions qualify as the minimal standard of health, which I apply to identify fundamental rights to health.

(1) Physical and mental functions directly related to life-saving (or maintaining life). Maintaining life is the basic requirement for individuals to fully maintain their fair opportunity range to pursue their life plans because it is impossible to declare a person a cooperating member of society if he or she suffers from life-threatening diseases or is facing death. Nussbaum also agrees that life – "not dying prematurely or before one's life is so reduced as to be not worth living"[152] – is the central capability. Categorizing physical and mental functions directly related to life-saving in the minimum standard of health also corresponds to the rights proclaimed in international human rights documents, such as the UDHR and ICESCR.[153]

(2) Physical and mental functions, which if substantially restricted, preclude an individual from being a free, equal, and fully cooperating member of the society. Since there are different levels of illness (severity of illness), diseases and disabilities may not have the same effects on people's physical and mental functions. For example, sleep and sexual disorders generally do not prevent individuals from thinking, reasoning,

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[152] *Id.* at 42-47.

[153] For example, Duxbury and Avila agree that life should be protected as the ultimate human right. Article 3 of the Universal Declaration of Human Rights (UDHR) states that everyone has the right to life. Article 6 of the International Covenant of Economic, Social, and Cultural Rights (ICESCR) states that "every human being has the inherent right to life. This right shall be protected by law and no one shall be arbitrarily deprived of his life." Alison Duxbury, *Saving Lives in the International Court of Justice: The Use of Provisional Measures to Protect Human Rights*, 31 CAL. W. INT'L L.J. 141, 143 (2000). Daniel Avila, *Assisted Suicide and the Inalienable Right to Life*, 16 ISSUES L. & MED. 111, 113 (2000). James W. Nickel, *Rethinking Rawls' Theory of Liberty and Rights*, 69 CHI.-KENT L. REV. 763, 776 (1994). UD HR, *supra* note 99, art. 3. ICESCR, *supra* note 99, art. 6.

communicating, and understanding information and choices, which individuals require to fully develop a conception of good and a sense of justice. However, exercising capabilities to form, revise, and pursue the conception of good in individuals' life plans still requires certain minimal physical and mental abilities, such as the ability to think, to question, to inquire, to discuss, to experiment, to travel, to organize, to campaign, and to vote.[154] For example, one's conception of the good cannot be put to work effectively in some important applications without knowledge or recognition of social institutions and problems. In another example, delusional disorders could also restrict individuals' fair opportunity because individuals with delusional disorders have abnormal subjective experiences (e.g., delusions of control, or delusions with bizarre and culturally inappropriate content) and accompanying behaviors (e.g., incoherence or poverty of speech).[155] Therefore, minimal health, which an individual needs to be a free and equal member of society in order to pursue good ends, then should be regarded as equivalent to a basic capability.

In this paper I cannot explore this issue any further because it requires a massive literature review and analysis.[156] For example, Lawerence Gostin adopted the rights-based approach (similar to welfarism) to support the right to the "highest attainable standard of health,"[157] while Norman Daniels[158] and Allen Buchanan[159] apply Rawlsian contract arguments to justify and specify an entitlement to a "decent minimum of health care." In opposition to assigning the state a positive obligation to fulfill individuals' health care needs (either highest attainable or decent minimum), some scholars apply Robert Nozick's entitlements theory[160] as a counter

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[154] Nickel, *supra* note 153.

[155] HEALTH CARE NEEDS ASSESSMENT: THE EPIDEMIOLOGICALLY BASED NEEDS ASSESSMENT REVIEWS VOLUME 2, at 168 (Andrew Stevens et al. eds., 2d ed. 2004).

[156] *See, e.g.*, Richard Glenn Abramson, Distributive Justice and Health Care: Balancing Individual Claims with Social Interests through an Extension of Rawls's Theory of Justice (1994) (unpublished A.B. thesis, Harvard University, on file with the Harvard University Library); Chuan-Feng Wu, The Right to Health Care and Health Care Distributive Justice (2007) (unpublished J.S.D. dissertation, University of California Berkeley School of Law, on file with the University of California Berkeley School of Law Library).

[157] However, as in Gostin's argument, considerable disagreement continues as to whether health is a meaningful, identifiable, operational, and enforceable right, or whether it is merely rhetorical or an ideal. He still hesitates to make a legal claim to the right to health because an unfettered legal right to health is not currently tenable. Gostin, *supra* note 98, at 29-30. Lawerence O. Gostin, *Securing Health or Just Health Care? The Effect of the Health Care System on the Health of America*, 39 ST. LOUIS U. L.J. 7, 11-12 (1994).

[158] *See* NORMAN DANIELS, JUST HEALTH CARE 39 (1985). Norman Daniels, *Fair Equality of Opportunity and Decent Minimums: A Reply to Buchanan*, 14(1) PHILOS. & PUBLIC AFF.106 (1985).

[159] Allen E. Buchanan, *The Right to a Decent Minimum of Health Care*, 13(1) PHILOS. & PUBLIC AFF. 55, 57-59 (1984).

[160] Nozick argued that so-called distributive justice is based on a false premise that there is a "social pot" waiting to be justly distributed by some central authority. But there is no such pot in

argument to reject the government's role in forcing people to contribute to projects (such as health care programs) that promote their own well-being (such as health).[161] Because this article mainly focuses on the interaction between intellectual property and human rights regimes, I will leave this important issue for future study.

Here I merely indicate – I cannot do more than this - that fundamental rights to health contain only health care needs for minimal health. Because fundamental health care entitlements are related to individuals' basic capabilities which are necessary to maintain individuals' fair opportunity range to pursue their good end of life plans, these entitlements should be regarded as the most essential elements in the right to health care. On the other hand, the non-fundamental rights to health contain health care needs beyond the minimal health (e.g., carrying out physical and mental functions with slight influences, being free from pain, or maintaining reasonably good spirits). Because these entitlements are irrelevant to individuals' basic capabilities, failing to fulfill them would not significantly shrink individuals' fair opportunity range.

