

Submission to the UN High Level Panel on Access to Medicines by the Global Health Law Committee of the International Law Association.

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Abstract

The Global Health Law Committee of the International Law Association appreciates the opportunity to submit proposals to the UN High-Level Panel on Access to Medicines to address the misalignment between the rights of inventors, international human rights law, trade rules and public health where it impedes the innovation of and access to health technologies.*

The right to essential medicines is a key component of the right to health as guaranteed under international human rights law. Essential medicines should be available, accessible, acceptable and of assured quality.

We recognise that addressing IP related challenges to access to medicines is but one aspect of medicines policies that need to be in place to ensure effective medical treatments of assured quality are available.

However, there is an embedded conflict between government obligations under human rights law to ensure access to medicines and obligations under intellectual property law to grant medicines patents.

A global public policy response that rebalances obligations under human rights law with obligations under IP law is needed.

We wish to submit the following proposals that would contribute to realigning rights and obligations under human rights and intellectual property law and contribute to reaching the Sustainable Development Goals (SDGs).

1. Establish an Essential Medicines Patent Pool through which licences are available to guarantee generic production and availability of quality assured essential medicines.
2. Support effectively automatic non-voluntary licensing of patents related to medicines on the WHO Model List of Essential Medicines or their national essential medicines list by national governments.
3. Authorize exemption of essential medicines from patenting through an authoritative interpretation of articles 27 and 30 of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights.

This submission offers a summary of the proposals. We recognise that substantial additional work is required to develop the proposals in detail.

1. The WHO Essential Medicines Concept and the challenges of ensuring access to new Essential Medicines as a component of the right to health in a post TRIPS era.

The right to essential medicines is a key component of the right to health as guaranteed under international human rights law. The most important treaty is the International Covenant on Economic, Social and Cultural Rights (ICESCR, 1966) enshrining the right to health in Article 12.** This provision is further interpreted in the non-binding yet authoritative General Comment 14 (2000), which defines the State's legal obligation to provide essential medicines.

According to the WHO, essential medicines are: '[T] hose that satisfy the priority health care needs of the population... selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness... [and] intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford'[1].***

The WHO published the first Essential Medicines List (EML) in 1977 and has updated the list every two years. The WHO EML guides countries in the selection and provision of essential medicines. Countries are encouraged to develop their own EML and to implement policies to ensure access to these medicines. Today, more than 150 countries have an EML [2].

Access to essential medicines is a key component of the fulfilment of the human right to health. A study of 186 national constitutions shows that 135 (73%) include provisions on health or the right to health. Some constitutions specifically mention access to medicines [3]. The SDGs include achieving Universal Health Coverage (UHC) and emphasise access to essential medicines and vaccines for all [4].

Essential medicines should be available, accessible, acceptable and of assured quality [5]. Essential medicines policies have traditionally been rooted in policies to encourage the availability of generic medicines. Countries have sought to keep the prices of essential medicines low by excluding them from patentability. The Andean Community, in 1991, adopted a decision providing that "inventions related to pharmaceutical products included in the List of Essential Drugs of the WHO" shall not be patentable [6]. India excluded medicines from patentability until 2005 [7]. This encouraged the development of a generic pharmaceutical industry that has served as the 'pharmacy of the developing world' [8]. When the Uruguay Round of trade negotiations was launched in 1986, 49 of the 98 parties to the Paris Convention excluded pharmaceutical products from patent protection [9]. Countries varied in the periods of protection granted and/or set out conditions that restricted patent holders' rights [10].

Adoption of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in 1994 diminished the legal space through which the availability of

generic medicines might be assured. TRIPS set out minimum standards for the protection of intellectual property rights. Members of the WTO may no longer exclude entire fields of technology, such as medicines, from patentability,^[11] and a minimum 20-year patent term is obligatory ^[12].

The 19th EML edition (2015) contains several important medicines including for the treatment of cancer, tuberculosis (TB) and hepatitis C (HCV) that are widely patented and highly priced ^[13]. The high prices of the new essential medicines illustrate the challenges to access in the post-TRIPS era ^[14]. When WHO labels a medicine as essential governments must act to ensure availability.

Yet, mandatory patenting of new essential medicines has entrenched price-setting power within the commercial industry, reducing the effective authority of governments. Monopoly pricing routinely precludes wide access. There is an embedded conflict between government obligations under human rights law and obligations under IP law.

