

UNITED NATIONS SECRETARY-GENERAL'S HIGH-LEVEL PANEL ON ACCESS TO
MEDICINES

IN THE MATTER OF
CONTRIBUTION SUBMISSION ON ACCESS TO MEDICINES

ON BEHALF OF:

Cynthia Ho, Professor of Law, Loyola Univ. of Chicago School of Law, cho@luc.edu
David Levine, Associate Professor at Elon University School of Law, dlevine3@elon.edu
Gabriel Levitt, President at PharmacyChecker.com, gabriel.levitt@pharmacychecker.com
Heesob Nam, Board Member at OpenNet, hurips@gmail.com
Alina Ng, Professor of Law, Mississippi College School of Law, ng@mc.edu
Andrew Rens, African Scholars for Knowledge Justice, andrew@aliquidnovi.org

Lead Author:

Sean Flynn, Associate Director
Luisa Guzman, Fellow
Program on Information Justice and Intellectual Property
American University Washington College of Law
Washington D.C., United States
sflynn@wcl.american.edu
+1(202) 274-4157

February 26, 2016

I give permission for the contribution to be made public on the High-Level Panel's website.

I. SUBMISSION 2

A. THE HIGH LEVEL PANEL SHOULD EXPOUND ON THE DUTY TO INTERPRET AND IMPLEMENT LAWS TO PROMOTE THE RIGHT TO HEALTH 2

B. THE NEED TO INTERPRET AND IMPLEMENT LAWS TO PROMOTE ACCESS TO MEDICINE ARISES FROM THE ECONOMICS OF EXCLUSION THAT INTELLECTUAL PROPERTY ON MEDICINES IN POOR COUNTRIES PROMOTES 4

C. THE HIGH LEVEL PANEL SHOULD CHART THE WAYS THAT COUNTRIES CAN (AND MUST) ACT TO PROMOTE ACCESS TO MEDICINES IN THE FACE OF THE GLOBALIZATION OF INTELLECTUAL PROPERTY RULES 7

 1. *The UN Panel should press countries to take full advantage of TRIPS flexibilities to limit the scope, duration and enforcement of pharmaceutical patents* 7

 2. *The UN Panel should promote the adoption of routine compulsory licensing programs for pharmaceuticals* 8

 3. *The UN Panel should promote the use of competition law to achieve routine licensing of pharmaceutical patents* 9

D. THE UN PANEL SHOULD ADDRESS THE ACTIONS OF COUNTRIES THAT ACTIVELY THWART USE OF PRO-ACCESS INTERPRETATIONS AND IMPLEMENTATION OF INTERNATIONAL LAW, INCLUDING THROUGH UNILATERAL TRADE PRESSURE 10

The Program on Information Justice and Intellectual Property at American University Washington College of Law (PIJIP) is an academic research program devoted to promoting the public interest in national and international intellectual property policy.

This statement calls on the High-Level Panel to promote policy coherence in the international intellectual property, human rights and global health system in part through a strong articulation and examination of the implications of the human rights duty to interpret and implement all legislation to promote the right to health and corresponding rights to access needed medicines. The submission describes why such a mandate – from the lens of international economic theory – would lead to the conclusion that states must make maximum use of routine compulsory licensing programs for pharmaceuticals to rectify intellectual property and health concerns. It then articulates how adoption of the interpretive rule should justify and motivate specific government actions – including minimizing the scope of patent rights and maximizing the use of routine compulsory licensing – that would help reduce the incoherence between rights of inventors, international human rights laws, trade rules, and public health objectives.

I. SUBMISSION

A. The High Level Panel Should Expound on the Duty to Interpret and Implement Laws to Promote the Right to Health

In addressing the human rights obligations to promote access to medicines, the High Level Panel should pay particular attention to the duties of states to interpret and implement existing law to promote access to medicines. Such an obligation provides one immediate step that states can take to protect, progressively realize, and fulfil human rights obligations.