It is important that the fundamental rights to health are limited in scope (within minimal health). Because the fulfillment of health care needs would compete with other essential social goods[162] (such as intellectual property rights), guaranteeing everyone's "equal" right to the best health care services available in a society[163] would be a huge drain on total resources and foreclose opportunities for other essential social goods.[164] Therefore, the fundamental rights to health then should be limited to the most basic health care that is normally adequate for an individual's fundamental interests. Minimal health satisfies this requirement, because this standard guarantees an individual's basic capabilities as a free and equal member of society, and thus protects the individual's fair opportunity range to pursue the good ends of his or her life plan. Applying this standard for minimal health based upon basic capabilities, which endorses only essential health care needs,[165] then not only recognizes the implausibility of the strong claim of equal access to health care but also rejects any absolutist

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the natural world. Individuals have natural rights (or entitlements) to their person and property, meaning that they can do what they want with their person or property as long as they do not violate others' person or property. Therefore, the state may not use its coercive apparatus to encourage (or coerce) individuals to aid others or to prohibit activities to people for their own good or protection. *See generally* ROBERT NOZICK, ANARCHY, STATE, AND UTOPIA 149-82 (1974).

[161] For example, according to Nozick, to seek to allocate health care in proportion to people's need for it is morally unjustified if the price of doing so is the violation of people's rights to acquire and dispose of their justly held assets in ways of their own choosing. *See* JOHN BUTLER, THE ETHICS OF HEALTH CARE RATIONING: PRINCIPLES AND PRACTICES 96 (1999).

[162] Elhauge, *supra* note 138, at 1461.

[163] ISESCR, *supra* note 99, ¶ 12. *CESCR General Comment No. 14*, *supra* note 2, ¶¶ 1-29.

[164] Buchanan, *supra* note 159, at 58.

[165] *Id*. at 58-59.

position.[166]

D. State's Multi-Layered Obligations of the Right to Health

Since the content of the right to health can be clarified and separated, the state's obligations to respect, protect, and fulfill the right to health should also be differentiated in accordance with the importance and priority of fundamental and non-fundamental rights to health.

Here I propose that the state has a legal obligation to immediately realize fundamental rights to health while it has only moral obligation to progressively realize non-fundamental rights to health.[167] Because basic capabilities are the capabilities of central importance in any human life plan whatever else the person pursues or chooses,[168] a society only has the responsibility to protect or to restore the most important physical or mental functions (minimal health). In other words, the minimal health standard applied in human rights assessment for different policies (e.g. international intellectual property policy) is understood in a society-relative sense because it requires a society to guarantee individuals only the basic capabilities to have a fair opportunity range. Beyond minimal health, a society is allowed to define the content of the right to health on the basis of a consensus among its members, and to adjust the level of health care the society provides based on its resources, standards, values, desires and priorities. Therefore, unless restricted human rights are fundamental rights to health which are strongly related to protection or restoration of individuals' minimal health (basic capabilities), the state only has moral obligations to protect non-fundamental rights to health and has authority to decide to promote economic interests or to protect public health in international trade policies. On the contrary, if restricted human rights are fundamental rights to health, the state then has legal obligations to prove that there are proper trade-off relationships between pursued economic interests and restricted rights to health in international trade policies.

My proposal, which imposes a legal obligation on the state to immediately realize fundamental rights to health, is obviously different

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[166] According to the absolutist position in health care distribution, health care must be provided whenever it has any positive health benefit. But this abstract, moral absolutism, despite its powerful emotive appeal, remains difficult to achieve in practice because it makes no sense to spend all of a society's resources on health care (for people to live longer) at the expense of those things that make life worth living. *See* Elhauge, *supra* note 138, at 1457-61.

[167] The immediate realizations of human rights means that state parties have the obligation to immediately respect, protect, and fulfill human rights regardless of whether enough resources are available or not. And the progressive realizations of human rights means that state parties' obligation to respect, protect, and fulfill human rights should be limited to taking reasonable legislative measures within its available resources. There is more discussion about the roles of immediate and progressive realizations in the framework of rights to health care in section 9.3.3.

[168] NUSSBAUM, *supra* note 148, at 223.

from the traditional human rights approach, which treats all contents of the right to health as progressive realizations.[169] For example, under Article 2.1 of the ICESCR, the right to health is subject to the principle of progressive realization because the state only needs to "take steps, individually and through international assistance and co-operation, especially economic and technical, to the maximum of its available resources, with a view to achieving progressively the full realization of the rights recognized in the present Covenant by all appropriate means, including particularly the adoption of legislative measures."[170] Thus, the progressive realization of the right to health means that accessibility to health care could be progressively facilitated, and legal, administrative, operational and financial hurdles could be examined and, where possible, lowered over time.[171] The provision "within available resources" then needs to be construed because, even though measures to meet the right to health care must be calculated to attain the goal expeditiously and effectively, "the availability of resources is an important factor in determining what is reasonable."[172] In conclusion, under the principle of progressive realization, the state can take steps to progressively achieve the realization of the right to health care based on available resources.[173] The state does not need to immediately devote its energies and resources to the full protection of the right to health care.

However, as discussed earlier in this section, it is improper to treat heterogeneous contents of the right to health homogenously with progressive realizations. Because health is a continuum of physical, mental and social functions, it is misleading to assume all contents of the right to health require only progressive realization. The relative importance of different contents of the right to health should be decided based upon whether these contents are worth realizing immediately, rather than based upon whether these contents fall under the right to health. Since failing to

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[169] On the contrary, because civil and political rights have often been characterized as negative rights, and because civil and political rights are cost-free rights, which means that protection of these rights can be achieved without incurring significant costs, civil and political rights then are considered to be capable of full and immediate realization. All the state must do is to enact legislation that outlaws the activities that violate these rights. *See, e.g.*, Cristina Baez et al., *Multinational Enterprises and Human Rights*, 8 U. MIAMI INT'L & COMP. L. REV. 183, 223 (2000). UNITED NATIONS DEVELOPMENT PROGRAMME, *supra* note 128.