2. Political coherence of States' obligations under international intellectual property treaties and obligations to ensure the human right to health.

The introduction of TRIPS coincided with the emergence of the HIV/AIDS pandemic, which fuelled a global campaign for access to medicines ^[15].

The global mobilization around HIV focussed on a number of flexibilities contained in TRIPS to bring down the price of medicines. These flexibilities include compulsory licensing (CL), parallel importation, delay and/or non-enforcement of medicines patenting and regulatory data protection by least developed countries, defining patentability criteria to reward meaningful innovation and prevent 'ever-greening' of patents, and implementing exceptions to patent exclusivity.

In 2001 the WTO adopted the Doha Declaration on TRIPS and Public Health expressly acknowledging these flexibilities and making clear that IP protection must not interfere with the protection of public health ^[16]. Paragraph 4 reads: *"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."*

Consistent with the Doha Declaration, developing countries that had ARV patents have widely used TRIPS flexibilities to procure generic ARVs, mostly from India where these products were not patented. In 2010 the Medicines Patent Pool was created to ensure that generic versions of new ARVs continue to be available. Today, first line ARV regimens are available from generic suppliers for US\$ 95 – 158 ^[17], a steep decrease from US\$ 10.000 - 15.000 a decade and a half ago. It is estimated that 80% of the people receiving HIV treatment access generic

prequalified ARVs. This progress is the result of unprecedented global mobilisation and the absence of medicines product patents in India until 2005.

The use of flexibilities for non-HIV products seems to be more difficult and politically more sensitive. For example when India issued a CL for a cancer medicine it provoked an out-of-cycle review by the US Trade Representative [18]. The MPP has recently expanded its mandate to include HCV and TB, but challenges remain for countries outside the scope of the MPP agreements. For other new essential medicines such regularized access strategies are lacking.

TRIPS-plus requirements (i.e. standards of IP protection higher than those mandated by TRIPS) in regional and bilateral trade agreements roll back much of the positive momentum represented by the Doha Declaration [19]. Investor to State Dispute Settlement (ISDS) mechanisms, often contained in such agreements, are being used by the pharmaceutical industry to contest decisions by national patent offices and courts [20].

The trend in international norm setting for patents reflects the IP agenda of corporations that seek expansion of their monopoly positions in the market through patents and other market exclusivity mechanism. For example: test data protection rules that prevent the marketing authorisation of generic and biosimilar medicines by a medicines regulatory agency for a certain period of time or marketing exclusivity granted under orphan drug laws.

The progress in access to ARVs has been the result of a unique and unprecedented global mobilisation. Other diseases have not sparked responses at the same scale, which raises the question of how to ensure access to new treatments for hepatitis, tuberculosis (TB), cancer, diabetes and other non-communicable diseases in the face of expanded patent and exclusivity rights. Affordable essential medicines are crucial to the success of UHC, an important target under the SDGs.

3. The human right to access to essential medicines – who is responsible for the fulfilment of this right?

Obligations of States parties

States are the primary duty holders under the international human rights treaties. Based on Article 12 ICESCR, they are under a legal obligation to take measures necessary for the prevention, treatment and control of diseases and for creating conditions assuring access to medical services [21]. General Comment 14 explains that States should ensure that medical services, including essential medicines, are available, accessible, acceptable and of good quality ('AAAQ') [22]. It identifies access to essential medicines as a legal core obligation of the right to health [23]. According to General Comment 14, the legal core obligation to provide essential medicines is 'non-derogable', which means that non-compliance would result in a *prima facie* violation of the ICESCR [24]. They are also under a legal obligation to

ensure that the pharmaceutical industry does not limit people's access to essential medicines (State's 'obligation to protect') [25].

Obligations of the international community of States

States and the international community of States at large are under an obligation to facilitate access to essential medicines in other countries and to provide the necessary aid when required [26]. They are to assist developing countries in realizing their core obligation to provide access to essential medicines to their population [27]. States should prevent third parties, including the pharmaceutical industry, from violating the right to health in other countries [28]. They should ensure that their actions as members of international organizations take due account of the right to health [29].

Responsibilities of the pharmaceutical industry

The preamble to the Universal Declaration of Human Rights calls on 'every individual and every organ of society' to promote and respect human rights. Similarly General Comment 14 recognizes that the private business sector has responsibilities under the right to health [30]. In line with this it is widely recognized that the pharmaceutical industry carries responsibilities under the right to health [31]. Based on the 'Ruggie Principles' (2008), endorsed by the Human Rights Council in 2011, pharmaceutical companies have the corporate responsibility to respect human rights. This means that they should avoid infringing on the human rights of others and should address the adverse human rights impacts of the activities in which they – or their business relationships – are involved [32].

