Realizing the Right to Health in the Context of Intellectual Property
Submission for the United Nations Secretary-General’s
High Level Panel on Access to Medicines

Submitted by

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Abstract

This submission describes the role that the United Nations Secretary-General’s High Level Panel on Access to Medicines can play in clearly articulating several implications for states and international organizations of the right to health in the context of intellectual property and innovation policy. In particular, we urge the High Level Panel to:

1. Recognize that the right to health supersedes intellectual property (IP) rights,
2. Acknowledge that the right to health not only permits but requires states to incorporate IP flexibilities into their laws, and requires states to use them when needed to protect and fulfil the right to health; and
3. Recognize that the right to health also requires states and international organizations to explore and implement research and development (R&D) systems that delink the price of medicines and payment for R&D.

The High Level Panel should also call upon United Nations and other human rights bodies to recognize these legal implications of the right to health, and should disseminate these findings to domestic governments and non-governmental organizations (NGOs).
Primary Contribution

This submission describes the role that the United Nations Secretary-General’s High Level Panel on Access to Medicines can play in clearly articulating several implications for states and international organizations of the right to health in the context of intellectual property and innovation policy. In particular, we urge the High Level Panel to:

1. Recognize that the right to health supersedes intellectual property (IP) rights,
2. Acknowledge that the right to health not only permits but requires states to incorporate IP flexibilities into their laws, and requires states to use them when needed to protect and fulfil the right to health; and
3. Recognize that the right to health also requires states and international organizations to explore and implement research and development (R&D) systems that delink the price of medicines and payment for R&D.

We proceed by explaining how our proposal (1) remedies policy incoherence, (2) impacts public health and (3) impacts human rights. We conclude by (4) suggesting methods of implementation.

Impact on Remediing Policy Incoherence

A. The Primacy of Duties to the Right to Health

The right to health is recognized in the Universal Declaration of Human Rights (UDHR), and the 164 state signatories to the International Covenant on Economic, Social and Cultural Rights (ICESCR) have recognized a binding right to the “highest attainable standard of physical and mental health.” Importantly, access to medicines has also long been recognized as a core minimum obligation of the right to the highest attainable standard of health. Importantly, nearly 50 countries also incorporate a right to health in their national constitutions.

Human rights law also mandates that states protect the moral and material interests of creators. However, this obligation does not imply that intellectual property rights per se are human rights; rather, IP is merely one among many ways to remunerate creators. Because protection of the right to health is mandatory for states, and IP is but one permissible way to protect the human rights of creators, as the Special Rapporteur in the field of culture rights recently stated, “where patents and human rights are in conflict, human rights must prevail.” Similarly, the Human Rights Council and the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health (the “Special Rapporteur on Health”) have both affirmed that the right to health supersedes IP protections.

B. State Recourse to Protecting and Using IP Flexibilities in the Context of Health

Improving access to medicines is critical to improving overall public health. Exceptions and limitations in IP law play a key role in promoting and protecting access to medicines, because patents and related forms of regulatory exclusivity give pharmaceutical companies the power to raise the price of medicines and restrict their supply. Patent and related exclusive rights, especially as these rights become stronger and broader, create serious barriers to access to medicines. This is true in wealthy as well as resource-poor countries, as has been so dramatically illustrated with respect to the recently approved antiviral drugs to treat Hepatitis C.
Unfortunately, patents often generate far too little incentive for innovation to justify their high costs for access. It has long been acknowledged that strengthening patent protection in low- and middle-income countries will generate little innovation because of the relatively small size of their markets.\textsuperscript{xii} Increasingly, however, there is evidence that strong IP protections can stifle needed innovation – as well as have negative implications for access – in high-income countries as well.\textsuperscript{xiii}

More than two decades of work at the intersection of IP and human rights makes plain that countries must retain “flexibilities” in their IP laws, to ensure that the right to medicines can be respected and protected. Many such flexibilities are permitted under the TRIPS Agreement, although also increasingly undermined by other trade and investment treaties.\textsuperscript{xiv} TRIPS flexibilities with particular public health implications include:

1. Transition periods, which allow countries to delay introduction of restrictive new IP laws;\textsuperscript{xv}
2. Carefully defined criteria of patentability, which help prevent patents for trivial inventions and “evergreening”;\textsuperscript{xvi}
3. Compulsory licenses and government use, which can be used to address excessive pricing;\textsuperscript{xvii}
4. International exhaustion rules, which facilitate parallel importation;\textsuperscript{xviii}
5. Patent opposition and revocation procedures, which help ensure patent quality;\textsuperscript{xix}
6. Strong competition law and policy frameworks;\textsuperscript{xx}
7. Bolar exemptions and other similar exemptions important to research and development.\textsuperscript{xxi}

