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Kevin Outterson

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LICENSES UNDER ARTICLES 31 AND 31 *BIS***

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Kevin Outterson

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Disease-Based Limitations On Compulsory Licenses Under Articles 31 and 31bis

Kevin Outterson[♣]

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Abstract: Compulsory licensure is one of the flexibilities retained under TRIPS to permit countries to support public health while granting pharmaceutical patents. The United States Government appears to take the position that compulsory licensure and other TRIPS flexibilities must be limited to certain infectious diseases, namely AIDS, tuberculosis, and malaria. These proposed limitations are not supported by the text of Articles 31 and 31bis of TRIPS or by the negotiating history of the Agreement. Introducing disease-based limitations would be unwise, as the developing world is undergoing a demographic transition, with increasing shares of its disease burden coming from non-infectious diseases. Public health calls for retaining TRIPS flexibilities in all categories of human need.

I. Disease-Based Limitations on Compulsory Licenses in TRIPS Article 31

Article 31 of the TRIPS Agreement permits a WTO Member country to issue a compulsory license of a patent under certain conditions.¹ Compulsory licenses are not limited to any category of diseases. The text of Article 31 never mentions any specific diseases, a deliberate decision by the negotiating group to avoid any disease-based limitation.²

This provision has been misunderstood – perhaps deliberately so - in the pages of the WALL STREET JOURNAL and the FINANCIAL TIMES to imply that Article 31 only applies to national public health emergencies like HIV/AIDS or only to the least-developed countries. When Thailand (a middle-income country) attempted to use TRIPS flexibilities

[♣] Associate Professor, Boston University School of Law. This chapter is a modified and expanded version of *Should Access to Medicines And TRIPS Flexibilities Be Limited To Specific Diseases?* 34 Am. J. L. & Med. 279 (2008), used by permission. An earlier version of this project was submitted to the WHO IGWG in 2007: *A Request for Clarification Concerning the Proper Scope of the IGWG's Work to Improve Access to Patented Medicines*, Submission to the WHO IGWG (30 September 2007).

¹ Section 31 of the TRIPS Agreement does not use the term “compulsory licenses,” preferring the longer phrase “other use without authorization of the rights holder.” Herein, I use the more traditional term “compulsory license” or its variations.

² See *infra* nn. 11-28 and text accompanying; Frederick M. Abbott & Jerome H. Reichman, *The Doha Round's public health legacy: strategies for the production and diffusion of patented medicines under the amended TRIPS provisions*, 10 J. Int'l Econ. L. 921, 936-37 (2007) (referring to the Doha Declaration).

guaranteed and encouraged by the *Doha Declaration* on drugs for cancer and heart disease, a backlash ensued from conservative media, pharmaceutical manufacturers, patent blogs, and the governments in the United States and the European Union.³ The WALL STREET JOURNAL editorial page attacked the Thai compulsory licenses as “seizures” that cynically distorted WTO rules, while a property-rights activist group charged the Thai government with violating global trade rules.⁴ The FINANCIAL TIMES also ran articles critical of Thailand’s moves.⁵ Abbott, the manufacturer of lopinavir/ritonavir, withdrew pending applications for drugs in Thailand, including a heat-stable version of an important fixed-dose combination drug for AIDS with particular usefulness in a tropical climate.⁶ The USTR then placed Thailand on the special 301 “priority watch list,” for alleged violations of intellectual property law, mentioning in particular the compulsory license.⁷ Peter Mandelson, the EU Trade Commissioner at that time, also warned Thailand not to issue the compulsory licenses.⁸ According to the FINANCIAL TIMES, his letter to Thailand claimed that compulsory licenses “allow countries to waive intellectual property rules to fight emergency health epidemics once all other avenues have been explored.”⁹ This claim is clearly mistaken, and finds almost no textual basis in Article 31.¹⁰ Nor does anything in Article 31 limit its application only

³ See Editorial, *Bangkok’s Drug War Goes Global*, WALL STREET JOURNAL, (March 7, 2007); M. Vaughan, *In Clash with Activists, Critics Charge Thailand Violation of Trade Rules*, INTELLECTUAL PROPERTY WATCH, (March 19, 2007); Editorial, *Drugs in Thailand*, FINANCIAL TIMES (Jan. 31, 2007) (acknowledging that Thailand’s proposal was legal under WTO rules, but questioning the wisdom of issuing a compulsory license for a preventative heart disease drug); Amy Kazmin & Andrew Jack, *Thai Government to Break Drug Patents*, FINANCIAL TIMES (Jan. 25, 2007) (“some diplomats questioned whether Bangkok’s breaking the Plavix patent would be consistent with Doha’s aim to support licensing as a response to extreme emergencies like the Aids epidemic”); Apiradee Treerutkuarkul, *Talks With Pharma-Giants Collapse*, BANGKOK POST (Dec. 18, 2007); Brent Savoie, *Thailand’s Test: Compulsory Licensing In An Era of Epidemiologic Transition*, 48 VA. J. INT’L L. 211 (2007); K. Noonan, *Worldwide drug pricing regime in chaos* (Patent Docs blog, May 9, 2007); K. Noonan, *The law of unintended consequences arises in applying TRIPS to patented drug protection in developing countries*, (Patent Docs Blog, May 1, 2007); see generally K. Outtersson & A. Kesselheim, *Market-based licensing for HPV vaccines in developing countries*, 27 HEALTH AFFAIRS (Jan/Feb 2008) 130-139, at 133-34 [hereinafter, OUTTERSSON & KESSELHEIM].

⁴ Editorial, *Bangkok’s Drug War Goes Global*, WALL STREET JOURNAL, (March 7, 2007); M. Vaughan, *In Clash with Activists, Critics Charge Thailand Violation of Trade Rules*, INTELLECTUAL PROPERTY WATCH, (March 19, 2007).

⁵ Editorial, *Drugs in Thailand*, FINANCIAL TIMES (Jan. 31, 2007) (acknowledging that Thailand’s proposal was legal under WTO rules, but questioning the wisdom of issuing a compulsory license for a preventative heart disease drug); Amy Kazmin & Andrew Jack, *Thai Government to Break Drug Patents*, FINANCIAL TIMES (Jan. 25, 2007) (“some diplomats questioned whether Bangkok’s breaking the Plavix patent would be consistent with Doha’s aim to support licensing as a response to extreme emergencies like the Aids epidemic”).

⁶ Médecins Sans Frontières, *Press Release: Abbott Should Reconsider its Unacceptable Decision to Not Sell New Medicines in Thailand*, (March 23, 2007).

⁷ Office of the United States Trade Representative, 2007 SPECIAL 301 REPORT 27 (2007) [hereinafter, SPECIAL 301 REPORT].

⁸ Andrew Boundsin, *Thais warned over drug pricing pressure*, FINANCIAL TIMES (August 10, 2007).

⁹ Andrew Boundsin, *Thais warned over drug pricing pressure*, FINANCIAL TIMES (August 10, 2007).

¹⁰ Frederick M. Abbott & Jerome H. Reichman, *The Doha Round’s public health legacy: strategies for the production and diffusion of patented medicines under the amended TRIPS provisions*, 10 J. Int’l Econ. L. 921, 949-956 (2007). Nor was any disease-specific limitation found in the relevant compulsory licensure provisions of the Paris Convention. Paris Convention For the Protection of Industrial Property, Art. 5 A(2) (1967) (“Each country of the Union shall have the right to take legislative measures providing for the grant

to the least developed countries. Compulsory licenses are permitted to all WTO Members, not just the poorest.

Those who would circumscribe compulsory licenses draw support from Article 31(b), which refers to “situations of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use.” But this language is not a general limitation on compulsory licenses. Article 31(b) is an exception to the requirement of prior negotiation on “reasonable commercial terms.” The Member may waive the negotiation requirement of Article 31(b) if one of three conditions exist: (1) national emergency; (2) other circumstances of extreme urgency; or (3) public non-commercial use. If none of these exceptions apply, the Member must negotiate on reasonable commercial terms before proceeding with the compulsory licensure process. In the case of Thailand, if the proposed use is limited to public noncommercial use, then the license satisfies the waiver in Article 31(b). In any event, Thailand does not rely on the waiver, since it also claims to have negotiated for two years in an attempt to reach an agreement with the patent holder. If either of these conditions are true, then Thailand need not prove the existence of “national emergency” or “other circumstances of extreme urgency” in order to issue a compulsory license.