Promoting access to affordable medicines for the poor is a widely recognized human rights duty.¹ Although the most directly applicable right to access to medicine concerns is contained in Article 12 of the International Covenant on Economic, Social, and Cultural Rights (ICESCR), it is notable that many of the sources of the right to health bind countries, such as the United States, which are not signatories to the ICESCR.²

The right to health, as all human rights, imposes “three types or levels of obligations on States parties: the obligations to respect, protect and fulfil.”³ The duty to fulfil the right is sometimes referred to as a positive obligation, which includes the duty “to take steps (...) 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.”⁴ The obligation to fulfil requires States “to adopt appropriate legislative, *administrative*, budgetary, *judicial*, promotional and other measures towards the full realization of the right to health” (emphasis added).⁵ By referencing specifically the duties of administrative and judicial arms of the state, the CESCR was highlighting the duties of state agencies to use the key resources at their disposal – which is the interpretation and implementation of law – to promote the right to health.⁶

Human rights duties to use the action of courts and regulatory agencies to promote access to medicine are encompassed as well in the duty to “protect” the right to health, which includes the duty “to regulate the activities of individuals, groups or corporations,” such as multinational pharmaceutical companies, “so as to prevent them from violating the right to health of others.”⁷

So-called “positive” and “negative” duties with regard to human rights are interrelated. Failing to interpret and implement laws to promote access to medicine could lead to state action (e.g. a decision to permit excessive pricing of medicines) that negatively affects existing access to medicines, thereby implicating the duty to “respect” human rights.

¹ U.N. Comm. on Econ. Soc. & Cultural Rights [CESCR], *General Comment No. 14: The Right to the Highest Attainable Standard of Health*, ¶ 2, E/C.12/2000/4 (2000).

² For example, health and social policies which increase mortality and morbidity implicate the right to life in Article 6(1) of the International Covenant on Civil and Political Rights as well as Articles 22 and 25.1 of the Universal Declaration of Human Rights. Universal Declaration of Human Rights, G.A. Res. 217A(III), at Arts. 22, 25, U.N. GAOR, 3d Sess., U.N. Doc. A/810 (Dec. 12, 1948) (protecting “the economic, social and cultural rights indispensable for his dignity” and “the right to a standard of living adequate for the health of himself and of his family, including . . . medical care”)

³ CESCR, General Comment No. 14, ¶ 33.

⁴ ICESCR, Art. 2(1).

⁵ CESCR, General Comment No. 14, ¶ 33.

⁶ Perhaps the clearest expression of the duty to promote human rights through interpretation can be found in Article 39(2) of the South African Constitution:

(2) When interpreting any legislation, and when developing the common law or customary law, every court, tribunal or forum must promote the spirit, purport and objects of the Bill of Rights.

⁷ CESCR, General Comment No. 14, ¶ 51.

The implications of clearly and forcefully recognizing the duty to interpret and implement law to promote access to medicines are far reaching. While in some circumstances the Panel may find that components of the international intellectual property (IP) system inherently conflict with global health and human rights norms and values – more often the conflict between the regimes will lie in their implementation. To avoid such regime conflict, it is paramount that states make every effort to interpret their law – including trade agreements, intellectual property laws and consumer protection and competition laws – to promote access to medicine.

B. The need to interpret and implement laws to promote access to medicine arises from the economics of exclusion that intellectual property on medicines in poor countries promotes

My co-authors and I have written on the subject of the economics of exclusion that defines markets for patented medicines in poor and middle income countries.⁸ The problem arises because of the extreme inequality of wealth and income that defines the markets in most developing countries. Patent and other IP rights are granted to incentivize invention and production. But these regimes were created for wealthy countries with less extreme inequality than we find in developing countries. Whether or not monopolies of pharmaceuticals benefit consumers through future innovation more than they harm them through higher prices in rich countries, in a market with extreme inequality, the balance of benefits and costs is very different.