[170] ISESCR, *supra* note 99, art. 2.1.

[171] Gov't of the Republic of S. Afr. v. Grootboom, 2000 SACLR LEXIS 6, at 12 (2000) (S. Afr.).

[172] *See id.* at 13.

[173] For example, Section 27(2) of the South African Final Constitution confines the right to health care to the state, which "must take reasonable legislative and other measures, within its available resources, to achieve the progressive realization of each of these rights" even when Section 27(1) states that "Everyone has the right of access to (a) health care services, including reproductive health care; (b) sufficient food and water; and (c) social security, including if they are unable to support themselves and their dependents, appropriate social assistance"; and Section 27(3) states that "[n]o one may be refused emergency medical treatment." S. AFR. CONST. 1996 art.27.

fulfill fundamental rights to health, which fall within minimal health, would significantly restrict individuals' basic capabilities and diminish their fair shares of the normal opportunity range, these entitlements are important and should be realized immediately even though they are parts of the right to health.

There are two main arguments to support the state's multilayered obligations to respect, protect, and fulfill different contents of the right to health. First, progressively realizing fundamental rights to health could immediately diminish an individual's fair opportunity to pursue his or her own good ends. Minimal health, which fundamental rights to health aim to guarantee, relates to an individual's basic capabilities. Because these basic capabilities can affect an individual's development of a conception of the good and a sense of justice, the recognition of their own achievements of a good life, the fair opportunity range to pursue his or her own good ends in their life plan, and the pursuit of human dignity, progressively realizing these basic capabilities then would significantly restrict an individual's fundamental interests. To secure fair equality of opportunity, rational deliberators would agree that society has the responsibility to protect an individual's basic capabilities by fulfilling these fundamental rights to health when they are related to basic capabilities, in order to protect an individual's fair opportunity range and guarantee him or her to be a free and equal member of society. Thus, fundamental rights to health should be realized immediately rather than progressively.

Second, the progressive realization principle is unreasonable and challengeable. The reason for treating the right to health (or other economic, social, and cultural rights) as progressive realizations while treating civil and political rights as immediate realizations is to build upon the conceptual issues of justifiability and multi-layered obligations of human rights. In other words, civil and political rights are primarily procedural and the extent of such rights is substantive, while the right to health, which involves substance or policy, are better left to parliaments and governments to decide.[174] However, the right to health also bundles a variety of contents with different functions (see section (V)(B)). Some contents (fundamental rights to health) which aim to protect individuals' basic capabilities should also be regarded as sustentative because these rights are strongly related to an individual's fundamental interests (fair opportunity range). Therefore, the state's multi-layered obligations of human rights should not be determined only on the basis of the difference between socio-economic rights and political rights. It is illogical and unreasonable to simply argue that fundamental rights to health are unsubstantial rights just because they

[174] PAUL HUNT, RECLAIMING SOCIAL RIGHTS: INTERNATIONAL AND COMPARATIVE PERSPECTIVES 44 (1996).

are under the category of the right to health care. The state should also have multi-layered obligations to respect, protect, and fulfill the right to health on the basis of the difference between fundamental and non-fundamental rights to health. Furthermore, since fundamental rights to health are substantive, as civil and political rights, they should be guaranteed immediately.

Recent human rights documents and cases seem to support my argument, though they do not expand much on this. For example, Article 8 of the Limburg Principles upholds that "although the full realization of the rights [to health care] . . . is to be attained progressively, the application of some rights can be made justiciable immediately."[175] The United Nations Development Programme (UNDP) also argued that rights to health care should not all be regarded as progressive realizations.[176] In South Africa, the *Soobramoney v. Minister of Health* Court[177] argued that the state only has progressive obligations[178] to fulfill the right to health care "within its available resources," while the *Government of South Africa v. Grootboom* Court [179] argued that the state is bound to meet the immediate recognition[180] of children's right to basic health care services "irrespective of the availability of resources." The CESCR also argued that states are obligated to perform certain duties (general legal and core obligations) on different levels to guarantee the fulfillment of different rights to health

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[175] *The Limburg Principles on the Implementation of the International Covenant on Economic, Social and Cultural Rights*, ¶ 8, U.N. Doc. E/CN.4/1987/17 (1987).

[176] For example, even though creating or promoting family planning often requires the state to have adequate resources, the UNDP declared that laws that discriminate based on race, religion, and/or gender in health care must be removed immediately. UNITED NATIONS DEVELOPMENT PRAGRAMME, *supra* note 128.

[177] Soobramoney v. Minister of Health, KwaZulu-Natal, 1997 SACLR LEXIS 41, at 42 (1997) (S. Afr.) (The applicant who suffered from chronic kidney failure claimed the public hospital violated his right to health because the hospital set the primary requirements for admission to the public dialysis program for patients (1) who suffer from acute renal failure, or (2) who are eligible for a kidney transplant with chronic renal failure. The Constitutional Court ruled that the state's obligations to grant some contents of the right to health care are limited to taking reasonable legislative measures within its available resources; in other words, the state can refuse to fulfill the right to health care due to the limit of health care resources).

[178] The progressive realization of human rights means that state parties only have the obligation to respect, protect, and fulfill such rights progressively and gradually using reasonable available resources.

[179] Gov't of the Republic of S. Afr. v. Grootboom, 1997 SACLR LEXIS 41, 58 (2000) (S. Afr.) (The applicants who were homeless sought the Constitutional Court to enforce their constitutional right to have access to adequate housing, in accordance with section 26 of the Final Constitution, and the right of every child to basic shelter, in accordance with section 28 of the Final Constitution. The Court ruled that the state was bound to fulfill children's right to health care irrespective of the availability of resources).

