Technical Brief
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From TRIPS to PPR: Addressing Intellectual Property Barriers on Lifesaving Medical Products

The 1995 Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) set the minimum standards for intellectual property (IP) protection in the world today. The TRIPS Agreement considered lifesaving medical products in the same vein as consumer goods, leading to tensions between IP protections, including patents, on medical products and the need to ensure timely, sufficient, affordable and equitable access to these products.[1] For nearly three decades, these tensions have remained unresolved.

Although voluntary license agreements on IP have often been used by pharmaceutical corporations to allow alternative production and supply of medical products, past and present experiences show that these voluntary actions are insufficient and lack the accountability necessary to ensure access to medical products for all, even during global public health emergencies.[2,3,4]

As an international medical humanitarian organisation, Médecins Sans Frontières/Doctors Without Borders (MSF) has repeatedly witnessed how IP monopolies stand in the way of people's access to lifesaving medical products, both during public health emergencies and beyond. The ongoing global negotiations at the World Health Organization (WHO) concerning pandemic prevention, preparedness and response (PPR) mechanisms present an important opportunity to improve current international rules and practices on access to medical products and IP.

This technical brief outlines the existing body of international law and instruments dealing with IP and access to medical products, explains why these have not always proven adequate, and argues that the ongoing PPR negotiations at WHO are the appropriate platform for addressing access challenges. In so doing, the brief refers to MSF's recommendations on IP measures needed to ensure access to medical products elaborated in an earlier position paper.[5]

Challenges and shortcomings in addressing public health issues using existing international IP rules

International IP rules typically fall within agreements administered by the World Trade Organization (WTO) and the World Intellectual Property Organization (WIPO). Although there is some recognition of the importance of safeguarding public health and facilitating access to medical products in these agreements, their primary objectives are not to address global public health challenges.

The Doha Declaration on the TRIPS Agreement and Public Health (the Doha Declaration) that was adopted in 2001 at the 4th WTO Ministerial Conference, the highest governing body of WTO, contains such a recognition of the importance of public health.[6] It reaffirmed the need for the TRIPS Agreement "to be part of the wider national and international action to address" "the gravity of public health problems" in epidemics, and reiterated WTO members' right to use TRIPS flexibilities to "protect public health" and "promote access to medicines for all". Since then, a substantial body of instruments, including nearly 30 World Health Assembly (WHA) resolutions and documents from other United Nation (UN) bodies, has specifically referred to the Doha Declaration.[7,8]

Despite this widespread and explicit international recognition, multiple challenges remain in fully realising access to medical products as a fundamental human right when confronted with IP barriers.

1. Unilateral political pressure

Governments of developing countries often face unilateral political pressure when utilising IP flexibilities to address national health needs.[9] For example, the United States Trade Representatives' Special 301 Report consistently criticises the implementation of IP rules and practices promoting access to medical products in various countries. In recent years, in a departure from convention, the report has recognised countries' right to use compulsory licenses as a public health safeguard to overcome IP barriers on medical products. However, the report continues its public criticism of countries' use of other TRIPS flexibilities, including stricter patentability criteria to check evergreening, stringent patent examination guidelines and restrictions on data and market exclusivities.[10]

2. Insufficient public health safeguards in national IP laws and policies

Even today, some countries continue to lack public health protections such as rigorous patent examination and strict patentability criteria in their national IP laws and policies, potentially impeding their capacity to implement measures to ensure access to medical products.[11] This issue is exemplified in South Africa, where MSF, alongside national civil society organisations and advocates, has repeatedly demonstrated how the absence of substantive examination of pharmaceutical patents within national IP laws has hindered timely and affordable access to medical products.[12]

The urgency of access to medical products during the COVID pandemic prompted several countries (such as Canada, Brazil, Germany, Australia, Italy and Indonesia) to swiftly introduce amendments or new rules to mitigate the gaps in their national laws for issuing compulsory licenses on patented medical products.[9]