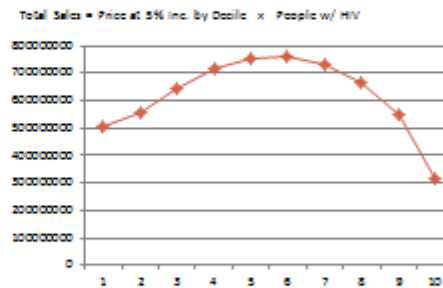
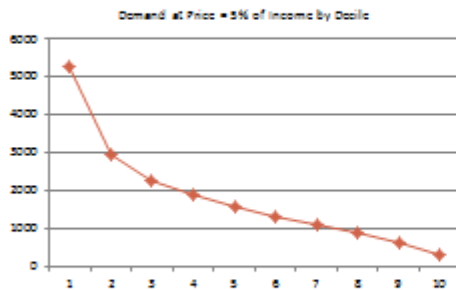
In countries with extreme inequality – where a small part of the population earns globally competitive salaries and the great majority is extremely poor – an unrestrained patent monopoly produces incentives to exclude the vast majority from access. The profit-maximizing firm will raise prices much higher to serve only the very wealthy portion of the demand curve -- which is highly inelastic -- creating large deadweight losses in the form of untreated people. On the other side, engaging in such practices yields very little additional profit to companies (the incentive to research and develop) compared to the global markets which are dominated by demand in wealthy countries. Costs to society from patents on needed products like medicine are enormous; the potential benefit in the form of increased incentive to develop global public goods is miniscule.

To illustrate the problem, I include several charts showing modeled behavior of a firm assumed to be setting prices at about 5% of the earnings of various income segments in different countries. The left chart shows the demand curve that such pricing would create – it shows the price that would occur if set at 5% of various income segments. At left is a chart showing the revenue generated at each price level. So if the price is set at 5% of the top 10% of earners, the assumption is that earners at that level buy the drug (producing the expected revenue) and all other segments would be priced out (producing deadweight

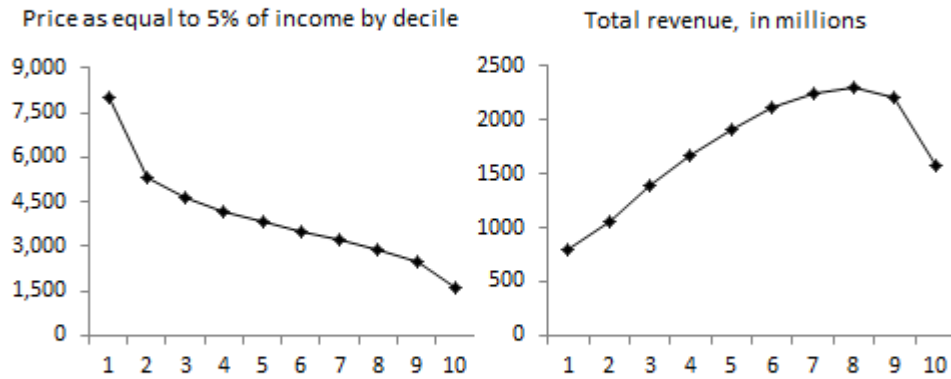
⁸ Sean Flynn, Aidan Hollis & Mike Palmedo, An Economic Justification for Open Access to Essential Medicine Patents in Developing Countries, 37 J.L. MED. & ETHICS 184 (2009); Eina V. Wong, Inequality and Pharmaceutical Drug Pricing: An Empirical Exercise (Ctr. for Econ. Analysis, Econ. Dep't, Univ. of Colo. at Boulder, Working Paper No. 02-19, 2002).

loss). What the models show is that firms will predictable serve much larger portions of the market in wealthy countries (the they make more money by lowering prices to increase volume) than in poorer ones, because of the inequality of income.

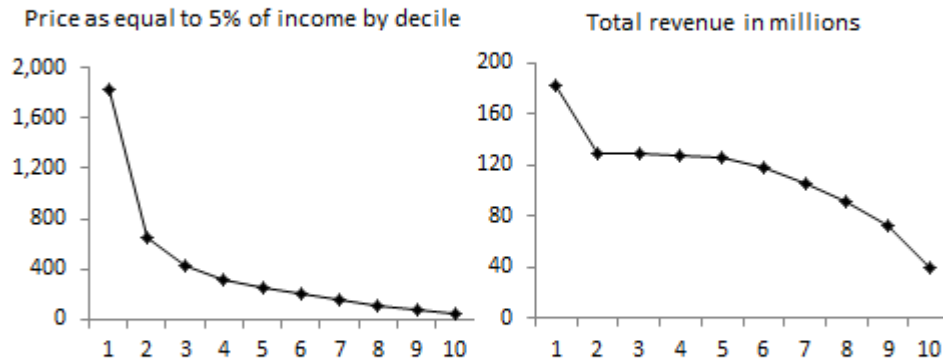
United States



Norway



Brazil



These problems are structural. The introduction of patent or other monopolies for any essential good or service in a poor and highly unequal country can be expected – absent some other regulation or intervention – to incentivize companies to set prices at exclusionary levels. The \$10,000+ being charged for AIDS drugs in the 1990s in Sub Sahara Africa – the same as charged in the U.S. – was not exceptional and it was not irrational. It

was the logical outcome of a market that laws created, and laws can cabin. It is a human rights duty to respond to this truth with action.