[180] The immediate realization of human rights means that state parties have the obligation to immediately respect, protect, and fulfill such rights regardless of whether or not enough resources are available.

care.[181] The CESCR thus prioritizes nations' obligations to implement the right to health as a core obligation,[182] international obligations, and general legal obligations by listing specific medical services.

Fundamental rights to health should be realized immediately, and the immediate realization means that state has a legal obligation to immediately respect, protect, and fulfill such rights regardless of whether enough resources are available. It is reasonable because the deprivation of minimal health (basic capabilities that fundamental rights to health aim to guarantee) would not only influence the accessibility to substance (such as health care services) but also relates to basic and absolute values (such as lives, or moral personality)[183]. The state still has the obligation to respect, protect, and fulfill non-fundamental rights to health because they can be found in international documents. However, because these non-fundamental rights to health do not relate to an individual's minimal health (basic capabilities) to pursue his or her good ends of life, it is unnecessary to obligate state parties to fulfill these entitlements immediately. This proposal then can further provide a theoretical basis for the right to health impact assessment of the

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[181] *CESCR General Comment No. 14*, *supra* note 2, ¶¶ 30-45.

[182] *Id.* ¶ 43: "In General Comment No. 3, the Committee confirms that States parties have a core obligation to ensure the satisfaction of, at the very least, minimum essential levels of each of the rights enunciated in the Covenant, including essential primary health care. … Accordingly, in the Committee's view, these core obligations include at least the following obligations: (a) To ensure the right of access to health facilities, goods and services on a non-discriminatory basis, especially for vulnerable or marginalized groups; (b) To ensure access to the minimum essential food which is nutritionally adequate and safe, to ensure freedom from hunger to everyone; (c) To ensure access to basic shelter, housing and sanitation, and an adequate supply of safe and potable water; (d) To provide essential drugs, as from time to time defined under the WHO Action Programme on Essential Drugs; (e) To ensure equitable distribution of all health facilities, goods and services; (f) To adopt and implement a national public health strategy and plan of action, on the basis of epidemiological evidence, addressing the health concerns of the whole population; the strategy and plan of action shall be devised, and periodically reviewed, on the basis of a participatory and transparent process; they shall include methods, such as right to health indicators and benchmarks, by which progress can be closely monitored; the process by which the strategy and plan of action are devised, as well as their content, shall give particular attention to all vulnerable or marginalized groups." *Id.* ¶ 44: "The Committee also confirms that the following are obligations of comparable priority: (a) To ensure reproductive, maternal (pre-natal as well as post-natal) and child health care; (b) To provide immunization against the major infectious diseases occurring in the community; (c) To take measures to prevent, treat and control epidemic and endemic diseases; (d) To provide education and access to information concerning the main health problems in the community, including methods of preventing and controlling them; (e) To provide appropriate training for health personnel, including education on health and human rights." *Id.* ¶ 45: "For the avoidance of any doubt, the Committee wishes to emphasize that it is particularly incumbent on States parties and other actors in a position to assist, to provide "international assistance and cooperation, especially economic and technical" which enable developing countries to fulfill their core and other obligations indicated in paragraphs 43 and 44 above."

[183] Rawls argued that persons regarded as having the two moral powers (the minimum standard of health) means that they have the requisite capacities not only to engage in mutually beneficial social cooperation over a complete life but also to be moved to honor its fair terms for their own sake. And these two moral powers are taken as defining "moral persons" and "moral personality" in a well-ordered society. RAWLS, JUSTICE AS FAIRNESS: A RESTATEMENT, *supra* note 111, at 19.

relationship between the intellectual property right and the right to health (see more discussion in section (VI)(D)).

VI. THE APPLICATION OF THE RIGHT TO HEALTH IMPACT ASSESSMENT IN THE INTERNATIONAL INTELLECTUAL PROPERTY REGIME

According to discussions in section (IV), an enforceable and monitorable human rights impact assessment can help the society to evaluate restrictions on the right to health under the international trade regime. The following human rights impact assessment involves a series of questions[184] designed to balance economic interests against the human rights burden (see Figure 1).

(1) Examine the burdens on the right to health placed by an international intellectual property policy. In this step, whether or not the policy restricts the right to health, and what contents of the right to health are possibly infringed upon, should be assessed.

(2) Clarify the purposes of an international intellectual property policy. In this step, what purposes an international intellectual property policy intends to achieve, and whether or not it can achieve its proposed purposes, should be assessed.

(3) Evaluate the effectiveness of an international intellectual property policy. In this step, whether or not the policy provides the least restrictive alternative to achieve its proposed purposes, should be assessed.