The absence of public health protections in national IP laws and policies has a drastic impact on access to lifesaving medical products even beyond pandemics. For instance, despite the expiry in July 2023 of the primary compound patent on bedaquiline—a medicine that has become the backbone of WHO-recommended regimens for drug-resistant tuberculosis (DR-TB) treatment—held by pharmaceutical corporation Johnson & Johnson (J&J), many countries with a high burden of DR-TB will not get access to generic bedaquiline immediately.[13] This is predominantly due to the unmerited secondary patents on bedaquiline held by J&J, often granted due to lenient patentability criteria and lack of rigorous patent examination, that remain in several high burden countries. The accessibility of the drug is further delayed in countries where patent term extensions are granted, beyond international rules, to prolong the monopoly period of the primary patent.[i]

3. Failure of compulsory license for export under Article 31bis of the TRIPS Agreement

Originally, the TRIPS Agreement limited the use of compulsory licenses primarily to the domestic market and imposed restrictions on the quantities of medical products that can be exported.[14] Recognising the impact of this restriction on countries with insufficient or no manufacturing capacity, Paragraph 6 of the Doha Declaration urged the TRIPS Council to find an expeditious solution. To address this challenge, WTO incorporated Article 31*bis*, which created an additional form of compulsory license specifically for exporting medical products to countries lacking the ability to manufacture these products themselves. This provision allowed for the exportation of a medical product under compulsory license and waived the requirement that production be predominantly for the domestic market. However, the new solution placed restrictive conditions under which a compulsory license can be granted for export.

MSF has shown that the mechanism provided under Article 31*bis* is neither an expeditious process nor a solution.[15] It is an inadequate follow-up of the Doha Declaration and has failed to demonstrate its utility during global public health emergencies due to design and implementation flaws.[16]

[i] The term of the primary compound patent has been extended until 2028 in at least Russian Federation, Ukraine, and Romania. See: https://www.medspal.org/?product%5B%5D=Bedaquiline+100+mg&countries%5B%5D=Romania&countries%5B%5D=Russian+Federation&countries%5B%5D=Ukraine&page=1

4. Failure to deliver a real IP waiver at the WTO

During the COVID pandemic, a landmark proposal for an IP waiver on COVID medical products was introduced at the WTO. However, WTO members failed to deliver an effective global IP waiver to promptly remove IP barriers on lifesaving medical products.[17] After more than 20 months of negotiations among WTO members for a global IP waiver, the final decision made at the 12th WTO Ministerial Conference in June 2022 was inadequate.[17] The outcome reached had several limitations. It did not allow WTO members to waive any IP protection completely, applied solely to vaccines and excluded COVID therapeutics and diagnostics, and lacked universal applicability. More than three years since COVID was declared as a global pandemic by the WHO, WTO members are still deliberating whether to extend the decision's scope to cover COVID therapeutics and diagnostics.[18]

5. Extension of IP monopolies through free trade agreements

While the TRIPS Agreement provides minimum standards for IP protection, additional and/or longer IP protection for medical tools, known as "TRIPS-plus" provisions, can be introduced through bilateral or regional free trade agreements (FTA) and bilateral investment treaty (BIT) negotiations. The current WTO legal framework, including the TRIPS Agreement, lacks a mechanism and standards to regulate FTA and BIT negotiations, and therefore cannot prevent the introduction of TRIPS-plus provisions that have long been proven detrimental to access to medical products.[19,20]

TRIPS-plus provisions have disproportionately favoured a select group of private entities, mainly multinational pharmaceutical corporations, by strengthening their monopolistic positions in the market. This allows them to maintain control over who receives medical products first, who can manufacture them, and where they are produced, all while dictating prices.

For instance, the United Kingdom (UK) and the European Union (EU) have proposed several TRIPS-plus provisions in their respective ongoing bilateral FTA negotiations with India.[20,21] If implemented, provisions such as patent term extensions and data exclusivity will restrict Indian generic manufacturers from supplying affordable lifesaving medical products to people living in developing countries.