In the negotiating history of Article 31, disease-specific limitations were discussed and rejected. The Secretariat of the Negotiating Group on TRIPS made notes of the TRIPS negotiating meetings that were restricted from public distribution, although copies circulated informally. These notes have now been publicly released on the WTO website. The earliest substantive discussion of the scope of compulsory licenses is recorded in paragraph 13 of the Notes of the Meetings May 16-19, 1988.¹¹ At that meeting, one participant suggested the complete elimination of compulsory licensing: “the prohibition of the use of compulsory licenses would be the most trade promoting solution, [but] there were many safeguards to limit the possible abuse of compulsory licensing that could be considered...”¹² Five safeguards were then discussed:

- (1) Non-exclusivity (now Article 31(d));
- (2) Limitation to the local market (now “predominately for the supply of the domestic market” in Article 31(f), as modified by Article 31*bis*);
- (3) Judicial review (now Article 31(i) and (j));
- (4) Limiting compulsory licenses for nonworking to workings that are economically feasible in the country (not in Article 31); and
- (5) Patents cannot be revoked for nonworking (not in Article 31).¹³

If disease-specific limitations were discussed at this meeting, it was not reflected in the Notes. Subsequent TRIPS negotiation meetings focused on potential limitations on the purposes for which compulsory licenses could be issued, but again specific diseases were

of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work.”)

¹¹ MTN.GNG/NG11/7, par. 13 (21 June 1988).

¹² MTN.GNG/NG11/7, par. 13 (21 June 1988).

¹³ MTN.GNG/NG11/7, par. 13 (21 June 1988).

not mentioned.¹⁴ The first recorded discussion of the special health needs of developing countries occurred in May 11-12, 1989:

“To address these concerns, a participant suggested ... a balance between the rights of intellectual property owners and the obligations to be fulfilled by them; that technologies notably those required to meet basic nutritional and health needs were made available to developing countries on fair and reasonable terms; and that effective curbs were imposed on abuses of intellectual property rights by rights holders.”¹⁵

More substantive discussions occurred in July 12-14, 1989 when some participants suggested special and differential treatment for developing countries regarding patents for public health.¹⁶ Other participants (apparently the US) argued for additional limitations on compulsory licensing,¹⁷ while India argued for allowing developing countries to exclude patenting on pharmaceutical products altogether, a point India eventually conceded in Article 27.¹⁸ The European Communities supported a stripped down version of Article 31, with fewer restrictions on compulsory licenses, but the United States strongly opposed that view and argued for additional restrictions on compulsory licensing.¹⁹ None of these discussions focused on specific diseases.

By the October 1989 meeting, the European Communities had changed course to support the US position on compulsory licensing. This meeting marked the debut of the key language requiring “serious efforts ... by the applicant in line with normal commercial practices to obtain a voluntary license.”²⁰ This text is the genesis of Article 31(b).

The representative of the European Communities also proposed a “positive list” of permitted compulsory license grounds, and others also suggested limiting compulsory licenses to specific grounds.²¹ Within a few months, by the April 1990 meeting, the EC abandoned their “positive list” proposal as not “useful” and likewise agreed not to specify

¹⁴ MTN.GNG/NG11/9, pars. 13, 14 (13 Oct. 1988).

¹⁵ MTN.GNG/NG11/12, par. 5 (13 June 1989).

¹⁶ MTN.GNG/NG11/14, pars. 70, 77 (12 Sept. 1989). Substantive policy discussions relating to patents and access to medicines occurred in the April 1990 meeting, the 20th meeting of the TRIPS negotiating group. MTN.GNG/NG11/20, pars. 29-41 (24 April 1990). Some of the arguments that are now familiar in the access to medicines literature were discussed here. For example, the history of patents in developed countries was noted as a recent development, with many developed countries having eschewed patents when they were at a “comparable level of development, including patents on pharmaceuticals.” MTN.GNG/NG11/20, par. 31 (24 April 1990). Delegates argued for flexibilities for “essential articles, such as medicine and food to be available to the public at reasonable prices.” MTN.GNG/NG11/20, par. 33 (24 April 1990). A developed country representative responded: “most pharmaceuticals, including the overwhelming majority of those on the WHO list of essential drugs, were in the public domain and not under patent protection.” MTN.GNG/NG11/20, par. 33 (24 April 1990). The low level of R&D into tropical diseases was blamed on the lack of patent protection in developing countries. MTN.GNG/NG11/20, par. 33 (24 April 1990).

¹⁷ MTN.GNG/NG11/14, par. 75 (12 Sept. 1989).

¹⁸ MTN.GNG/NG11/14, par. 79.1 (12 Sept. 1989).

¹⁹ MTN.GNG/NG11/14, pars. 83.1 – 83.7 (12 Sept. 1989).

²⁰ MTN.GNG/NG11/16, par. 22 (4 Dec. 1989); MTN.GNG/NG11/17 par. 39 (Jan. 23, 1990).

²¹ MTN.GNG/NG11/16, pars. 22, 23, 33(5) (4 Dec. 1989).

the grounds for a compulsory license.²² The final text of Article 31 simply refers to the law of the Member for these issues and does not specify grounds.²³

The representative of Japan in the December 1989 negotiations initiated the first substantive discussion of a disease-specific limitation, namely an “epidemic.”²⁴ The context was a discussion of the proper limitations on compulsory licensing in paragraph 2(1)(i) of the draft text. The proposal supported by Japan included a phrase “actual peril to life of the general public or body thereof.” In response to questions, the representative of Japan said “the proposal was meant to be illustrative of certain situations, including for example the actual occurrence of events, such as an epidemic, that were of sufficiently serious magnitude to warrant the grant of compulsory licenses.”²⁵ In the next meeting, Mexico also proposed grounds including a “critical shortage of a product in the domestic market.”²⁶

None of these ideas survived in the Dunkel Draft of December 1991,²⁷ or in the final text of Article 31. The last appearance of limited purposes in Article 31 may be the draft dated July 23, 1990, but that draft also included a broad provision permitting compulsory licenses for food and medicines.²⁸ The Japanese comment represents the high water mark of discussion of disease-specific limitations in the public history of the TRIPS committee negotiation, and it was merely a comment in response to a question. The provision in question did not survive in Article 31. Even so, it was not a limitation to any specific disease, but at most a limitation specifying epidemics. More properly understood, the Japanese phrase was focused on events that were actually occurring, as opposed to theoretical events. An epidemic was merely one possible example.

In short, nothing in the negotiating committee history of TRIPS supports a disease-specific limitation in Article 31. In fact, the “positive list” approach to the granting of compulsory licenses was discussed and rejected.

In addition to Article 31 itself, three other texts should be examined for disease-specific restrictions: the *Doha Declaration*, the WTO TRIPS Council Decision of August 30, 2003 (the *Council Decision*), and Article 31*bis*, a proposed amendment to the TRIPS Agreement.

²² MTN.GNG/NG11/20, pars. 4, 22 (24 April 1990). Grounds for compulsory licensure were still being discussed as late as November 1990. MTN.GNG/NG11/27 par. 4 (1 Nov. 1990).

²³ TRIPS Art. 31. Carlos M. Correa, *TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS: A COMMENTARY ON THE TRIPS AGREEMENT 314-15* (Oxford Univ. Press, 2007) (“WTO Members can determine the *grounds* under which such licenses can be granted. Said Article [31], as discussed below, only stipulates the *conditions* that governments must comply with. Paragraph 5(b) of the Doha Declaration categorically confirmed this interpretation”).

²⁴ MTN.GNG/NG11/17 par. 39 (Jan. 23, 1990).