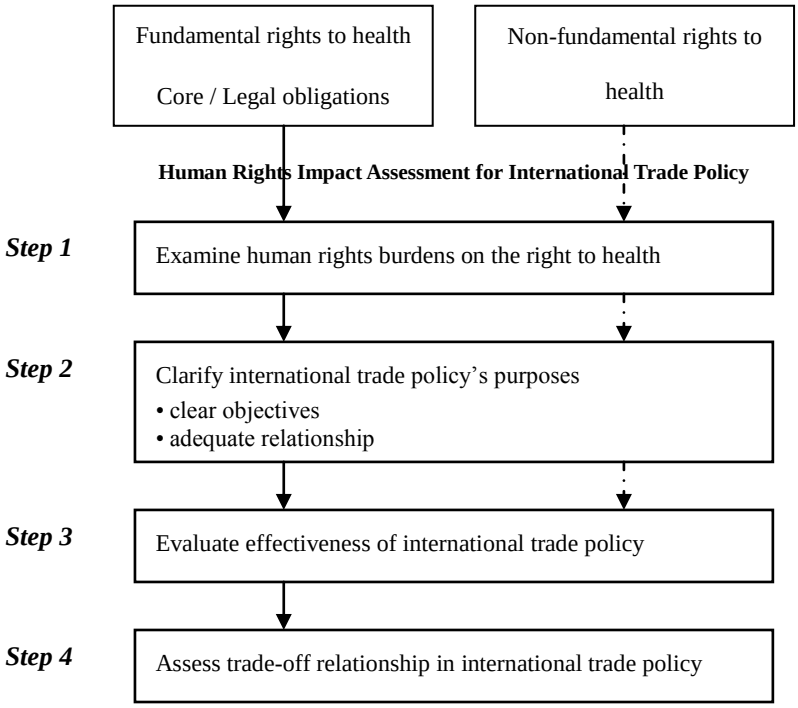
(4) Assess the trade-off relationships between restricted right to health and pursued policy purposes in an international intellectual property policy. In this step, whether there is a proper trade-off between restricted right to health and the social orders (economic or social benefits) served by an international intellectual property policy, and whether such a trade-off is balanced and justified, should be assessed. In my proposal, the priority status of the right to health care (see section VI) should then be applied to help to assess the trade-off. The difference between fundamental contents of the right to health (with immediate realizations) and the non-fundamental contents of the right to health (with progressive realizations) should be shown in this step. Briefly speaking, if restricted rights to health are non-fundamental, the state only has the burden to prove that the international intellectual property policy has a clear objective (step 2), and the policy is the least restricted alternative (step 3). The state has no burden to prove whether the trade-off relationship between restricted right to health and pursued economic interests is proper (step 4). However, if the

[184] Gostin and Mann also proposed a human rights impact assessment similar to my proposal. This principle is also similar to the principle of proportionality *See generally* Gostin & Mann, *supra* note 116, at 54-71.

restricted rights to health are fundamental, in addition to steps 2 and 3, the state also has the burden to prove that the trade-off relationship is proper (step 4).

(5) If the answer to any one of these questions in steps 2 to 4 is "no", the state's acts in restricting individuals' right to health should be considered as unjustified.

Figure 2. Human Rights Impact Assessment for International Trade Policy



A. Examine Burdens on the Right to Health

Even in a well-designed international intellectual property policy, the burdens on the right to health may outweigh the pursued economic interests. Therefore, it is important to identify all the potential infringements on health care freedoms and to evaluate them.[185] Therefore, in this first step, we must identify all potential infringements on the right to health and evaluate those most likely to occur. Plenty of international documents and

[185] Gostin & Mann, *supra* note 116, at 61.

domestic statutes can be cited as the source of different rights to health (see Table 2) when considering whether international trade policies violate the right to health. These documents include the Universal Declaration of Human Rights (UDHR), WHO Constitution, International Covenant on Social, Economic and Cultural Rights (ICESCR), Convention on the Elimination of All Forms of Discrimination against Women (CEDAW), Convention on the Right of the Child (CRC), and CESCR General Comments 14 and 15. Applying these human rights markers of the right to health as a rough basis, upon which to construct the framework and contents of the right to health[186], can help us to evaluate the possible human rights burdens imposed by international trade policy. In other words, if the state's international trade policy fails to protect or to fulfill the right to health listed in international human rights documents or domestic laws, this policy would be held to impose a potential human rights burden on the right to health.

[186] In the theory of justice, Rawls is not confident either that the parties in the original position could generate an adequate list of rights and liberties, given the restraints on their knowledge. Instead, Rawls suggests that in setting up the original position we can construct such a list on the basis of our historical knowledge of the rights and liberties usually protected by the constitutions of democratic states and offer it to the parties as part of one of the conceptions of justice they may choose. *See* RAWLS, POLITICAL LIBERALISM, *supra* note 111, at 292-93 (1993).

Table 2 Contents of the Right to Health[187]

(compiled by the authors from cited sources)

Topics	Contents of the Right to Health	Treaty Provisions
Health Care	General Medical Care	UDHR 25.1 WHO Constitution ICESCR 12.2(c)(d) CESCR General Comment 14
	Primary Health Care	ICESCR 12.2(c) CRC 24.2(f) CESCR General Comment 14
	Preventive Health Care	ICESCR 12.2(c) CRC 24.2(f) CESCR General Comment 14
	Maternal/Reproductive Health Services	UDHR 25.2 ICESCR 12.2(a) CEDAW 12.2 CRC 24.2(d) CESCR General Comment 14
	Infant /Child Health Services	UDHR 25.2 ICESCR 12.2(a) CRC 24 CESCR General Comment 14
	Mental Health Services	ICESCR 12.1 WHO Constitution CESCR General Comment 14
	Family Planning Services	CEDAW 12 CRC 24.2(f)
	Quality	CESCR General

[187] Chuan-Feng Wu, *State Responsibility for Tobacco Control: The Right to Health Perspective*, 3(2) ASIAN J. WTO & INT'L HEALTH L. & POL'Y 379, 396-97 (2008).

		Comment 14
Health-Related Information	Health-Related Information	WHO Constitution CRC 24(2)(e) ESC 11(2)
	Health Education	WHO Constitution CRC 24.2(e) CESCR General Comment 14
Underlying Preconditions For Health	Healthy Natural & Workplace Environments	ICESCR 12(2)(b) CRC 21(c) CESCR General Comment 14
	Clean Drinking Water	ICESCR 12(2)(b) CRC 24(2)(e) CESCR General Comment 15
	Adequate Nutritious Foods	CRC 24(2)(c) CEDAW 12(2)
	Adequate Sanitation	ICESCR 12(2)(b) CRC 24(2)(e)

In addition, even though these documents provide only a cursory basis, in this step it is sufficient enough to provide us with a starting point to recognize what contents of the right to health, among various human rights, might be infringed upon and should be further evaluated in later steps. In other words, if we have "reasonable doubt" that an international trade policy might violate the right to health (as prescribed in international documents and domestic laws), we can then move from this initial examination to the next step. Thus, this examination is merely an initial assessment, and whether this human rights burden is justified or not should be further evaluated in later steps of human rights assessment on the right to health.