C. The High Level Panel should chart the ways that countries can (and must) act to promote access to medicines in the face of the globalization of intellectual property rules

The most globally efficient set of policies under such conditions would be to permit – as in times past – for the poorer and highly unequal countries to be “fair followers” and use the innovations of the wealthy at no or very low cost.⁹ Such systems would help solve the access problem that global intellectual property creates – but it does not solve the innovation problem. Other systems of innovation funding are needed to meet the needs of countries whose markets are defined by the inequality described above.

The international IP system does not prevent countries from adopting the kind of routine use of compulsory licensing that is necessary to balance intellectual property with health and human rights obligations – a point that should feature prominently in the work of the Panel. But unlike in the past – where countries could elect to not patent pharmaceuticals or other essential health goods at all – now it requires affirmative state action to implement such systems. A core challenge for the High Level Panel is to move forward toward defining and promoting such systems through the UN system.

1. The UN Panel should press countries to take full advantage of TRIPS flexibilities to limit the scope, duration and enforcement of pharmaceutical patents

One area where the duty to interpret law to promote the right to health can come into play is in the debate about what “flexibilities” exist in TRIPS to promote access to medicines. Human rights bodies have repeatedly affirmed that the flexibilities available in TRIPS to promote access to medicines must be safeguarded and implemented.¹⁰ It is sometimes

⁹ See Jerome H. Reichman, *From Free Riders to Fair Followers: Global Competition Under the TRIPS Agreement*, 29 *New York University Journal of International Law & Politics* 11-93 (1996). http://scholarship.law.duke.edu/faculty_scholarship/95/

¹⁰ See “Human Rights and Intellectual Property” Statement by the Committee on Economic, Social and Cultural Rights,” Follow-up to the day of general discussion on article 15.1(c), 26 November 2001, E/C.12/2001/15, 14 Dec. 2001, ¶ 2-3 (“any intellectual property regime that makes it more difficult for a State party to comply with its core obligations in relation to health, food, education, especially, or with any other right set out in the Covenant is inconsistent with the legally binding [human rights] obligations of the state party”); African Commission on Human and Peoples’ Rights, Resolution on Access to Health and needed Medicines in Africa, ACHPR/Res.141 (XXXIII)08 (November 24, 2008) (defining the human rights duty of “refraining from measures that negatively affect access, such as “(...) implementing intellectual property policies that do not take full advantage of all flexibilities in the WTO Agreement on Trade Related Aspects of Intellectual Property that promote access to affordable medicines, including entering “TRIPS Plus” free trade agreements”); U.N. Human Rights Council [UNHRC], *Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, Anand Grover*, 31 March 2009, A/HRC/11/12 at ¶ 27 (developing countries “should incorporate the flexibility to: (a) Make full use of the transition periods; (b) Define the criteria of patentability; (c) Issue compulsory licenses and provide for government use; (d) Adopt the international exhaustion principle, to facilitate parallel importation; (e) Create

posited that TRIPS and the Doha Declaration on TRIPS and Public Health only safeguard those features – like compulsory licensing and the freedom to allow parallel importation – explicitly mentioned in the TRIPS text. But adoption of a pro-health interpretation of TRIPS would go much further – making clear that the TRIPS flexibilities that countries can and must safeguard include the right to interpret and implement undefined terms in a manner that promotes the right to health and access to medicines.

Such an interpretation would cast light on how to promote coherence between TRIPS and pro-health policies such as those of India, Philippines, Argentina, Brazil (proposed) and other countries to limit patents on new forms and uses of known products. A strong conclusion on this issue may also be relevant to the litigation in the *Eli Lilly v. Canada* case being litigated under NAFTA.