²⁵ MTN.GNG/NG11/17 par. 39 (Jan. 23, 1990); MTN.GNG/NG11/21 par. 52 (22 June 1990).

²⁶ MTN.GNG/NG11/18 par. 5 (Feb. 27, 1990).

²⁷ MTN.TNC/W/FA (Dec. 20, 1991).

²⁸ W/76 Art. 1A.2, 1B (July 23, 1990).

II. Disease-Based Limitations in the Doha Declaration, the Council Decision, and Article 31bis

In the negotiations leading to the *Doha Declaration*, the US requested an explicit “positive list” including only the “Big 3” diseases (HIV/AIDS, tuberculosis, and malaria).²⁹ This early demand specifically excluded all other epidemics. After much opposition, in an attempt to get some positive list limitation, the US finally proposed a broader list of 23 covered diseases, including the additional catch-all category of “other epidemics of comparable gravity.”³⁰ This proposal was also not accepted. The US was the last country to assent to the unanimous resolution without their sought-after provisions.³¹ The ultimate language of the *Doha Declaration* should be understood as a defeat for the US positive list approach, and a broad re-affirmation that Article 31 is not limited to particular diseases.

The *Doha Declaration* extended the technical deadline for least-developed countries to fully comply with TRIPS, although many were compliant with the pharmaceutical patent provisions years in advance.³² Thailand did not rely on this delayed implementation provision, as it is not a least-developed country. The *Doha Declaration* mentions specific diseases in two contexts; neither operates as a disease-based limitation on compulsory licensure:

“1. We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.”³³

“5. c. 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.”³⁴

The *Doha Declaration* does not limit compulsory licenses to specific diseases or epidemics. Any such interpretation would be odd, since the express purpose of the *Doha Declaration* was to promote access. Paragraph 1 of the *Doha Declaration* merely uses

²⁹ IP/C/W/340 (March 14, 2002). *Drugs for the poor*. Wash Post p. A32 (Nov. 14, 2002).

³⁰ See Daniel Gervais, *THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS*, 3RD EDITION par. 1.64 (2008).

³¹ GAO Report 07-1198, *U.S. TRADE POLICY GUIDANCE ON WTO DECLARATION ON ACCESS TO MEDICINES MAY NEED CLARIFICATION 23* (Sept. 2007) [hereinafter, *GAO TRADE POLICY REPORT*]; Duncan Matthews, “Lessons from Negotiating an Amendment to the TRIPS Agreement: Compulsory Licensing and Access to Medicines,” in Guido Westkamp, ed. *EMERGING ISSUES IN INTELLECTUAL PROPERTY – TRADE, TECHNOLOGY AND MARKET FREEDOM: ESSAYS IN HONOR OF HERCHEL SMITH 227* (UK: Edward Elgar, 2007). Holger Hestermeyer, *HUMAN RIGHTS AND THE WTO: THE CASE OF PATENTS AND ACCESS TO MEDICINES 263* (Oxford Univ. Press, 2007).

³² Phil Thorpe, *Study on the Implementation of the TRIPS Agreement by Developing Countries 1* (Comm. on Intellectual Prop. Rights, Study Paper 7 (circa 2004)).

³³ *Doha Declaration*, at par. 1 WT/MIN(01)/DEC/2.

³⁴ *Doha Declaration*, at par. 5.c WT/MIN(01)/DEC/2.

some diseases as illustrative examples of “public health problems afflicting many developing countries.” Paragraph 1 does not purport to limit or interpret Article 31. The core provisions of the *Doha Declaration* clearly apply to all diseases, such as the language of paragraphs 4 and 5(b):

“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.”

“5. b. Each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.”

The *Doha Declaration* clearly supports WTO Members’ rights to utilize TRIPS flexibilities – including compulsory licensure and parallel trade – to “protect public health” without regard to the type of disease or development level of the country.³⁵

The second specific disease list in the *Doha Declaration* is found in paragraph 5(c). Likewise, it is not a disease-specific limitation on compulsory licenses. Rather, it interprets Article 31(b) to create a safe harbor for situations when the government can waive the requirement of advance negotiations on reasonable commercial terms:

“5.c. 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.”³⁶

The first part of paragraph 5(c) grants WTO members autonomy in determining the meaning of “national emergency or other circumstances of extreme urgency.” That phrase includes two of the three alternative grounds for a waiver of the commercial negotiation requirement in Article 31(b). (The third ground is “public non-commercial use”). The disease list is essentially a safe harbor for national decision-making. Arguments that disease-specific limitations are found in paragraph 5(c) of the *Doha Declaration* misinterpret the waiver provisions of Article 31(b).

The well-regarded treatise by Daniel Gervais discusses these provisions of the *Doha Declaration*:

“The list contained in the Declaration is not exhaustive and its emphasis on diseases ‘afflicting many developing and least-developed countries’ affords some

³⁵ *Doha Declaration*, at par. 4, 5(b), 5(c), 5(d); GAO TRADE POLICY REPORT, at 11-26. Paragraph 7 grants an additional flexibility to least-developed countries, but that doesn’t constrain existing rights under TRIPS.

³⁶ *Doha Declaration*, at par. 5(c).

flexibility in relation to diseases that affect those Members particularly. By application of the *ejusdem generis* interpretation rule, the reference to HIV/AIDS, tuberculosis, malaria and other epidemics shows that Members envisaged the application of the Decision to serious diseases. This must be read in context, together with paras 5(b) and (c) of the 2001 Declaration on TRIPS and Public Health...³⁷

Gervais is not asserting disease-specific limitations under Article 31 generally, nor is he claiming that the *Doha Declaration* is limited to specific diseases. The point is more nuanced: under the *Council Decision* and Article 31*bis*, when attempting to define the terms “national emergency or other circumstances of extreme urgency,” for the limited purpose of the new exception to Article 31(f), then public health crises relating to the HIV/AIDS, tuberculosis, malaria and other epidemics are generally understood to qualify.³⁸ The WTO has effectively agreed, in advance, that these epidemics will presumptively qualify for the new exception to Article 31(f).

His application of the *ejusdem generis* interpretation rule might also be proper in this very limited context (“other epidemics”), as examples of diseases that are understood to presumptively qualify under paragraph 5(c) of the *Doha Declaration*. In other words, Members gain additional flexibility with regard to epidemic diseases, without any limitation on the application of Article 31 to other diseases. Members remain free to claim other diseases as the basis for action under Article 31, the *Council Decision*, and Article 31*bis*, but they do so without the additional presumptions afforded these particular epidemic diseases.

Another possible source of confusion arises under paragraph 6 of the *Doha Declaration*, which subsequently led to the *Council Decision* and then to proposed Article 31*bis*. Under these provisions, compulsory licenses could be issued for export to least-developed countries, suspending Article 31(f) of the TRIPS Agreement, which restricts compulsory licenses predominantly for domestic use. Paragraph 6 does not limit compulsory licenses to any specific diseases or types of countries. Gervais also comments on these provisions, suggesting, “that Members envisaged the application of the Decision to serious diseases.”³⁹ This “serious diseases” position was discussed in the negotiating history of Article 31 when some participants voiced objections to compulsory licenses on “lifestyle” medicines. But these provisions were not adopted in the text of Article 31*bis*, which argues against their inclusion through interpretive principles. Furthermore, the Article 31*bis* process is itself a suspension of Article 31(f). The provisions in the *Council Decision* and Article 31*bis* 1(b) are a safe harbor for exports that would otherwise violate Article 31(f) rather than a general limitation on compulsory licensing. The fact that some Members voluntarily waived application of Article 31*bis* to

³⁷ Daniel Gervais, *THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS*, 3RD EDITION par. 2.288 (2008). See also *id.* at par. 1.64.

³⁸ Decision on the Implementation of para.6 of the Doha Declaration on the TRIPS Agreement and Public Health, adopted by the General Council on August 30, 2003.