B. Step 2: Clarify the Purposes of International Intellectual Property Policies

This evaluation strategy has two elements: clear objectives and adequate relationships. First, the state has a responsibility to articulate the policy purpose of an international intellectual property policy, which imposes potential restrictions on the right to health. Clearly articulated goals of international intellectual property policies can help "to identify the true purposes of the intervention, to facilitate public understanding and debate [about] legitimate purposes, and to reveal prejudice [(or pre-justice)], stereotypical attitudes, or irrational fear."[188] A clear understanding of the policy purposes can also help to evaluate the impact of state intervention on the right to health. The policy purpose must be clearly articulated to inform the debate about legitimate health purposes, and to reveal prejudice, stereotypical attitudes, or irrational fears.[189]

It is important to identify policy purposes, because the international intellectual property policy requires different means to achieve different purposes, and different means have different influences on the right to health. Without a clear policy purpose, it is difficult to evaluate whether the policy means are adequate to achieve its purpose. The WTO also applies similar scrutiny to evaluate international trade policies. For example, if a state's regulatory agency finds that one or few cases of cancer caused by "toxin T" per 10,000 exposed people with "imprecise" scientific understanding (about 1% range of uncertainty) of the relationship between exposure level and incidence of cancer, the state can designate only the lowest exposure level in this range as the highest permissible exposure. Without specific health policy goals (e.g. disease incidence targets), the state then has no ground to reduce health risks by banning the manufacture, domestic sale, and import of "toxin T" containing products. Therefore, even though the state "ha[s] a right to determine the level of protection of health that they consider appropriate in a given situation,"[190] such a right cannot, by itself, define health policy goals nor can it be a justification of trade restrictions. A state's ban on the import of "toxin T" containing products then should be evaluated by the state's health policy goals. Since clarifying the purpose of international trade policies is an accepted part of the review process in the international trade regime, it is also appropriate to require those who advocate international intellectual property policies to state their policy purposes.

Second, in order to articulate the international intellectual property policy purposes, a conceptualization of purpose should be narrowly defined

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[188] Gostin & Mann, *supra* note 116, at 61.
[189] RAWLS, POLITICAL LIBERALISM, *supra* note 186, at 292-93.
[190] *EC Asbestos AB Report*, *supra* note 22, ¶ 168.

and precisely specified. Claims, for instance, that the purpose of clinical trial data protection is to protect intellectual property or to promote research and development (R&D) are too vague and broad. A clear policy purpose should include, for example, protection of brand name companies' investment and fair return in R&D from generic competitors' unfair free-ride on the investment of the originator firm[191].

Third, the state has the burden to prove that the means used in international intellectual property policy is reasonably likely to achieve the stated policy purpose. This evaluation is important because, the real issue of assessing human rights burden on the right to health is not about what the government does but about whether the international intellectual property policy adequately leads to an effective outcome.[192]

C. Step 3: Evaluate Effectiveness of International Intellectual Property Policies

If an international intellectual property policy is proven to "reasonably" and "likely" achieve its proposed objectives, the state then should compare this policy with other alternatives. In other words, the proposed international intellectual property policy that restricts the right to health should be compared with a wide range of more humane and just policy alternatives to create viable options and a fresh perspective. If other policies can infringe less on the right to health but provide similar functions as the proposed international intellectual property policy does, the proposed policy then could be regarded as a violation of the right to health because it fails to adopt a least restrictive alternative to achieve the same objective.

The least restrictive alternative principle seeks a policy that is least intrusive while achieving the proposed objective as well or better than the policy under consideration. For example, there are plenty of policy instrument options when a state decides to protect pharmaceutical patents in order to encourage research and development-based investment. In data protection, Robert Weissman proposed that there are four broad sets of options for countries in implementing Article 39.3 of the TRIPS.[193]

(1) Bans on misappropriation. This approach provides the lowest level of protection for registration data that is compatible with TRIPS. It bans parties from fraudulently or dishonestly gaining access to registration data and using it to seek marketing approval.

(2) The cost-sharing approach to registration data. This approach gives generic firms an automatic right to use originators' data, but requires them

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[191] Robert Weissman, *Data Protection: Options for Implementation*, *in* NEGOTIATING HEALTH: INTELLECTUAL PROPERTY AND ACCESS TO MEDICINES 151, 154 (Pedro Roffe et al. eds., 2006).
[192] Gostin & Mann, *supra* note 116, at 61-62.
[193] Weissman, *supra* note 191, at 151.

to pay a share of the documented costs of generating the data, proportionate to the size of the markets in which they are selling their product.

(3) Provision of data exclusivity. This approach gives those firms submitting original registration data an effective marketing monopoly for a specified period of time and is likely to result in denials of access to medicines.

(4) Public health variants of the data-exclusivity approach. These modifications and clarifications to a strict and inflexible data-exclusivity rule can advance public health objectives by limiting the scope of the data exclusivity provided, or by creating exceptions to data exclusivity.

Choosing the right option then is important because "the provision of exclusive rights to registration data can provide patent-like protections in cases where pharmaceuticals are not covered by patents."[194] The third approach (provision of data exclusivity) is the norm adopted in some developing countries, especially those who have entered in bilateral or regional FTAs with the U.S.[195] However, the level of pharmaceutical patent protection that is generally imposed by FTAs with the U.S. would go beyond what is necessary to accomplish these goals because generic drugs will be delayed in entering the market, and prices will rise accordingly.[196] Therefore, the provision of data exclusivity, which no doubt would also achieve the policy purpose, might impose broad and profound restrictions on the right to health and is not the least infringing policy instrument. On the contrary, the cost-sharing approach might be a proper policy because even though it is a TRIPS-plus approach to TRIPS Article 39.3, it is nonetheless one designed to impose minimal obstacles to generic competition.[197]

There should be no problem requiring international trade institutions and states to evaluate effectiveness (the least infringement principle) of the international intellectual property laws and policies because the WTO actually applies similar approaches in some cases. One example is the well-known decision by the Thai government to impose restrictions on the importation of and internal taxation on cigarettes. In short, Thailand banned foreign-produced cigarettes but allowed the sale of domestic-produced cigarettes, justifying the measure based on Article XX(b) of the GATT on the grounds that such restrictions were "necessary to protect human . . .