2. *The UN Panel should promote the adoption of routine compulsory licensing programs for pharmaceuticals.*

An important way to balance intellectual property and public health and human rights concerns, while recognizing administrative efficiency needs, would be to set up a routine compulsory licensing system at nominal royalties such as Canada operated for many years prior to the WTO accords.¹¹ Such systems could be adopted through public health or competition authorities and the high Level Panel should explore how the UN could promote their creation.

Justifying routine compulsory licensing under international law is an area that calls for coherence between the IP and human rights regimes. It is often posited that a routine compulsory licensing system for medicines would run afoul of the obligation in Article 31 or TRIPS that compulsory licensing be case by case, or afoul of the obligation in Article 27 that IP rights be non-discriminatory. But neither of these arguments are clear on their face. Canada did make case by case determinations as part of its system – it just did so on a rapid basis with strong presumptions favoring licensing at low royalties. And the “discrimination” argument is not conclusive – the WTO has ruled that Article 27 does not prohibit rational differentiation.¹² There can be no more rational differentiation than a policy designed to promote human rights and global health by treating essential goods differently than widgets.¹³

limited exceptions to patent rights; (f) Allow for opposition and revocation procedures. In addition, countries need to have strong pro-competitive measures to limit abuse of the patent system.”

¹¹ See Jerome Reichman, *Non-voluntary Licensing of Patented Inventions Historical Perspective, Legal Framework under TRIPS, and an Overview of the Practice in Canada and the USA*, *UNCTADICTSD Project on IPRs and Sustainable Development, Issue Paper No.5* (2003).
http://www.ictsd.org/downloads/2008/06/cs_reichman_hasenzahl.pdf

¹² See Canada — Patent Protection of Pharmaceutical Products, WTO Panel Decision DS114.

¹³ See Carlos Correa, *Implications of the Doha Declaration on the TRIPS Agreement and Public Health*, World Health Organization, EDM Series No. 12, WHO/EDM/PAR/2002.3, 43-44 (2002) (“It is implicit within the Doha Declaration that differentiation in patent rules may be necessary to protect public health. The singling

Interpreting TRIPS in line with human rights obligations to promote access to medicines should lead to the conclusion that states are not prohibited from adopting routine compulsory licensing programs for pharmaceuticals— indeed, they may be required to do so where necessary to promote access to medicines. Defining this principle as a matter of international law – and then using UN institutions to promote concrete policy options in this area – would go far toward promoting coherence between public health, IP and human rights objectives.

3. *The UN Panel should promote the use of competition law to achieve routine licensing of pharmaceutical patents*

A key policy tool to promote routine licensing, recently endorsed by UNDP, is through adoption or interpretation of “essential facility” and “refusal to deal” standards for needed medicine patents in competition and anti-monopoly laws.¹⁴

This is an area where a strong duty to promote public health interpretations of local laws (here competition laws) could help motivate states to adopt the kind of affirmative policies needed to achieve access to medicines in the face of the globalization of intellectual property law. TRIPS is very permissive with regard to what competition policies can be applied to the exercise of intellectual property rights.¹⁵ Whether an essential facility or refusal to deal ground in a competition law can apply to a refusal to license a state granted intellectual property right is an open question of law interpretation in most countries.

Competition laws generally authorize compulsory dealing wherever the refusal to deal with a competitor maintains or extends the monopoly and causes more social harm than benefit. As discussed above, the economic case for why exclusionary practices for medicine suppliers cause more harm than good in developing countries is clear. The barrier to applying such grounds to patents is most often one of interpretation, e.g. whether an ambiguous definition of a monopoly, when silent as to its relation to intellectual property, should be applied to refusals to license patent rights.

out of public health, and in particular pharmaceuticals as an issue needing special attention in TRIPS implementation constitutes recognition that public health-related patents deserve to be treated differently from other patents.”). http://www.who.int/medicines/areas/policy/WHO_EDM_PAR_2002.3.pdf