³⁹ Daniel Gervais, *THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS*, 3RD EDITION par. 2.288 (2008).

imports by their own countries isn't relevant to countries like Thailand, except to strongly establish that Thailand did not join in this voluntary action.

The TRIPS Agreement is subject to dispute resolution under the WTO Dispute Settlement Understanding, but the US Government is unlikely to initiate a WTO panel against Thailand. The TRIPS Agreement authorizes members like Thailand to issue compulsory licenses for these drugs.⁴⁰ For all the bluster in the WALL STREET JOURNAL, it is clear that the controlling legal texts do not limit the use of TRIPS flexibilities to any particular set of diseases. Nor should they. From the perspective of public health, limiting access programs and TRIPS flexibilities to particular diseases would be quite dangerous and unnecessary. Dangerous because the diseases of the world's rich and poor countries are converging, including non-communicative diseases such as heart disease, stroke, diabetes, cancer and depression. Radically cheaper medicines for these conditions could significantly improve health in LMICs. Limitation is also unnecessary because proven tools can be deployed to preserve high-income markets while LMICs pursue equitable flexibilities.⁴¹

Perhaps another factor is at work here as well. An implicit assumption is that the diseases of developing countries are *essentially different* from diseases in the United States or Europe. Paradigmatic cases include exotic tropical diseases such as Ebola Hemorrhagic Fever⁴² and onchocerciasis (river blindness). These neglected diseases and their victims are so remote from the US experience that special charitable programs seem unobjectionable. But only a very small portion of the disease burden in developing countries comes from these exotic tropical neglected diseases. Drugs produced for high-income markets can treat most of the global disease burden, such as the pressing need for cancer therapies in LMICs, where cancer deaths outnumber AIDS deaths.⁴³ The number one cause of death in LMICs isn't a neglected tropical disease, but a familiar "rich country" killer: heart disease.⁴⁴

Finally, the implementation of the *Council Decision* and Article 31*bis* has introduced some disease-specific limitations under national law. When Canada enacted its Access to

⁴⁰ Indeed, as the GAO reports, the USTR itself concedes the point. GAO TRADE POLICY REPORT, at 48-49. The USTR stated that the decision to place Thailand on the Special 301 "priority watch list" was "not solely on [Thailand's] compulsory license decision." *Id.*, at 49. See also Frederick M. Abbott & Jerome H. Reichman, *The Doha Round's public health legacy: strategies for the production and diffusion of patented medicines under the amended TRIPS provisions*, 10 J. Int'l Econ. L. 921, 949-956 (2007).

⁴¹ For my most recent defense of equitable access in the face of diversion, see OUTTERSON & KESSELHEIM, at 136-137. For an earlier defense set in a broader theoretical context, see *Pharmaceutical Arbitrage*, at 261-68. In the context of adaptive innovation leading to the creation of a distinctive product, diversion is much less likely.

⁴² The Centers for Disease Control and Prevention, *Special Pathogens Branch* (2007) available at <http://www.cdc.gov/ncidod/dvrd/spb/mnpages/dispages/ebola.htm>.

⁴³ Institute of Medicine, *CANCER CONTROL OPPORTUNITIES IN LOW- AND MIDDLE-INCOME COUNTRIES* (National Academies Press: 2007).

⁴⁴ Thomas A. Gaziano, *Reducing The Growing Burden of Cardiovascular Disease In The Developing World*, 26 HEALTH AFFAIRS 13 (2007); The Center for Global Health and Economic Development, *A RACE AGAINST TIME: THE CHALLENGE OF CARDIOVASCULAR DISEASE IN DEVELOPING ECONOMIES* (New York: Columbia University, 2004).

Medicines Regime to permit Paragraph 6 exports, the law limited compulsory licenses to specific listed medicines.⁴⁵ This list has been criticized for its excessive narrowness – only 57 drugs or vaccines were included.⁴⁶ The list is effectively limited to AIDS and off-patent medications. Why any off-patent drugs were included is a mystery. Many of the listed drugs treat AIDS; most of those AIDS drugs are available generically already. Almost all of the other drugs on the list are off patent or face legal generic competition in a similar form.⁴⁷ The only patented non-AIDS drugs on the list are eflornithine (for the treatment of African sleeping sickness) and levofloxacin (an important antibiotic). Others are just curious choices considering the global burden of disease (testosterone injection).⁴⁸ Ivermectin is also listed, despite Merck’s promise to donate it in the river blindness campaign. The very narrow positive list in the Canadian Access to Medicines Regime operates as a disease-specific limitation on compulsory licensure for export under Canadian law.

III. The Shifting Global Burden of Disease

To date, the important global legal texts retain broad application to all relevant diseases, but the some parties continue to propose disease-specific limitations, most recently in the World Health Organization’s Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (the “WHO IGWG”).⁴⁹ The WHO IGWG’s task is to distill the WHO CIPIH REPORT⁵⁰ into a global strategy and plan of action.

While pharmaceutical markets vary significantly with the wealth of customers and governments, variations in global disease burdens call for careful analysis. As described above, attempts have been made to limit access initiatives and TRIPS flexibilities to

⁴⁵ The Jean Chretien Pledge to Africa Act, House of Commons, 3d Sess., 37th Parliament, 52-53 Eliz. II, 2004 (Bill C-9) (received Royal Assent on 14 May 2004) [hereinafter CANADIAN ACCESS TO MEDICINES REGIME OR CAMR]. The law created a positive list of drugs eligible for compulsory licensure, a procedural hurdle not required by the WTO. *Id.* Sched. 1, available at <http://www.canlii.org/ca/as/2004/c23/part2620%2Ehtml> (visited January 2, 2008).

⁴⁶ Jillian C. Cohen-Kohler, Laura C. Esmail, Andrea Perez Cosio, *Canada’s Implementation of the Paragraph 6 Decision: Is It Sustainable Public Policy?*, 3 GLOBALIZATION AND HEALTH (2007) available at <http://www.globalizationandhealth.com/content/3/1/12> (visited Dec. 17, 2007).

⁴⁷ The off-patent drugs include: amphotericin B, azithromycin, beclomethasone/beclometasone, ceftazidime, ceftriaxone, ciclosporin(e), ciprofloxacin, daunorubicin, doxorubicin, enalapril, erythromycin, etoposide, ibuprofen, isoniazid + pyrazinamide, insulin, ivermectin, levodopa + carbidopa, lithium carbonate, metoclopramide, metronidazole, morphine, nifedipine, nitrofurantoin, ofloxacin, potassium chloride, rifampin, salbutamol/albuterol, timolol. Patent status was taken from the US FDA Orange Book, available at <http://www.fda.gov/cder/ob/default.htm> (visited January 2, 2008).

⁴⁸ Even in the absence of a “national emergency or other circumstances of extreme urgency” the importing country could use the process for “public non-commercial use.” TRIPS Art. 31*bis*, sec. 1(b). Presumably, Canadian testosterone injections could qualify for the Paragraph 6 process under the “public non-commercial use” provision.

⁴⁹ WHO Intergovernmental Working Group on Public Health, Innovation and Intellectual Property, A/PHI/IGWG/2/2 (31 July 2007) [hereinafter, the WHO IGWG]. An early form of this article was submitted to the WHO IGWG Public Hearing in September 2007, available at http://www.who.int/phi/public_hearings/second/contributions_section1/Section1_Kevin_Outterson_Boston_Uni_Full_Contribution.pdf (visited January 2, 2008).