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[194] *See* Weissman, *supra* note 191.

[195] *Id*. at 164.

[196] For example, in addition to intellectual property protection, "[t]he World Health Organisation predicted that Colombia's generic industry would lose up to 71% of its market share due to its US FTA, while one-third of Australia's generic companies had to close or merge when data exclusivity alone was introduced in Australia." Jacqueline Ann Surin, *Local drug makers may lose out under US FTA*, THE EDGE DAILY, July 17, 2006, *available at* http://www.bilaterals.org/article.php3?id_article=5279&lang=en (last visited Mar. 4, 2010).

[197] Weissman, *supra* note 191, at 160.

health." Even though the GATT panel agreed that "[allowing] contracting parties to impose trade restrictive measures inconsistent with the General Agreement to pursue overriding public policy goals to the extent that such inconsistencies were unavoidable,"[198] it disagreed with Thailand's policy and found that "the import restrictions imposed by Thailand could be considered to be "necessary" in terms of Article XX(b) only if there were no alternative measure consistent with the General Agreement, or less inconsistent with it, which Thailand could reasonably be expected to employ to achieve its health policy objectives."[199] In other words, "Thailand's actions could only be justified if they were the least restrictive means of achieving the legitimate policy objective."[200] This "least-restrictive-means" test is somewhat similar to my proposed human rights impact assessment for international intellectual property policy, except the evaluated object in my proposal is the right to health rather than trade interests.

Therefore, the least infringement principle should be applied in the right to health impact assessment in an international trade policy. Given this standard (step 3) and the evaluation of the effectiveness (step 2), the state would not be permitted to resort to restrictions on the right to health if it could achieve the proposed policy purpose through less drastic, less coercive means.

D. Step 4: Access Trade-Off Relationships in International Intellectual Property Policies

When an international intellectual property policy restricts individuals' right to health in order to achieve a proposed policy purpose (step 1), in addition to evaluating the adequacy (step 2) and the effectiveness (step 3), the state must also show that the weight of the restricted right to health is not out of proportion with the weight of the pursued economic interests (or social benefits). If a proper balanced trade-off relationship cannot be achieved in an international intellectual property policy, the state should abandon such a policy due to the potential violations of the right to health.

It is important to assess the trade-off between restricted rights to health and pursued public order because this assessment provides a procedural and substantial standard to determine whether the state has retained considerable discretion when pursuing international intellectual property policy purpose or not. For example, according to the UDHR, limitations of human rights (including the right to health) must be "determined by law solely for the purpose of securing due recognition and respect for the rights

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[198] *Thailand Cigarettes GATT Panel Report*, *supra* note 23, ¶ 74.
[199] *Id.*
[200] *Id.*

and freedoms of others and of meeting the just requirements of morality, public order and the general welfare in a democratic society."[201] The WTO panels and the appellate body also adopted a similar conception to identify and weigh competing health risks and economic possibilities. For example, in European Communities – Measures Affecting Asbestos and Asbestos-Containing Products, the appellate body argued that the more "vital or important" the ends at issue, "the easier it [is] to accept as 'necessary' measures designed to achieve those ends."[202] And health is "both vital and important in the highest degree."[203]

However, it is debatable about how to evaluate the degree of invasiveness of the human rights burden in international intellectual property policy. The distinguishable fundamental and non-fundamental rights to health – non-fundamental rights to health with progressive realizations while fundamental rights to health with immediate realizations (see section (V)) – can provide us a direction to evaluate the trade-off relationship between the intellectual property right and the right to health. It is important to distinguish different contents of the right to health because the nature (or essence) of these rights are different. And these different natures further influence the assessment outcomes ― the state only needs to show proper trade-offs between the intellectual property rights and the fundamental rights to health, but is not obligated to assess trade-offs between the intellectual property rights and the non-fundamental rights to health.

(1) Non-Fundamental Rights to Health: Because the state has only moral obligations to progressively realize non-fundamental rights to health within available resources, the state then can freely decide, without proving a proper trade-off, to fulfill non-fundamental rights to health or not in international intellectual property policies. It is justified for the state to maintain substantial authority here because failing to fulfill these non-fundamental rights to health would not restrict individuals' basic capabilities in terms of minimal health nor lessen the range of their fair opportunity to achieve the good ends of their life plans. In addition, the

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[201] UDHR, *supra* note 99, art. 29(2).

[202] Appellate Body Report, *European Communities – Measures Affecting Asbestos and Asbestos-Containing Products*, ¶ 172, WT/DS135/AB/R (Mar. 12, 2001).

[203] *See id.*; however, it must be noticed that the appellate body's approach adopted in *European Communities – Measures Affecting Asbestos and Asbestos-Containing Products*, was a much less restrictive alternative regulatory measure under Article XX(b)'s necessity test under the GATT. For example, in Thailand - Restrictions on Importation of and Internal Taxes on Cigarettes, the GATT dispute settlement panel concluded that Article XX(b) necessity test requires a finding that "[there is] no alternative measure consistent with the [GATT], or less inconsistent with it," which member states could "reasonably be expected to employ to achieve its health policy objectives." *Thailand Cigarettes GATT Panel Report*, *supra* note 23. M. Gregg Bloche & Elizabeth R. Jungman, *Health Policy and the World Trade Organization, in* GLOBALIZATION AND HEALTH 250, 255 (Ichiro Kawachi & Sarah Wamala eds., 2007).

state's moral obligations to fulfill non-fundamental rights to health, in the international human rights approach, are analogous to so-called "soft law" obligations that have moral but no direct legal force,[204] as a result the state then has the authority and autonomy to restrict non-fundamental entitlements without proving whether there is a proper trade-off relationship.