¹⁴ Abbott, Frederick M., Sean M. Flynn, Carlos M. Correa, Jonathan Michael Berger, and Natasha Nayak, UNDP, *Using Competition Law to Promote Access to Health Technologies: A Guidebook for Low-and Middle-Income Countries*, (2014). <http://www.undp.org/content/undp/en/home/librarypage/hiv-aids/using-competition-law-to-promote-access-to-medicine.html>. See *generally* Sean Flynn, *Using Competition Law to Promote Access to Knowledge, Access to Knowledge in the Age of Intellectual Property*, Zone Books, MIT Press, (2010). http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1654023

¹⁵ See TRIPS Article 31(b), (f), (k) (waiving duties to prior negotiate and restrict licenses to domestic markets and authorizing: “the need to correct anti-competitive practices may be taken into account in determining the amount of remuneration”). See Doha Declaration on the TRIPS Agreement and Public Health, Paragraph 5. For a discussion of the legal implications of the Doha Agreement, see Carlos Correa, *Implications of the Doha Declaration on the TRIPS Agreement and Public Health*, World Health Organization, Health Economics and Drugs, EDM Series No. 12 (2002) (“Each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted”).

There is a clear example where uses of competition law to promote licensing of pharmaceuticals has worked. In 2013, the South African Competition Commission embraced this reasoning and demanded licensing on key aids drugs under refusal to deal and essential facility grounds.¹⁶ This action gave a strong regulatory incentive for other medicine suppliers to license their innovations before entering the South African market. A strong embrace of this norm elsewhere could promote routine licensing needed to lower costs without routine intervention or resort to compulsory licenses.

There are numerous agencies in the UN, including UNCTAD and UNDP, that have expertise in competition law. They should be convened with public health agencies, such as those at the WHO and UNAIDS, to work with countries to adopt widespread use of competition law strategies to promote access to medicines as one key step toward balancing human rights, global health and intellectual property laws.

D. The UN Panel should address the actions of countries that actively thwart use of pro-access interpretations and implementation of international law, including through unilateral trade pressure

One of the biggest barriers to the widespread adoption of policies that would promote access to medicine and implicates human rights duties is foreign policy pressure.

States are bound to promote and protect the rights to life and health not only of their own citizens, but also of the citizens of other countries affected by foreign policy, trade and assistance programs.¹⁷ These duties include human rights obligations to avoid pressuring developing countries to give up the use of TRIPS flexibilities to promote access to medicine.¹⁸

¹⁶ See CPTech's 2003 reports for the RSA Competition Commission, in Hazel Tau et al. v GSK, Boehringer, et al. <http://keionline.org/node/2074>

¹⁷ ICESCR, Art.2(1) (requiring “to undertakes to take steps, individually and through international assistance and co-operation”), Universal Declaration of Human Rights, G.A. Res. 217A(III), at Arts. 22, 28, U.N. GAOR, 3d Sess., U.N. Doc. A/810 (Dec. 12, 1948) (requiring “national effort and international cooperation” and that “[e]veryone is entitled to a social and international order in which the rights and freedoms set forth in this Declaration can be fully realized.”); U.N. Charter arts. 55-56 (calling on members to take “joint and several action” to promote “a higher standard of living,” “solutions of international economic, social health and related problems,” and “universal respect for, and observance of, human rights”); Denmark, Summary Record, ¶ 7, E/C.12/2004/SR.37 (Nov. 16, 2004).

¹⁸ See UNHCR, Comm. on the Rights of the Child, Concluding Observations: Thailand, ¶ 58(f), CRC/C/THA/CO/2 (Mar. 17, 2006) (admonishing Thailand to “[e]nsure that regional and other free trade agreements do not have a negative impact on the enjoyment of the right to health”); UNHCR, Comm. on the Rights of the Child, Concluding Observations: Peru, ¶¶ 48-49, CRC/C/PER/CO/3 (Mar. 14, 2006); UNHCR, Comm. on the Rights of the Child, Concluding Observations: Ecuador, Concluding Observations, ¶ 21, CRC/C/15/Add.262 (Sept. 13, 2005); UNHCR, Comm. on the Rights of the Child, Concluding Observations: Nicaragua, ¶ 16, CRC/C/15/Add.265 (Sept. 21, 2005); UNHCR, Comm. on the Rights of the Child, Concluding Observations: Philippines, ¶ 59, CRC/C/15/Add.259 (June 3, 2005) (recommending that the State use “all the flexibilities reaffirmed by the Doha Declaration . . . to ensure access to affordable medicines”); UNHCR, Comm. on the Rights of the Child, Concluding Observations: Chile, ¶ 59, E/C.12/1/Add.105 (Nov. 26, 2004) (encouraging Chile “to provide greater access to generic medicine making use of the flexibility clauses permitted in [TRIPS]”); UNHCR, Comm. on the Rights of the Child, Concluding Observations: Ecuador, ¶ 55,