⁵⁰ WHO, REPORT OF THE COMMISSION ON INTELLECTUAL PROPERTY RIGHTS, INNOVATION AND PUBLIC HEALTH 13 (2006) [hereinafter, the WHO CIPIH REPORT].

specific diseases or categories, such as the “Big 3” infections diseases (AIDS/HIV, malaria and tuberculosis) or “public health emergencies.” Similarly, global drug companies have generally limited their differential pricing policies in LMICs to drugs treating AIDS, malaria and a small number of other drugs.⁵¹ An implicit assumption is that these conditions represent the greatest disease burdens in LMICs. In fact, these infectious diseases are not the most significant drivers of disease burden in LMICs, where noncommunicable or chronic diseases play an increasingly significant role.⁵²

The Global Forum for Health Research categorizes diseases and disease burdens in LMICs. Their system focuses on medical categories:

Group 1: communicable diseases, maternal and perinatal conditions and nutritional deficiencies

Group 2: noncommunicable conditions (NCDs), including cardiovascular disease, diabetes, cancer and mental and neurological conditions

Group 3: injuries, both intentional and unintentional⁵³

In high-income countries, the great majority of burden of disease comes from Group 2; in LMICs, Groups 1 and 2 both account for large shares of the burden of disease.⁵⁴ Historically, some thought of Group 2 diseases such as heart disease as diseases of affluence and Group 1 diseases such as infant mortality and infections as diseases of poverty. But the diseases of affluence and poverty are converging. As the Global Forum for Health Research states:

“A long-standing stereotype has held that noncommunicable conditions are ‘diseases of affluence’ characteristic of developed countries, while developing countries mainly suffer from communicable diseases. It is clear that this no longer applies and that a major epidemiological transition has taken place: there is an almost equal level of BoD due to Group 1 and Group 2 for LMICs and a significantly higher rate of DALYs in LMICs due to injuries.”⁵⁵

The top ten causes of death and burden of disease in LMICs include several conditions that are also top killers in high-income countries, in addition to more “traditional” diseases of poverty:

⁵¹ Oxfam, INVESTING FOR LIFE: MEETING POOR PEOPLE’S NEEDS FOR ACCESS TO MEDICINES THROUGH RESPONSIBLE BUSINESS PRACTICES 13-15 (Nov. 2007) (Oxfam Briefing Paper 109).

⁵² See, e.g., Roger S. Magnusson, *Non-Communicable Diseases and Global Health Governance: Enhancing Global Processes to Improve Health Development*, 3 GLOBALIZATION AND HEALTH (May 22, 2007) available at <http://www.globalizationandhealth.com/content/3/1/2> (visited Dec. 27, 2007).

⁵³ Global Forum for Health Research, 2 GLOBAL FORUM UPDATE ON RESEARCH FOR HEALTH 10-11 (2005) (verbatim); see also Alan Lopez & Colin Mathers, *Inequities in Health Status: Findings From the 2001 Global Burden of Disease Study*, 4 Global Forum Update on Research for Health 163, 164 (2007).

⁵⁴ Global Forum for Health Research, 2 GLOBAL FORUM UPDATE ON RESEARCH FOR HEALTH 11 (Fig. 3) (2005).

⁵⁵ Global Forum for Health Research, 2 GLOBAL FORUM UPDATE ON RESEARCH FOR HEALTH 11 (2005).

Table 1. Burden of Disease in LMICs

	Death (2001)⁵⁶	Death (2020 est.)⁵⁷	Burden of disease (2001, DALYs)⁵⁸
1.	Ischaemic heart disease	Ischaemic heart disease	Perinatal conditions
2.	Cerebrovascular disease	Cerebrovascular disease	Lower respiratory infections
3.	Lower respiratory infection	Chronic obstructive pulmonary disease	Ischaemic heart disease
4.	HIV/AIDS	Tuberculosis	Cerebrovascular disease
5.	Perinatal conditions	Road traffic accidents	HIV/AIDS
6.	Chronic obstructive pulmonary disease	Lower respiratory infections	Diarrhoeal diseases
7.	Diarrhoeal diseases	Trachea, bronchus, and lung cancers	Unipolar depressive disorders
8.	Tuberculosis	Stomach cancer	Malaria
9.	Malaria	Diarrhoeal disease	Chronic obstructive pulmonary disease
10.	Road traffic accidents	HIV/AIDS	Tuberculosis

Noncommunicable diseases (NCDs) are an increasingly significant problem in the developing world.⁵⁹ As Lopez and Mathers note:

“Surprisingly, almost 50% of the adult disease burden in low- and medium-income countries is now attributable to noncommunicable disease. Population ageing and changes in the distribution of risk factors have accelerated the epidemic of noncommunicable disease in many developing countries.”⁶⁰

The WHO CIPIH REPORT took a different taxonomic path to describe the global burden of disease, following the terminology of the Commission on Macroeconomics & Health

⁵⁶ Alan Lopez & Colin Mathers, *Inequities in Health Status: Findings From the 2001 Global Burden of Disease Study*, 4 GLOBAL FORUM UPDATE ON RESEARCH FOR HEALTH 169 (Table 2) (2007).

⁵⁷ Shah Ebrahim and Liam Smeeth, *Non-Communicable Diseases in Low and Middle-Income Countries: A Priority or a Distraction?*, 34 INT'L. J. EPIDEMIOLOGY 961, 962 (Table 2) (2005).

⁵⁸ Alan Lopez & Colin Mathers, *Inequities in Health Status: Findings From the 2001 Global Burden of Disease Study*, 4 GLOBAL FORUM UPDATE ON RESEARCH FOR HEALTH 171-72 (Tables 7 & 8) (2007) (correcting numbering errors in original chart).

⁵⁹ See, e.g. the special issue of THE LANCET in December 2007 devoted to the burden of chronic diseases, with several articles focusing upon LMICs. Dele O Abegunde et al., *The Burden and Costs of Chronic Diseases in Low-Income and Middle-Income Countries*, 370 THE LANCET 1929-38 (2007); Stephen S Lim, et al., *Prevention of Cardiovascular Disease in High-Risk Individuals in Low-Income and Middle-Income Countries: Health Effects and Costs*, 370 THE LANCET xxx (published online Dec. 5, 2007); Robert Beaglehole, Shah Reddy, Janet Voûte, Steve Leeder, *Prevention of Chronic Diseases: A Call To Action*, 370 THE LANCET xxx (2007). For a somewhat contrarian view, see Shah Ebrahim and Liam Smeeth, *Non-Communicable Diseases in Low and Middle-Income Countries: A Priority or a Distraction?*, 34 INT'L. J. EPIDEMIOLOGY, at 961 (2005); but see Kathleen Strong, Colin Mathers, Joanne Epping-Jordan, and Robert Beaglehole, *Preventing Chronic Disease: A Priority For Global Health*, INT'L. J. EPIDEMIOLOGY 492 (2006) (letter responding to the Ebrahim & Smeeth article). The WHO CIPIH REPORT strongly noted the growing rate of noncommunicable disease. WHO CIPIH REPORT, at 2-5, 44.

⁶⁰ Alan Lopez & Colin Mathers, *Inequities in Health Status: Findings From the 2001 Global Burden of Disease Study*, 4 GLOBAL FORUM UPDATE ON RESEARCH FOR HEALTH at 172.

(CMH).⁶¹ The CMH and the WHO CIPIH Report categorized diseases with a market-based approach, according to their intrinsic appeal to global capitalism, and in particular the markets for innovation and medicine.

Type I Disease Innovations

Type I diseases occur in high-income countries. The purchasing power of the high-income countries drives innovation for Type I diseases. Examples include cardiovascular disease, stroke, cancer, depression, and diabetes. These diseases may also be prevalent in LMICs,⁶² but the defining characteristic of Type I diseases is a strong market demand for treatment of high-income patients. SARS and pandemic influenza are also Type I disease markets. Innovation in Type I diseases can be sufficiently supported by high-income markets alone.

Some Type I diseases disproportionately affect people in LMICs. Take the example of cervical cancer. The WHO Commission listed cervical cancer as a Type I disease.⁶³ In high-income countries, deaths from cervical cancer are relatively rare due to expensive population screening and treatment. About 260,000 women in developing countries die from cervical cancer each year,⁶⁴ exceeding the deaths from all diseases in the tropical-disease cluster.⁶⁵ A highly effective vaccine is now available to prevent most cases of cervical cancer,⁶⁶ but the price – US\$360 per person – exceeds the per capita annual health budgets for most of the women worldwide who need it.⁶⁷ A relatively small number of deaths in high-income countries led to these two HPV vaccines that hold great promise in LMICs as well. These vaccines could be provided generically to the poorest without undermining optimal innovation. The deaths of less than 17,000 women per year in wealthy countries offered sufficient financial rewards to prompt both Merck and GlaxoSmithKline to spend hundreds of millions of dollars to bring HPV vaccines to market. The deaths of more than 222,000 poor women per year may have provided moral, scientific or humanitarian incentives to create HPV vaccines, but the potential financial rewards were modest, since these women can't afford it.⁶⁸ Merck has

⁶¹ WHO CIPIH REPORT, at 13.