The Special Rapporteur in the field of cultural rights has concluded that human rights obligations require states to adopt such flexibilities into their national law.\textsuperscript{xxii} The Human Rights Commission, Committee on Economic, Social and Cultural Rights (CESCR) and the Special Rapporteur on Health have suggested the same.\textsuperscript{xxiii} Importantly, as other submissions highlight,\textsuperscript{xxiv} and as special rapporteurs have acknowledged,\textsuperscript{xxv} the right to health may also require the use of flexibilities that are not currently permissible under international trade law. This is another implication of the primacy of human rights obligations: Where IP flexibilities are needed to protect health, states must meet their obligations to incorporate these into their law.

Incorporating IP flexibilities into national law and rejecting trade agreements that undermine or bar these flexibilities is critical to the protection of the right to health. However, flexibilities that are not used cannot facilitate access to affordable medicines. Logically, nations not only must have but also must use these flexibilities in order to fulfill their obligations protect, respect, and fulfill the right to health.

The point is a simple one: Access to medicines is a core minimum obligation under the right to health.\textsuperscript{xxvi} Progressive realization requires that states move as expeditiously as possible toward the full realization of those rights to which it applies. However, ‘progressive realization’ is not the test for the realization of every aspect of rights such as health—some aspects are immediate obligations. If a particular change to IP law will increase access and is possible without the expenditure of resources, it can be seen as an immediate obligation. This is in contrast with the obligation to take actions that could assist in realizing the right to health that are subject to resource constraints. IP flexibilities do not require net expenditure of state resources,
but rather, free up such resources. As such, the use of IP flexibilities is not subject to the same limits as steps towards progressive realization that do require state resources.\textsuperscript{xxvii}

Importantly, there is a growing international acceptance that states have an obligation to exercise IP flexibilities to protect the right to health. For example, the Special Rapporteur on Health has recommended that states, and particularly least-developed countries, “should” make full use of TRIPS flexibilities, and avoid signing trade and investment agreements that undermine these flexibilities.\textsuperscript{xxviii} Other Rapporteurs have noted in recent reports that “states have a positive obligation to provide for a robust and flexible system of patent exclusions, exceptions and flexibilities based on domestic circumstances.”\textsuperscript{xxix} Similarly, states must avoid imposing IP obligations on other countries that interfere with their ability to protect the right to health.\textsuperscript{xxx} At the national level, courts have also recently recognized that the right to health obliges states to adopt certain flexibilities, and forbids IP laws that undermine access to medicines that generate no commensurate benefits in return.\textsuperscript{xxxi}

C. Delinking the Price of Medicines and the Cost of R&D

The right to health also requires appropriate frameworks for research and development (R&D), so that (1) medicines and medical technologies are developed to meet global health needs and especially the needs of the poor, and (2) these medicines and medical technologies are affordable. The right to health therefore can be the basis of obligations on states and international bodies to pursue R&D models that meet these needs. Indeed, over the last decade, there has been an increasing focus on developing alternative R&D models.

As noted above, existing IP protections create little incentive for innovation to solve the health challenges of poor or marginalized groups. In addition, reliance on IP generates other challenges, such as the conflicts of interest between profit-motive and the broad dissemination of clinical trial data.\textsuperscript{xxii} It may be difficult, absent a move to delink the profit motive from the funding of clinical trials, to remedy this conflict of interest.

Recognizing such problems with market-led R&D, the Special Rapporteur in the field of cultural rights has called for “incentives and purposive funding” that encourages research to “address societal needs, especially in the areas of health, food and the environment.”\textsuperscript{xxxiii} This mirrors comments from the Special Rapporteur on the Right to Food that notes that most scientific research “neglect[s] the real needs of the poorest and most marginalized groups.”\textsuperscript{xxxiv}

Similarly, the Special Rapporteur in the field of cultural rights has stated that “affordability [of medicines] is crucial and may require delinking research and development costs from product prices.”\textsuperscript{xxxv} The World Health Organization has endorsed the need to look for alternative models for financing R&D.\textsuperscript{xxxvi} Doing so will benefit not only those affected by neglected diseases in low-income countries; those in high income countries will also accrue “direct benefits from the products of R&D into new antibiotics and vector-borne diseases.”\textsuperscript{xxxvii} Alternative financing models and innovation prizes are both mechanisms for encouraging an alternative R&D model that can increase access to medicines.\textsuperscript{xxxviii}

The right to the “highest attainable standard of physical and mental health” extends to the
poor. Therefore, human rights is not silent on whether national and international institutions should pursue R&D models that will help foster the innovation of affordable drugs to fight diseases afflicting the poor. Rather, the right to health suggests that national and international institutions must support models that delink the price of medicines from the funding of R&D. Such delinkage is a means both to direct research to meet pressing global health needs, and to generate medicines that are more affordable for those who need them.