The World Trade Organization's 2001 Doha Declaration on TRIPS and Public Health was passed in direct response to U.S. pressure that sought to minimize exceptions and maximize the rights of intellectual property owners in the face of a burgeoning health crisis.¹⁹ The agreement affirmed "the right of WTO Members to use, *to the full*, the provisions in the TRIPS Agreement, which provide flexibility [to promote access to medicines for all]." The World Health Organization has frequently pressed developing countries to maximize the use of TRIPS flexibilities to promote access to medicine.²⁰

One of the central tools used by the U.S. to promote "TRIPS-plus" policies on access to medicines has been the "Special 301" program.²¹ Another is through its free trade agreement negotiations.²²

This is an area where a pro-access interpretation of international law would be helpful. There are strong arguments that the U.S.'s continued use of its Special 301 program to threaten or deny general system of preferences or other trade benefits violates the World Trade Organization ban on unilateral dispute resolution as well as ban on reciprocal, discriminatory or non-development oriented GSP programs.²³ Using a pro-access interpretation of the WTO agreement strengthens these arguments. It would be useful for the Panel to explain how a pro-access interpretation of the WTO accords would favor a determination that the continuation of 301 pressure on developing countries on medicines issues is in contravention of a coherent interpretation of international trade and human rights law.

The High Level Panel should review U.S. policy in this area and make recommendations on how it should promote coherence between IP, global health and human rights systems. This review should include how international enforcement systems – such as the human rights enforcement system and the WTO ban on unilateral trade action – could be brought to bear.

E/C.12/1/Add.100 (June 7, 2004) ("strongly urges the State party . . . to make extensive use of the flexibility clauses permitted in [TRIPS] in order to ensure access to generic medicine"); UNHCR, Comm. on the Rights of the Child, Concluding Observations: Botswana, ¶ 20, CRC/C/15/Add.242 (Nov. 3, 2004); UNHCR, Comm. on the Rights of the Child, Concluding Observations: El Salvador, ¶¶ 47-48, CRC/C/15/Add.232 (June 30, 2004); UNHCR, Comm. on the Rights of the Child, Concluding Observations: Uganda, CCPR/CO/80/UGA (May 4, 2004).

¹⁹ See Ellen 't Hoen, *Trips, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way from Seattle to Doha*, 3 Chicago Journal of International Law 27, 30-42 (2002).

²⁰ See WHO, *Report of the Commission on Intellectual Property Rights, Innovation and Public Health*, at 126 (Apr. 2006); WHO, *Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property of the Sixty-first World Health Assembly*, WHA61.21, element 5.2.c, (May 24, 2008); WHO, *Globalization, TRIPS and Access to Pharmaceuticals*, WHO/EDM/2001.2 at 4-5 (Mar. 2001).

²¹ See Special 301 and Global Administrative Law in Balancing Wealth and Health: The Battle Over Intellectual Property and Access to Medicines in Latin America (Rochelle Dreyfuss and Cesar Rodriguez-Garavito eds. 2014); Special 301 of the Trade Act of 1974 and Access to Medicine, 309 Journal of Generic Medicines 1 (2010); Sean Flynn, What is Special 301? A Historical Primer, <http://infojustice.org/archives/29465>

²² The US Proposal for an Intellectual Property Chapter in the Trans-Pacific Partnership Agreement, 28 AUJLR 105 (2013) (with Brook Baker, Margot Kaminski and Jimmy Koo).

²³ See Sean Flynn, How Listing Ukraine As A Priority Foreign Country In Special 301 Violates WTO Agreements, <http://www.ip-watch.org/2013/05/13/how-listing-ukraine-as-a-priority-foreign-country-in-special-301-violates-wto-agreements/>.