⁶² See Bradly Condon & Tapen Sinha, *Global Diseases, Global Patents and Differential Treatment in WTO Law: Criteria for Suspending Patent Obligations in Developing Countries*, NW. J. INT'L L. & BUS. 1, 25-28 (2005).

⁶³ WHO CIPIH REPORT, at 14 (Tab. 1.3).

⁶⁴ F. Kamangar, G.M. Dores, & W.F. Anderson, *Patterns of Cancer Incidence, Mortality, and Prevalence Across Five Continents: Defining Priorities to Reduce Cancer Disparities in Different Geographic Regions of the World*, 24 J. CLIN. ONCOLOGY 2137-2150 (2006).

⁶⁵ C.D. Mathers, A.D. Lopez, & C.J.L. Murray, GLOBAL BURDEN OF DISEASE AND RISK FACTORS (Table 3B.1) (Oxford/World Bank, 2006).

⁶⁶ D.M. Harper, E. L. Franco, C.M. Wheeler, A. B. Moscicki, B. Romanowski, et al., *Sustained Efficacy Up To 4.5 Years of a Bivalent L1 Virus-Like Particle Vaccine Against Human Papillomavirus Types 16 and 18: Follow-Up From a Randomised Control Trial*, 367 THE LANCET 1247-55 (2006).

⁶⁷ OUTTERSON & KESSELHEIM, at 130 and ffg.

⁶⁸ Id.

announced an equitable access program,⁶⁹ and some limited donations, but the scope of the program remains unknown at the present.⁷⁰

Type III Disease Innovations

Type III diseases are overwhelmingly or exclusively incident in developing countries. Little or no global commercial market exists for Type III diseases. Examples include onchocerciasis (river blindness), leishmaniasis (kala-azar), Chagas disease, and African sleeping sickness.

Many have recognized the market failures inherent in Type III diseases.⁷¹ For these diseases, normal market conditions will be inadequate to stimulate sufficient R&D. Impoverished sick people are not attractive markets for global for-profit R&D programs.⁷² Type III disease innovation will require substantial non-market incentives, such as public private product development partnerships⁷³ and market-making devices such as Advanced Market Commitments⁷⁴ or patent prizes.⁷⁵ Others look to non-market incentives such as grants and government-sponsored research.⁷⁶ Occasionally proposals are coupled with an expansion of IP rights in poor countries,⁷⁷ or a choice between exercising IP rights in either developed or developing countries, but not both.⁷⁸ Expanded IP rights are an unnecessary and unwelcome addition for neglected disease research. Expansion of IP rights will not create incentives in the absence of money to

⁶⁹ Bill and Melinda Gates Foundation Press Release, *Cervical Cancer Vaccine Project* (2006) available at http://www.path.org/files/RH_cc_vacc_proj_fs_update.pdf (accessed 16 August 2007).

⁷⁰ Merck Press Release, *Merck To Donate Three Million Doses of Gardasil, Its Cervical Cancer Vaccine, to Support Vaccination Programs in Lowest Income Nations*, (Sept. 26, 2007). Three million doses will vaccinate 1 million women, a very small percentage of the need.

⁷¹ WHO CIPIH Report, at 22 (“as is the case for diseases affecting millions of poor people in developing countries, patents are not a relevant factor or effective in stimulating R&D and bringing new products to market.”); see also Carl Nathan, *Aligning Pharmaceutical Innovation With Medical Need*, 13 NATURE MEDICINE 304-308 (2007). For a review of the literature, see *Pharmaceutical Arbitrage*, at 244-50.

⁷² See, e.g. Médecins Sans Frontières, *FATAL IMBALANCE: THE CRISIS IN RESEARCH AND DEVELOPMENT FOR DRUGS FOR NEGLECTED DISEASES* (September 2001).

⁷³ Mary Moran, et al., *The New Landscape of Neglected Disease Drug Development* (2005) available at www.wellcome.ac.uk.

⁷⁴ Michael Kremer and R. Glennerster, *STRONG MEDICINE: CREATING INCENTIVES FOR PHARMACEUTICAL RESEARCH ON NEGLECTED DISEASES* (2004).

⁷⁵ Aiden Hollis, *AN EFFICIENT REWARD SYSTEM FOR PHARMACEUTICAL INNOVATION* (July 2, 2004) (unpublished manuscript, on file with author). **[check to see if it is published now]**

⁷⁶ Tim Hubbard and James Love, *A New Trade Framework for Global Healthcare R&D*, 2 PLOS BIOLOGY 0147-50 (Feb. 2004); but see Joseph DiMasi and Henry G. Grabowski, *Patents and R&D Incentives: Comments on the Hubbard and Love Trade Framework For Financing Pharmaceutical R&D 2* (2003) available at <http://www.who.int/intellectualproperty/news/en/Submission3.pdf>.

⁷⁷ Alan O. Sykes, *TRIPS, Pharmaceuticals, Developing Countries, and the Doha “Solution,”* 3 Chi. J. Int’l. L. 47, 56 (2002); *Neglected Diseases: Towards Policies Without Borders*, 262 OECD OBSERVER (July 2007).

⁷⁸ Jean O. Lanjouw & William Jack, *Trading Up: How Much Should Poor Countries Pay to Support Pharmaceutical Innovation?*, 4 CTR. FOR GLOBAL DEVELOPMENT 1-8 (2004), available at <http://www.cgdev.org/content/publications/detail/2842/>.

buy the product. These diseases are neglected due to the poverty of the afflicted, not the lack of IP rights.⁷⁹

While Type III diseases are significant, we should note that total global deaths from the tropical-disease cluster in 2001 were only 128,000 people.⁸⁰ Residents of LMICs suffer from higher infectious disease burdens, but much of the DALYs lost stems from noncommunicable diseases, injuries, and communicable diseases other than the tropical and neglected disease cluster.⁸¹

Type II Disease Innovations

Type II diseases occupy an intermediate category, sharing some characteristics of the other categories. LMICs suffer a disproportionately large burden from Type II diseases. Tuberculosis and malaria were once Type I diseases, but are now classified as Type II by the WHO after virtual eradication of malaria in the US and Europe, and a significantly lower disease burden from tuberculosis in high-income countries. Malaria is classified as Type II rather than Type III because it retains a small but significant financial footprint in the high-income countries to meet the needs of the military and international travelers. If multiple-drug resistant and extremely-drug resistant tuberculosis spread significantly in high-income countries, tuberculosis may regain Type I status.

Innovation in Type II diseases also occupies an intermediate category. In many cases, innovation for high-income markets will be sufficient to create the necessary drugs. Such was the case with AIDS and the existing treatments for malaria and tuberculosis. But the global medical burden of malaria and tuberculosis has outmatched the innovation spurred by relatively modest high-income country markets. Type II diseases will require additional non-market incentives to fully correlate global need with innovation incentives.⁸²

The WHO Commission classified AIDS as a Type II disease,⁸³ but that appears to be a debatable choice. AIDS is perhaps better classified as a Type I disease. While the greatest burden of AIDS disease falls outside of high-income countries, more than 2 million people are living with HIV in high-income countries⁸⁴ and infection rates are rising.⁸⁵ This high-income patient base is more than sufficient to spur innovation. The AIDS cases in the US and Europe sparked an avalanche of research, even before the true scope of the global crisis was known. AIDS may be considered a Type I disease at present, with the exception of adaptive research.

⁷⁹ WHO CIPIH REPORT, at *Pharmaceutical Arbitrage*, at 22, 244-50; *Pharmaceutical Arbitrage*, at 244-60.