Achieving this delinkage will require more than just incentives at the national level. It will require new norms and solutions at the global level. The High Level Panel can assist on this front by recommending that UN bodies and member states begin an international process to negotiate a global R&D agreement that facilitates access and affordability of new medicines, and that supports innovation that meets the health needs of the poor.

**Impact on Public Health**

The three principle entailments of the right to health for IP and innovation policy articulated here (supremacy of the right to health, mandatory recourse to IP flexibilities, delinking drug prices and R&D investment for drugs) will help address the underlying policy incoherence between IP law and human rights. By embracing these three implications, the High Level Panel can strengthen the emerging consensus described above. By encouraging other UN bodies to similarly recognize these arguments, and disseminating its report to the local level, the High Level Panel can encourage action at both the international and domestic level to protect and fully employ IP flexibilities. This is particularly important in the face of ongoing trade negotiations that potentially undermine these flexibilities and, by extension, the right to health.

Because IP protections are codified in states’ laws or incorporated treaties, domestic action is also an important tool for managing instances where IP protections conflict with the right to health. For example, states alone have the power to issue compulsory licenses or utilize IP flexibilities, and can play an important role in implementing delinkage in R&D. However, governments may be reluctant to use these tools, and may require both support and a clear sense of their internationally supported human rights obligations, to withstand the pressures arrayed against these health measures. Similarly, courts can draw on an international human rights consensus to support rulings that advance access to medicines. Such favorable rulings can have a snowball effect, where domestic courts cite to favorable international precedent to support a local ruling in favor of access to medicines.

The Panel should therefore encourage local organizations and actors to bring these arguments to their own national human rights bodies, courts, and agencies. For example, organizations concerned with the right to health can bring actions to mandate the issuance of compulsory licenses when this is needed to address the unavailability or unaffordability of particular medicines. Organizations in Colombia and Peru have helped reduce the price of drugs by pursuing such cases.\(^{xl}\) Organizations can also intervene in patent disputes, urging against injunctions in instances where these would exclude generic medicines from the market and undermine the right to health.\(^{xli}\) In February 2016, organizations in India helped people living with HIV to oppose a patent application for essential medicines that the manufacturer has refused
to “make available for people . . . who have run out of other treatment options.” Local organizations can also bring direct challenges to ill-conceived IP laws, to invalidate them in the name of the right to health.

In exercising IP flexibilities, countries can and should consider the implications for innovation. However, courts and states should be careful not to accept at face value assertions that IP protections necessarily foster innovation. As discussed above, this is often not the case, in the high income, as well as low- and middle-income context. Therefore, courts and states should require those who argue against the use of IP flexibilities in the name of innovation to carry the burden of production and proof for such claims.

Furthermore, High Level Panel action of the kind advocated in this contribution can hasten the World Health Organization and other international and national bodies’ pursuit of models for de-linking R&D from the cost of medicines. This is a critical, long-term structural shift that is essential to redressing the inaccessibility and unavailability of medicines, particularly in low- and middle-income countries.

Impact on Human Rights

Human rights tools have not, to date, been used as prominently as they should be to redress the policy incoherence between poorly designed IP and innovation policies and the right to health. Our contribution calls on the High Level Panel to recognize that the right to health has clear, actionable implications for IP and innovation policy, and that states are obliged to recognize these implications, and alter their domestic laws, and appropriately shape their international commitments, as a consequence. Full recognition of the three principles above would require substantial changes at the national level, not only in low- and middle-income but also in high-income countries: states would incorporate new IP flexibilities, and deploy them when needed to advance health. They would also alter their priorities in trade negotiations, and prioritize health over agreements that excessively constrain the use of IP flexibilities, where needed.