Enforcing responsibilities to the human right to health

The tension between IP and human rights is perpetuated by the differences in how these two frameworks are enforced. IP rights enjoy binding enforcement mechanisms at the international level through the WTO Dispute Settlement Mechanism and through ISDS. While both IP and human rights standards are legally enforceable and binding on State parties, the authority of human rights norms is not often recognised within the IP framework. Although WTO dispute settlement no longer insists on a self-contained regime approach, human rights have yet to play a material role. On the other hand, States are held accountable to human rights norms in several authoritative, albeit often non-binding, fora (i.e. CESCR).

Access to medicines as part of the human right to health has been increasingly enforced before domestic courts, with one of the most prominent cases filed by the Treatment Access Campaign seeking access to ARVs in South Africa [33]. Domestic enforcement is highly contingent on a functional national judiciary and patients' own access to justice - both of which may be lacking in countries where access urgently needs to be scaled up. In successful cases where patients cannot afford their medicines, the courts often shift the financial burden from the patient to the State, which must pay for expensive, sometimes patented, medicines, rather than address the root causes of high prices. For example in Brazil, where unplanned government spending on court-mandated medicines grew by 11 times over 2 years, reaching US\$47,8 million in 2009 [34]. In these circumstances, achieving UHC and

health system sustainability becomes a major concern. These shortcomings show that a more equitable solution is needed to address the core issue of how health systems can provide high-priced, essential medicines rather than ease only the symptom of patient affordability through the courts.

A global public policy response that rebalances obligations under human rights law with obligations under IP law is needed to address patent challenges to access to new essential medicines.

4. Proposals to realign obligations under human rights treaties and IP treaties.

Access to essential medicines is a key component of the right to health. Essential medicines should be available “at a price the individual and the community can afford” [35]. The patent status of an essential medicine can be an impediment to achieving an affordable price and to a government’s obligation to fulfil its population’s right to essential medicines. This is the case when the patent holder refuses cooperation through equitable pricing or licensing of the relevant patents.

We recommend realigning obligations under human rights treaties and IP treaties by ensuring that effective mechanisms to overcome patent barriers to access to essential medicines are in place.

We therefore make the following proposals aimed at reconciling access to essential medicines under the right to health and patent rights for consideration by the High-Level Panel:****

1. Establish an Essential Medicines Patent Pool (EMPP) under the auspices of the UN.

The EMPP could be modelled after the MPP and pursue public health focused licence terms and conditions [36, 37]. The unmet need for treatments for both communicable and non-communicable diseases justifies the application of the patent pool model beyond only a few infectious diseases.

Companies should license their patents related to essential medicines to the EMPP, which would align with their responsibility to promote and protect human rights.

Both voluntary licensing and CL (Proposal 2) through an EMPP should be coupled with a tiered royalty system to remunerate the patent holder and contribute to R&D expenditure at levels proportionate to GDP. The WHO and UNDP have provided guidelines for the remuneration of non-voluntary use of medical technologies that could be used or further adapted for that purpose [38].

A patent owner’s refusal to license an essential medicine to the EMPP would satisfy the CL grantee’s requirement under article 31 to have made efforts to obtain authorization from the right holder on reasonable commercial terms and

conditions, recognizing that there is no prior negotiation requirement in cases of national emergency, extreme urgency or public non-commercial use.

The right of states to exempt essential medicines from patenting should be authoritatively recognized by the WTO (Proposal 3), including taking into account obstacles that could arise in the implementation of the EMPP. This would assure that the priority needs of individuals, in accordance with basic human rights principles, are given first priority among interests.

2. National governments should establish effectively automatic non-voluntary licensing of patents related to medicines on the WHO EML or their national EML.

The UN and its specialised agencies in collaboration with the WTO should develop guidance for countries including model legislation to implement the effectively automatic provision of CL for essential medicines. This effectively automatic non-voluntary system should be implemented immediately and should be integrated with the EMPP when the latter is established.