⁸⁰ Mathers, et al., GLOBAL BURDEN OF DISEASE AND RISK FACTORS, at Table 3B.1.

⁸¹ WHO CIPIH REPORT, at 3-4, Table 1.1 & 1.2.

⁸² See, e.g. Carl Nathan, *Aligning Pharmaceutical Innovation With Medical Need*, 13 NATURE MEDICINE 304-308 (2007).

⁸³ WHO CIPIH REPORT, at 14.

⁸⁴ UNAIDS, FACT SHEET: KEY FACTS BY REGION – 2007 AIDS EPIDEMIC UPDATE (Nov. 2007) (estimating that 2.1 million people are living with HIV in 2007 in North America, Western and Central Europe).

⁸⁵ Gardiner Harris, *Figures on H.I.V. Rate Expected to Rise*, NY TIMES (Dec. 2, 2007) (reporting that estimates on US infection rates may be 50% higher than previously thought).

Adaptive Innovations for Type I Diseases

Additional incentives may be required to adapt Type I innovations to developing country conditions.⁸⁶ Heat-stable formulations and fixed-dose combinations⁸⁷ are examples of adaptive innovations for a Type I disease (AIDS). Simpler and cheaper diagnostics are required for resource-constrained settings. Geographic variations in HPV subtype incidence might require additions to the cervical cancer vaccines.⁸⁸ All of these are examples of adaptive innovation for Type I diseases. In the language of the WHO DRAFT GLOBAL STRATEGY (2007), these are “needs of developing countries in relation to Type I diseases.”⁸⁹ Some of this adaptive innovation may come from drug companies located in developing countries, where cost structures are lower and researchers may be closer to the ground.⁹⁰ Other adaptive innovations may require non-market incentives, similar to other neglected disease issues.

Important Distinctions Between Markets for Innovation and Medicine

The WHO typology is helpful for analyzing differences in the markets for innovation and medicine between high-income countries and LMICs. *Disease-specific incentives are required for innovation market failures in Type II and III diseases, but limitations are not appropriate for access programs and TRIPS flexibilities.* The relevant factors are summarized in Table 2 below:

Table 2. Markets for innovation and medicines, by disease type and income level.

	Innovation Market	Medicine Market
Type I		
- HICs	High-income country purchasing power drives the market (ex: Lipitor for high cholesterol). Innovation follows purchasing power rather than medical need (ex: additional life style and me-too drugs rather than a first-in-class Gram-negative antibiotic).	Patent protection and sophisticated branding and marketing yield high drug prices. The impact of high prices is ameliorated by private and social insurance mechanisms, relatively high per capita incomes, and (in some cases) government monopsony procurement.
- LMICs	Adaptive R&D may be needed to account for resource-constrained settings (ex. non-refrigerated vaccines, polyvalent HPV vaccines, fixed-dose combinations).	Patent-based pricing denies access to the majority of direct purchasers. Robust generic competition would drive prices closer to marginal cost (ex. unlicensed AIDS drugs)

⁸⁶ WHO CIPIH REPORT, at 16-19, 44.

⁸⁷ *Pharmaceutical Arbitrage*, at 234.

⁸⁸ N. Munoz N, et al., *Against Which Human Papillomavirus Types Shall We Vaccinate and Screen? The International Perspective*, 111 INT’L. J. CANCER 278-85 (2004).

⁸⁹ WHO, DRAFT GLOBAL STRATEGY AND PLAN OF ACTION ON PUBLIC HEALTH, INNOVATION AND INTELLECTUAL PROPERTY: PROGRESS TO DATE IN DRAFTING GROUPS A AND B (14 Dec. 2007) (A/PI/IGWG/2/Conf.Paper No.1 Rev.1) [hereinafter, WHO DRAFT GLOBAL STRATEGY (2007)].

⁹⁰ WHO CIPIH REPORT, at 45.

	Regional companies may be able to supply some adaptive R&D. The balance must be provided through non-market incentives.	LMIC governments and donors have limited ability to subsidize access (cf: Thailand & Brazil's AIDS programs).
Type II		
- HICs	Largely ignored by high-income markets, except by tourists, military and other modest markets (ex: prophylaxis for malaria).	Patented Type II innovative medicines are generally limited to HIC citizens who are residents in LMICs (ex: military, tourists, expats, wealthy local elites).
-LMICs	Adequate levels of innovation require additional R&D support from non-market incentives (ex: malaria vaccine)	LMIC governments and donors have limited ability to subsidize access. Best medical practice may require significant subsidies to prevent resistance to communicable diseases (ex: subsidies for ACTs for malaria).
Type III		
- HICs	No market in HICs.	No medical need in HICs.
- LMICs	These very neglected diseases require non-market incentives to support innovation.	Significant unmet medical need in LMICs.

IV. Disease-Specific Limitations in the WHO IGWG

With this background, we now turn to the recent discussions within the WHO IGWG concerning disease-specific limitations. The December 14, 2007 draft of the WHO DRAFT GLOBAL STRATEGY (2007)⁹¹ frequently uses the following disease-limiting phrase or its permutations: “*diseases which disproportionately affect developing countries.*”⁹² The phrase was prominently discussed in the WHO CIPIH REPORT,⁹³ and was mentioned in the World Health Assembly Resolution that established the IGWG.⁹⁴ The phrase is occasionally used as an apparent synonym for Type II and III diseases.

The US Position

The United States Government appears to consider the phrase as a limitation on access programs. In the US COMMENTS to the WHO ELEMENTS OF A GLOBAL STRATEGY (2006), the United States claimed that the IGWG’s mandate was limited to Type II and III diseases:

“The IGWG should not consider Recommendation 2.4 as the focus of its work should be on diseases that disproportionately affect developing countries, more commonly referred to as Type II and Type III diseases.”⁹⁵

⁹¹ WHO DRAFT GLOBAL STRATEGY (2007), at xxx. An earlier draft is: WHO, ELEMENTS OF A GLOBAL STRATEGY AND PLAN OF ACTION, A/PHI/IGWG/1/5 (8 December 2006) [hereinafter, WHO ELEMENTS OF A GLOBAL STRATEGY (2006)].

⁹² WHO DRAFT GLOBAL STRATEGY (2007), at 3, par. 3 (consensus text), par. 4 (bracketed text, consensus pending decision by USA), at 4, par. 13 (with bracketed text), par. 14 a) (consensus text), par. 14 b) (consensus text, except for omitted footnote).

⁹³ WHO CIPIH REPORT.

⁹⁴ WHA 59.24.

⁹⁵ US COMMENTS, at 2.

The United States was commenting on Recommendation 2.4 from the WHO CIPIH Report, which explicitly included Type I diseases in its ambit:

“When addressing the health needs of people in developing countries, it is important to seek innovative ways of combating Type I diseases, as well as Type II and Type III diseases. Governments and funders need to assign higher priority to combating the rapidly growing impact of Type I diseases in developing countries, and, through innovation, to finding affordable and technologically appropriate means for their diagnosis, prevention and treatment.”⁹⁶

Other actions by the US Government have attempted to limit IGWG consideration of TRIPS flexibilities, especially with regard to Type I diseases. For example, the WHO CIPIH REPORT⁹⁷ and the World Health Assembly Resolution 59.24⁹⁸ supported the use of TRIPS flexibilities by developing countries. The WHO ELEMENTS OF A GLOBAL STRATEGY (2006) included the following “areas for action:”

“6(a) enact legislation in developed and developing countries for application of the flexibilities provided for in TRIPS and other international agreements”

“6(f) assure that bilateral trade agreements do not seek to incorporate “TRIPS-plus” protection in ways that might reduce access to medicines in developing countries”

“6(i) focus on specific aspects of the intellectual property system, such as test data exclusivity, “me-too” patents, and patent linkages”

“7(i) take necessary legislative steps in developed countries, and other countries with manufacturing and export capacity, to allow compulsory licensing for export consistent with the flexibilities provided for in TRIPS”

“7(j) provide in national legislation for measures to encourage generic entry on patent expiry, such as the “early working” exception, and more generally policies that support greater competition between generics, whether branded or not, as an effective way to enhance access by improving affordability; restrictions should not be placed on the use of generic names”⁹⁹

The US COMMENTS requested that these discussions of TRIPS flexibilities be excluded

⁹⁶ WHO CIPIH REPORT, at 48 (Recommendation 2.4).