Implementation

This proposal calls on the High Level Panel to clearly recognize the growing consensus around the three implications of human rights law for IP that are outlined above. The High Level Panel can also actively advance these positions by disseminating its findings to the following sets of actors:

- International bodies, including UN agencies and the WTO: UN agencies like the World Intellectual Property Organization (WIPO) and the World Health Organization (WHO) play a critical role in defining the global agenda and convening resources around it. The High Level Panel can engage these agencies so that the three conclusions outlined above are fully incorporated into their work. WIPO in particular could be an important means of facilitating the use of IP flexibilities locally. WHO could make a critical difference, promoting human rights by promoting the use of IP flexibilities and embracing an ambitious agenda for delinkage in R&D. Dialogue with the WTO should emphasize the
implications of IP for the right to health, and the primacy of the latter where the two conflict.

- **States and national agencies:** The High Level Panel should work to inform states that they are required to use IP flexibilities to fulfil the right to health. This will embolden states that already believe this to be the case. It will also provide extra support to states attempting to fulfil the right to health in the face of pressure from countries or corporations working against health interests in trade negotiations or patent disputes.

- **Local NGOs and citizens groups:** As detailed above, local organizations play a critical role in advancing the right to health through local courts and institutions. The High Level Panel should disseminate its findings to local NGOs and other citizens’ groups through easily accessible materials available online and in print. This can help provide these groups with legal precedent and international support for arguments to protect the right to health when it comes in conflict with IP protections.
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procedures”) the legitimate trade of medicines, and to provide for safeguards against the abuse of such measures and procedures for enforcing intellectual property rights in such a manner as to avoid creating barriers to the legitimate trade of medicines, and to provide for safeguards against the abuse of such measures and procedures.

1 This contribution builds upon GLOBAL HEALTH JUSTICE PARTNERSHIP, A HUMAN RIGHTS APPROACH TO INTELLECTUAL PROPERTY AND ACCESS TO MEDICINES. (September 2013). http://media.wix.com/ugd/148599_c76ed67341fa426bc2227f5c5f453ea04.pdf

[Hereinafter GHJP Report].


http://ap.ohchr.org/documents/dpage_e.aspx?si=A/HRC/23/L.10/Rev.1 at 3. (“Stresses the responsibility of States to ensure the highest attainable level of health for all, including through access, without discrimination, to medicines, in particular essential medicines, that are affordable, safe, efficacious and of quality”)


vi ICESCR Art 15(1)c; Comm. on Econ, Soc., & Cultural Rights. U.N. Doc. E/C.12/GC/17. General Comment No. 17: The right of everyone to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he or she is the author (Jan. 12, 2006).


vii General Comment 17 (“Human rights are fundamental, inalienable and universal entitlements belonging to individuals and, under certain circumstances, groups of individuals and communities… In contrast to human rights, intellectual property rights are generally of a temporary nature, and can be revoked, licensed or assigned to someone else… Moreover, the scope of protection of the moral and material interests of the author provided for by article 15, paragraph 1 (c), does not necessarily coincide with what is referred to as intellectual property rights under national legislation or international agreements.”) In addition, the protection of moral and material interests is limited to individual persons and does not extend to corporations. Id.


ix See Human Rights Commission. A/HRC/RES/12/27 (Oct. 22, 2009). http://www2.ohchr.org/english/issues/hiv/docs/A-HRC-RES-12-27.pdf (“The Agreement [i.e. TRIPS] can and should be interpreted and implemented in a manner supportive of the right to protect public health and, in particular, to promote access to medicines for all including the production of generic antiretroviral drugs and other essential drugs for AIDS-related infections”), See also; Human Rights Commission. A/HRC/RES/12/24 (Oct. 12, 2009). http://daccess-dds-ny.un.org/doc/RESOLUTION/GEN/G09/167/45/PDF/G0916745.pdf?OpenElement (“Encourages all States to apply measures and procedures for enforcing intellectual property rights in such a manner as to avoid creating barriers to the legitimate trade of medicines, and to provide for safeguards against the abuse of such measures and procedures”).
See e.g. Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Promotion and Protection of all Human Rights, Civil, Political, Economic, Social and Cultural Rights. Including the Right to Development. UN Doc. A/HRC/11/12. (Mar. 31, 2009). [Hereinafter “Health Rapporteur”] (recommending that in order to protect the right to health, developing countries use IP flexibilities to prevent IP law from being a barrier to access to medicines).


On innovation, in high-income countries see Petra Moser, Patents and Innovation: Evidence from Economic History, 27 Journal of Economic Perspectives 1, 23-44 (2013) (“The findings of this literature…suggest that when patent rights have been too broad or strong, they have actually discouraged innovation.”). For one recent example of access concerns, see Sovaldi Senate Report, supra.