Compulsory licensing of patents related to essential medicines is possible under TRIPS. The Doha Declaration specifies: "Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted." While Article 31 (a) of the TRIPS Agreement requires that CLs should be considered on their individual merits, a legal mechanism meeting that requirement may employ identification as an essential medicine as the means through which the individual merits of a licence are determined [39] [40]. Export of the predominant part of essential medicines produced under such a CL should be understood to fall within the August 30 2003 'waiver'/pending amendment inserting article TRIPS 31*bis*, satisfying the requirement for authorization of export of medicines produced under a CL.

3. Authorize exemption of essential medicines from patenting.

The WTO Ministerial Conference should provide an authoritative interpretation of articles 27 and 30 of TRIPS to allow Members to exclude essential medicines from patentability. The UN General Assembly should adopt a resolution urging the WTO to take this action.

The priority needs of individuals for access to essential medicines should take precedence over commercial interests, and should be facilitated. The recommended authoritative interpretation would demonstrate unqualified recognition by the international community of the priority of human rights over commercial interests.

5. Conclusion

Impact on policy coherence and advancing human rights

All three proposals will increase policy coherence by strengthening the human rights aspects of access to medicines and by providing effective remedies to patent barriers to generic low-priced essential medicines.

Impact on public health

The impact on public health is expected to be significant. High prices are a serious impediment for providing new essential medicines as is evidenced by the global rationing of new antivirals for the treatment of HCV, challenges of access to new ARVs in countries excluded from voluntary licence agreements and the lack of cancer treatment. While affordability is only one aspect of ensuring access to medicines, lack of affordability is often the single most important barrier.

Implementation

Proposal 1: Establish an Essential Medicines Patent Pool.

An EMPP can be modelled after the MPP, or established in collaboration with the MPP and does not require legislative changes. The MPP has enjoyed the cooperation of the industry, suggesting that stakeholder support could be expected for an EMPP. An EMPP offers the industry a mechanism to honour its human rights responsibilities.

The establishment of an EMPP under the auspices of the UN would give it a sustainable organisational and financial base and ensures involvement of States. This will help create a synergy with the implementation of Proposals 1 and 2, which require the involvement of governments.

Proposal 2: National effectively automatic non-voluntary licensing of patents related to essential medicines.

Proposal 2 can be implemented by national governments without further changes in the international IP legal framework. The fact that some countries have started to grant CLs for cancer and heart disease medication may indicate growing political willingness for broader application of CL. Strong technical, legal and political support from relevant UN and international agencies will enhance uptake of this proposal.

Proposal 3: Authorize exemption of essential medicines from patenting.

Authoritatively authorizing exemption of essential medicines from patent subject matter coverage provides a global solution, is predictable and long-term. This will not address the potential impact of TRIPS-plus rules, but it will send a persuasive normative message.

Implementing this recommendation will require cooperation at the WTO. Today the political commitment of WTO Members to implement this proposal may be weak. It will therefore be important that the UN make the recommendation to authoritatively authorize exemption of essential medicines from patentability forcefully and demand action from the WTO.

Notes, References and Bibliography

Notes

* The perspectives in this submission may not necessarily reflect the totality of views of each member of the GHLC. It is intended to further public dialogue and the development of needed options. Peter Beyer, as current staff at WHO, has recused himself from this submission. Frederick Abbott, co-chair of the GHLC, is a member of the Expert Advisory Group. For the Members of the Committee, see:

<http://www.ila-hq.org/en/committees/index.cfm/cid/1053/member/1>).

** Other important right to health provisions are contained in the Convention on the Elimination of All Forms of Discrimination Against Women (CEDAW), the Convention on the Rights of the Child (CRC and General Comment 15), and the Convention on Persons with Disabilities (CPD).

*** For the purpose of this submission the term Essential Medicines refers to medicines included in the WHO Model List of Essential Medicines and national Essential Medicines Lists.

**** The Committee wishes to stress that the proposals made in this submission should be seen in the context of proposals for reform of the global pharmaceutical R&D framework to ensure financing for R&D while maintaining prices within reach of the people and communities that need access to the innovations (see for example the recommendation of the WHO Consultative Expert Working Group (2012) to start negotiations on a medical R&D agreement (http://www.who.int/phi/implementation/CEWG_Report_5_April_2012.pdf), proposals for creating an intergovernmental consortium for new antibiotics (<http://www.globalhealthdynamics.co.uk/wp-content/uploads/2015/06/AMR2015-June-3.pdf>) and the proposal "The Framework Convention on Pharmaceutical Innovation and its Related Protocols" submitted to the UNHLP by the GHLC.)

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