⁹⁷ WHO CIPIH REPORT, at 22.

⁹⁸ WHA 59.24, at par. 2(4).

⁹⁹ WHO ELEMENTS OF A GLOBAL STRATEGY (2006), at 6-8.

from the WHO IGWG process:¹⁰⁰

“Accordingly, the IGWG should not consider Subsection (a) of Paragraph Six of the document. The WHO Secretariat should not expand its work on matters better addressed by another international organization. Therefore, the IGWG should not consider Subsections (f) and (i) of Paragraph Six of the document, because they more appropriately fit within the scope and mandate of the WTO and WIPO.”¹⁰¹

“While Subparagraph (j) of Paragraph Seven is important when balanced with incentives to develop new drugs, neither subparagraph (i) or (j) are appropriate areas of action for the WHO Secretariat; thus the IGWG should not consider them.”¹⁰²

The US Comments are thus making a narrow, technocratic argument that the WHO is an inappropriate forum for discussing the intellectual property rights issues relating to access to medicines. They are trying to prevent discussion in a forum that might actually give some weight to global health. This argument ignores the history of the IGWG process, which was designed to offer a balanced, integrated analysis of intellectual property rights, innovation and public health. Each step of this process has highlighted all three issues: The WHO Commission on Intellectual Property Rights, Innovation and Public Health; the WHO CIPIH Report entitled PUBLIC HEALTH, INNOVATION & INTELLECTUAL PROPERTY RIGHTS; and the WHO IGWG ON PUBLIC HEALTH, INNOVATION AND INTELLECTUAL PROPERTY. The WHO is not claiming exclusive jurisdiction over these issues, merely the opportunity to speak to issues which impact global public health.

Disease-Specific Limitations Are Not Appropriate

Nothing in the TRIPs Agreement or the *Doha Declaration* limits access programs or TRIPs flexibilities to Type II and III diseases. Neither does the WHO CIPIH REPORT, which cannot be read as arguing for any such restriction.

The phrase “diseases which disproportionately affect developing countries” is best understood as an explanation for why the market has failed to produce medicines for neglected (Type II) or very neglected (Type III) diseases: diseases which occur disproportionately in poor people in LMICs are not an attractive market for the patent-based drug industry. As the WHO CIPIH REPORT concluded:

“Too few R&D resources are directed to the health needs of developing countries. In the private sector, companies do not have the incentive to devote adequate resources to develop products specifically adapted to the needs of developing countries, because profitability is mainly to be found in rich country markets. The

¹⁰⁰ US COMMENTS, at 4-6, pars. 7-8. The US COMMENTS suggest that the WTO and WIPO are the better fora.

¹⁰¹ US COMMENTS, at 5, par. 6.

¹⁰² US COMMENTS, at 5, par. 7.

great majority of health research funded by the public sector, takes place in developed countries, and its priorities principally reflect their own disease burden, resource position and social and economic circumstances.”¹⁰³

Difficulties with the US position are made more evident when one attempts to construct a list of qualifying diseases. The adverb “disproportionately” appears to require that incidence on a *per capita* basis be significantly higher. Surely the list includes all Type III diseases, including the very neglected tropical diseases, for by definition the *per capita* incidence is almost exclusively in LMICs. Similarly, the largest Type II diseases such as malaria and tuberculosis appear to qualify. For all of these diseases, markets are unable to stimulate the R&D required for global health.

AIDS presents a more troublesome case. The incidence and burden of AIDS falls disproportionately on sub-Saharan Africa, but the same may not hold true for India or China. As discussed above, AIDS may not be properly classified as a Type II disease at all, and its incidence is rising in the United States.¹⁰⁴

Other infectious diseases are quite common in LMICs, and result in a substantial burden of disease there. In general, the incidence of infectious diseases falls disproportionately in LMICs, but significant medical need exists also in high-income countries for many infectious diseases.¹⁰⁵

Most noncommunicable or chronic diseases would probably not qualify. While heart disease, depression, stroke, and diabetes are certainly major contributors to the burden of disease in LMICs, they do not impose a disproportionately higher *per capita* burden. If the phrase “diseases which disproportionately affect developing countries” is considered a limitation on access programs and TRIPS flexibilities, then almost all chronic and noncommunicable diseases must be excluded.

Clearly, this is not an acceptable result. This interpretation is without support in the WHO CIPIH REPORT, and is at odds with the mandate of the WHO IGWG. The Report does not limit access programs or TRIPS flexibilities to specific diseases. In fact, it recommended exactly the opposite. Recommendations 4.13 to 4.27 are primarily concerned with encouraging developing countries to take advantage of TRIPS flexibilities and other laws in order to protect public health, without any limitations as to disease.¹⁰⁶ Recommendation 4.7 specifically includes noncommunicable diseases:

¹⁰³ WHO CIPIH REPORT, at 172.

¹⁰⁴ See *supra*, nn. 83-85 and text accompanying.

¹⁰⁵ See, e.g., E. Klein, D.L. Smith, R. Laxminarayan, *Hospitalizations and Deaths Caused By Methicillin-Resistant Staphylococcus aureus, United States, 1999-2005*, 13 EMERGING INF. DIS. 1840-46 (2007); RM Klevens, et al., *Invasive Methicillin-Resistant Staphylococcus aureus Infections in the United States*, 298 J. AM. MED. ASSN. 1763-71 (2007).

¹⁰⁶ WHO CIPIH REPORT, at 180-82.

“4.7 For noncommunicable diseases, governments and companies should consider how treatments, which are widely available in developed countries, can be made more accessible for patients in developing countries.”¹⁰⁷

The phrase is relevant only as a descriptive term, identifying innovation market failures: patent-based pharmaceutical innovation doesn't work for diseases which disproportionately affect developing countries. Global markets under perform commercial research into Type II, Type III diseases and adaptive research for Type I innovations for resource-constrained settings. No substantial market in high-income countries exists for these disease conditions, necessitating various non-market mechanisms in order to facilitate innovation. By definition, these conditions disproportionately affect developing countries; otherwise they would be Type I innovations.

But the innovation gap is not the only problem facing the IGWG. Its terms of reference also include ensuring equitable access to patented innovations treating all diseases, including Type I, II and III diseases. The market for medicines and the market for innovation must both be valued. WHA 59.24 urges member states:

“to work to ensure that progress in basic science and biomedicine is translated into improved, safe and affordable health products – drugs, vaccines and diagnostics – to respond to all patients' and clients' needs, especially those living in poverty, taking into account the critical role of gender, and to ensure that capacity is strengthened to support rapid delivery of essential medicines to people;”¹⁰⁸

V. Conclusion

The pharmaceutical IP system works well in high-income countries with social insurance. It does not work for the poor in low- and middle-income countries. Governments should be free to fully utilize all TRIPS flexibilities to protect the health of their citizens, without regard to the type of disease. In particular, WTO Members must be permitted to confront the growing burden of chronic diseases by using TRIPS flexibilities for any type of disease, including, without limitation, Type I conditions such as cancer and cardiovascular diseases.

From the initial negotiations that led to the TRIPS Agreement until today, some governments – particularly the US government – have attempted to limit the flexibilities afforded to WTO Members under Article 31. This activity continues today in the WHO IGWG process, now using the phrase “diseases disproportionately affecting developing countries.” Limiting TRIPS flexibilities to specific diseases is not supported under Article 31, the *Doha Declaration*, the *Council Decision*, the *WHO Commission Report*, or by the shifting global burden of disease.

¹⁰⁷ WHO CIPIH REPORT, at 180.

¹⁰⁸ WHA 59.24 par. 2(3).