Health Rapporteur at 21 and 69.

Id.
Id.
Id.
Id.
Id.
Id.
Id.
Id.

Id.


Culture Rapporteur, supra note viii. (“States have a positive obligation to provide for a robust and flexible system of patent exclusions, exceptions and flexibilities based on domestic circumstances”)

See Health Rapporteur, supra. note x (“The framework of the right to health makes it clear that medicines must be available, accessible, acceptable, and of good quality to reach ailing populations without discrimination throughout the world. As has been evident, TRIPS and FTAs have had an adverse impact on prices and availability of medicines, making it difficult for countries to comply with their obligations to respect, protect, and fulfill the right to health….Developing countries and LDCs need to incorporate in their national patent laws all possible grounds upon which compulsory licences, including government use, may be issued.”); General Comment 14, supra para. 51 (“Violations of the obligation to protect [the right to health] follow from a failure of a State to take all necessary measures to safeguard persons within their jurisdiction from infringements of the right to health by third parties…[This includes] failure to regulate the activities of individuals, groups or corporations so as to prevent them from violating the right to health of others: the failure to protect consumers… from practices detrimental to health, e.g.,… by manufacturers of medicines…”); Human Rights Commission. A/HRC/RES/12/24 supra (“Encourages all States to apply measures and procedures for enforcing intellectual property rights in such a manner as to avoid creating barriers to the legitimate trade of medicines, and to provide for safeguards against the abuse of such measures and procedures.”)

Special Rapporteur in the field of cultural rights. The right to enjoy the benefits of scientific progress and its applications. UN Doc. A/HRC/20/26 (May 14, 2012), para. 59.
http://www.ohchr.org/Documents/HRBodies/HRCouncil/RegularSession/Session20/A-HRC-20-26_en.pdf (“States must establish “minimum standards of protection,” and that surpassing these may not always be compatible with human rights standards. Furthermore, it is pertinent to assess whether existing minimum standards accord with human rights standards.”)

General Comment 14

This argument quotes from GHJP report, supra.

See e.g., Health Rapporteur at 97. (“The Special Rapporteur therefore recommends that developing countries and LDCs should review their laws and policies and consider whether they have made full use of TRIPS flexibilities or included TRIPS-plus measures, and if necessary consider amending their laws and policies to make full use of the flexibilities.”); Health Rapporteur at 96 (“Flexibilities were included in TRIPS to allow States to take into consideration their economic and development needs. States need to take steps to facilitate the use of TRIPS flexibilities.”); see generally Health Rapporteur at 94-109.

Culture Rapporteur, supra, note viii.

http://www2.ohchr.org/english/bodies/cescr/docs/statements/E.C.12.2001.15HRIntel-property.pdf (“It is incumbent upon developed States, and other actors in a position to assist, to develop international intellectual property regimes that enable developing States to fulfill at least their core obligations to individuals and groups within their jurisdictions.”)

F. Hoffmann-La Roche AG v. Cipla Ltd., (2008) High Court of Delhi (India). (“[T]his Court is of the opinion that as between the two competing public interests, that is, the public interest in granting an injunction to affirm a patent during the pendency of an infringement action, as opposed to the public interest in access for the people to a life saving drug, the balance has to be tilted in favour of the latter.”); Patricia Asero Ochieng, Maurine Atieno, Joseph Munyi, & AIDS Law Project v. Attorney General, Petition No. 409. (2009) High Court of Kenya (Kenya). (Declaring an anti-counterfeiting law that would have prohibited the sale of generics to be unconstitutional and contrary to Kenya’s international treaty obligations). See also GHJP report, supra at 58-62.

There is growing evidence that patent-holding companies have deliberately designed trials and manipulated the published literature to minimize awareness of harmful side-effects of their drugs. The Vioxx case vividly illustrates the problem. Harlan Kumbholz et al. What Have We Learned from Vioxx. 334 BMJ 7585, (2007)
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The Special Rapporteur in the field of cultural rights. A/HRC/20/26, supra at 33. The report focused on the right to benefit from scientific progress, but as noted above, this intersects with and supports the right to health in this context.


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Investor-State Dispute Settlement chapters can also pose risks to IP flexibilities. See Eli Lilly and Company v. The Government of Canada, UNCT/14/2 (ICSID) (challenging an aspect of Canada’s patent’s doctrine as a violation of investor protections in NAFTA).

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