6. Insufficiency of voluntary IP licensing and technology transfer

Although voluntary licensing and voluntary transfer of technologies have often been used to share IP-protected medical products, they are inherently insufficient to ensure access to medical products for all, even during global public health emergencies.[2]

During the COVID pandemic, three pharmaceutical corporations licensed their COVID treatments to the Medicines Patent Pool. However, none of the licenses offered world-wide coverage, excluding many countries from accessing these treatments.[4] In the case of Ebola virus disease, too, exclusive IP licenses on lifesaving new treatments have restricted timely and sufficient access for people in endemic countries.[22] Existing international rules such as Article 66.2 of the TRIPS Agreement concerning technology transfer contain no direct and clear obligations for states to ensure transfer of technology beyond encouraging voluntary actions.[4]

The current PPR negotiations and processes should concretely move away from only relying on voluntary actions of the private sector to address IP issues, and should instead establish binding norms for states to act.

Why the WHO PPR process is the right platform to introduce much-needed changes on IP

In view of all these challenges, we have provided the following recommendations on IP for the WHO's PPR negotiations.[5] These recommendations aim to establish unambiguous and positive obligations for states as follows:

During pandemics:

- *At the global level, time-bound waivers should be instituted in order to provide expeditious legal options for governments to restrict the use of relevant forms of IP on all medical products needed to tackle the pandemic;*
- *At the national level, all legal and policy options, public health safeguards and flexibilities should be used by governments to address all barriers to access created by IP protections and facilitate rapid production, supply, export and import of lifesaving medical products.*

Outside of pandemic situations, but as an integral part of preparedness strategies and for the purpose of ensuring equity at all times:

- *Governments should review and revise national laws, policies and regulations to ensure full incorporation of all relevant IP flexibilities protecting access to medical products; and*
- *Governments should refrain from introducing IP provisions beyond existing TRIPS requirements in unilateral actions and bilateral/regional trade and investment negotiations and agreements or any other provisions that could undermine states' ability to use TRIPS flexibilities.*

Meanwhile, affirmative steps should be taken by governments to ensure technology transfer, especially to entities in developing countries, both during and outside of pandemic times. Multiple measures and incentives should be considered to ensure that transfer of technologies is not solely based on voluntary actions, but is backed by mandatory requirements and obligations which contribute towards growing geographically diverse independent capacity for production and supply of essential medical products.

Considering that the agreements administered by the WTO and WIPO are not primarily aimed at addressing public health challenges and ensuring access to lifesaving medical products, it is hard to anticipate the aforementioned challenges being addressed sufficiently within these existing international rules. Mere recognition of the right of using public health flexibilities is insufficient without mechanisms to ensure practical utilisation.

The WHO PPR negotiations, in contrast, offer a more promising route. These negotiations aim to establish new or revise existing international law instruments explicitly designed to address global public health challenges and to ensure equitable access to medical products. They represent an appropriate platform for countries to deliberate and institute these changes for the following reasons:

1. Inadequacy of existing WTO mechanisms

The inability to conclude a meaningful emergency IP waiver during the COVID pandemic under WTO's negotiation framework underscores the importance of having time-bound IP waivers to ensure the right to health and access to medical products during global public health emergencies, a priority in WHO PPR negotiations.

Rather than repeating the painstaking process of negotiating IP waivers in the middle of a pandemic every time, a more effective option is for states to proactively agree on IP waivers for future pandemics during WHO PPR negotiations. Including provisions for time-bound IP waivers at global level in the WHO PPR process to support public health objectives does not raise any normative conflict with WTO rules, as these rules already allow exceptional waivers.

WTO also lacks the mandate and mechanisms to prevent or regulate FTA and BIT negotiations which may introduce TRIPS-plus provisions affecting access to medical products and public health. However, this issue

can be addressed effectively and legitimately through WHO PPR negotiations through an obligation for states to refrain from introducing such provisions.