(2) Fundamental Rights to Health: The state's restrictions on fundamental rights to health in international trade policies cannot be justified unless there is a proper trade-off relationship between restricted fundamental entitlements and pursued social benefits. Because fundamental entitlements are directly related to individuals minimal health (basic capabilities), failing to fulfill these entitlements can deprive his or her capacities and significantly shrink an individual's fair opportunity range to pursue good end of the life plans as a free and equal member of the society. Thus, the state has the legal obligation to protect and fulfill fundamental rights to health immediately regardless of available resources. However, the fact that the state has a legal obligation does not mean that the state cannot restrict fundamental rights to health. The state's immediate legal obligation merely means that, the state cannot simply use resource limitations or pursuits for economic interests as a defense to reject its obligation to fulfill fundamental rights to health, and to justify the restrictions on such rights. However, if the state can prove that fundamental rights to health must be regulated in order to pursue or to guarantee the greater social benefits, or that pursued social benefits are much greater than restricted fundamental rights to health, the restrictions of fundamental rights to health are justified. In other words, fundamental rights to health are not absolute rights.

This argument, departing from the traditional human rights approach, states that the state's obligations to fulfill rights to health in international intellectual property policy should be placed on different levels (fundamental and non-fundamental rights to health) according to their relevance (or correlation) to the minimal health and individuals' basic capabilities. By applying this assessment in the international intellectual property, the state then has a more objective criterion to decide what "epidemics" should be regarded as public health crises in Paragraph 5(c) of the Doha Declaration. Only an epidemic that would significantly influence individuals' minimal health and undermine their basic capabilities could be regarded as a "public health crisis" because these epidemics would substantially restrict individuals' fundamental rights to health and their fair opportunities to pursue good lives.

Furthermore, this assessment also provides developing and developed

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[204] Obijiofor Aginam, *Public Health Law in South Africa*, 8 IND. J. GLOBAL LEGAL STUD. 479, 483 (2001) (book review).

countries an independent standard with a theoretical basis to settle the conflicts between the intellectual property and the right to health:

(1) If the international intellectual property policy would restrict only the non-fundamental rights to health, the state then cannot use the TRIPS-exemptions to restrict the intellectual property right because the state maintains substantial authority and autonomy to restrict non-fundamental entitlements without proving whether there is a proper trade-off relationship. It is justified for the state to restrict the non-fundamental rights to health to protect the intellectual property right is more important, if the state can simply prove that it has adopted reasonable legislative and other measures within reasonable available resources (progressive realization) in international intellectual property policy.

(2) However, this progressive realization approach alone cannot provide a sufficient reason for the state to justify the restrictions it places on fundamental rights to health in international intellectual property policy. In other words, if the international intellectual property policy would restrict the fundamental rights to health, the state has the burden to prove a compelling interest that is substantially furthered by restricting fundamental rights to health. Therefore, developing countries then have a legal ground to resist developed countries' demands that impose stricter obligations to protect intellectual property rights through TRIPS-plus provisions.

But fundamental rights to health should not be regarded as absolute rights. For developing countries, even though they can adopt necessary measures (e.g. compulsory licensing) to restrict intellectual property rights and to protect fundamental rights to health (as proposed in the Doha Declaration), they also need to prove that there is a proper trade-off relationship between the restricted intellectual property rights and the pursued fundamental rights to health. If the state cannot prove there is a proper trade-off relationship, the application of TRIPS-exemptions would be regarded as unjustified.

I will not further discuss how to evaluate the trade-off relationship because such an evaluation needs more explicit health-related information (such as the prevalence and incidence of diseases, their severity, pathogenic mechanisms, and impacts on physical and mental functions). In this paper I cannot comprehensively review all health-related information, as the aim here is to explore how to apply the right to health in the international intellectual property regime at the macro level rather than at the micro level.

VII. CONCLUSION

In the international intellectual property regime, the ambiguity and vagueness of the TRIPS-exemptions leaves great flexibility and discretion

to states to arbitrarily assign a priority to intellectual property rights when they conflict with the right to health. By applying the human rights approach to the international intellectual property regime, the state would have an objective and monitorable standard to balance the conflicts between the intellectual property right and the right to health. The right to health impact assessment would be beneficial for both developing and developed countries because the developing countries can have a legal ground to refuse unjustified intellectual property protection required by developed countries, while the developed countries can apply the assessment to determine whether the developing countries abuse the TRIPS-exemptions.

However, this paper only provides conceptual clarity and theoretical foundations to refine the relationships between the intellectual property right and the right to health. More discussion and case studies are needed on how to practically apply the right to health impact assessment so that intellectual property laws and policies may be evaluated.

In addition, I must clarify again that, even though it is important to coordinate international human rights institutions with the international intellectual property laws to address public health issues, it is also important not to establish a hierarchy of international intellectual property laws and human rights laws. It is because if international intellectual property laws are interpreted mainly in light of existing international human rights documents, the state might refuse to recognize patents on pharmaceuticals arguing that it wants to fulfill its obligation on the right to health. The absence of patent protection in domestic laws might cause international pharmaceuticals' withdrawal of investments and applications for drugs. In addition, inventors might also lose their incentive to develop new drugs to treat different diseases. Thus, there is every possibility that such a policy, which claims to equally protect all contents (fundamental and non-fundamental contents) of the right to health, would in fact harm the right to health for citizens of that state. In order to avoid this situation, applying the right to health approach in the international intellectual property regime should be done very cautiously. More empirical studies should be established to evaluate influences on public health (the right to health) and economic interests (intellectual property rights) caused by different intellectual property policies. Society then can use the data to explicitly evaluate the trade-off relationships between the right to health and the intellectual property rights, and then choose a better policy to balance these two equally important sets of rights.

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