2. Consistency with the WHO Constitution and mandate of the WHO PPR process

WHO PPR negotiations are guided by the WHO Constitution which highlights the importance of extending benefits of medical knowledge to all people for optimal health.[23] It also states achieving the right to health depends on cooperation of individuals and states, and that disparities in disease control and health promotion among countries are a common danger.[24]

To address these disparities and counteract the threats posed by TRIPS-plus provisions, it is justifiable for WHO PPR negotiations to introduce explicit obligations for states to refrain from introducing TRIPS-plus provisions in FTA and BIT negotiations. This approach aligns with states' existing obligations to cooperate fully for promoting health for all and provides a clear illustration of pursuing such cooperation.

The introduction of explicit obligations for states to review and/or change national IP laws and practices to protect public health and ensure equity in access to lifesaving medical products outside of pandemic situations also aligns with the objectives of the WHO PPR negotiations and the WHO Constitution. While immediate legal changes are possible, as seen during the COVID pandemic, enhancing national laws and regulations pre-emptively ensures that public health measures can be put in place to balance the possible impacts of IP protections, both during and outside of pandemic situations.

3. Consistency with existing international law and practice

Though the Doha Declaration has recognised the right of states to use TRIPS flexibilities, a more explicit legal provision is needed for states to incorporate the full range of TRIPS flexibilities and other safeguards to ensure global equity and access to medical products. The obligation for states to review and revise their national IP laws and regulations through the WHO PPR process will support the realisation of their existing rights under the TRIPS Agreement.

Furthermore, although vaguely stated, Articles 7 and 8 of the TRIPS Agreement affirm that IP protection should be conducive to social and economic welfare, public health and public interest. Therefore, improving laws and regulations for public health and access to medical products through the WHO PPR instrument aligns with the TRIPS Agreement's public interest principles.

The call for the review and possible revision of national IP laws and regulations to incorporate comprehensive public health safeguards, such as exceptions to and limitations on IP protections, may appear to introduce new positive obligations not found in other IP treaties and agreements. However, recent public interest driven international law development provides a crucial legal basis for this recommendation.

The Marrakesh Treaty to Facilitate Access to Published Works for Persons Who Are Blind, Visually Impaired, or Otherwise Print Disabled (Marrakesh Treaty) states that contracting parties "shall provide in their national copyright laws for a limitation or exception" to the rights to "facilitate the availability of works in accessible format copies for beneficiary persons".[25,26] This is a mandatory requirement, and not just an option, for states to utilise copyright exceptions to protect the rights of visually impaired people.

The Marrakesh Treaty approach provides a pertinent reference for the WHO PPR negotiations. It establishes the importance of a positive obligation for states to review national IP laws and to use flexibilities to address the intersection of IP protection and equitable access to lifesaving medical products within the PPR context.

Conclusion

The existing IP rules under agreements governed by WTO and WIPO lack adequate mechanisms to address the tension between IP protection and ensuring timely, equitable and affordable access to lifesaving medical

products. Voluntary licensing of IP by pharmaceutical corporations is insufficient to address IP barriers to access to medical products for all. The ongoing WHO PPR negotiations provide a significant opportunity to establish binding provisions and positive obligations for states, clarifying how IP issues should be dealt with within the context of preparing for and responding to global public health emergencies.

These positive obligations for states should include supporting and using IP waivers during pandemics, leveraging the full range of IP flexibilities for access to medical products, reviewing and revising national IP laws and regulations to incorporate public health flexibilities, and refraining from introducing TRIPS-plus provisions in FTA and BIT negotiations.

These obligations align with the objectives of the WHO PPR process and are consistent with states' existing obligations under the WHO Constitution. They also do not affect states' existing rights under other treaties concerning IP, and follow the recent international legal norms set by the Marrakesh Treaty.

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