Examples of potential opportunities related to intellectual property rights

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1. Brief summary of Unitaid's approach to intellectual property

Unitaid recognizes that there can be many determinants of access; intellectual property rights (IPR) – notably patents – are one of them.

The patent system is designed to support innovation, and has been effective in stimulating and rewarding innovation in several of the disease areas that Unitaid works on. But while patents can incentivize innovation, they also limit competition that could stabilize supply and/or reduce prices. A number of challenges identified through the disease narratives can be traced to intellectual property rights.[1]

Within the patent system, several mechanisms exist to overcome barriers to access. These can be grouped in two types:

i. Voluntary approaches/voluntary licenses;
ii. TRIPS flexibilities (such as compulsory licensing, extended transition period for least developed countries, patent oppositions and stringent patentability criteria).[2]

Both types of approaches can play an important role in facilitating access to medicines. Unitaid considers them to be complementary and supports projects that negotiate voluntary licenses as well as projects that use certain TRIPS flexibilities. The IP approach document outlines the impact of these projects.

The document *Unitaid's approach to intellectual property* (document EB26/2016/8) is available here

2. Brief overview of consultation process

2.1 Online consultation to solicit suggestions for investment

The Secretariat conducted an on-line consultation (from 25 August to 15 September 2016), seeking high level suggestions and ideas on possible solutions to overcome IP barriers, where they occur.

The consultation asked for suggestions and ideas on IP-related opportunities for Unitaid investment. The announcement clarified that potential ideas would not be funded directly, but could lead to a competitive call for proposals – upon endorsement by the Executive Board.

2.2 Review of suggestions

Based on the ideas and suggestions received through the on-line consultation, three opportunities were identified for further consideration in this document:

1. Improve patent examination in order to increase the quality of patents;
2. Support a Patent Opposition Facility;
3. Support a Platform or Policy Laboratory.

[1] See *Unitaid's approach to intellectual property*, Table 1.

[2] "TRIPS flexibilities" refer to a diverse range of mechanisms (see for example Table 3 in *Unitaid's approach to intellectual property*).

Section 3 explores these three opportunities in greater detail, and analyses them on the basis of the following questions:

- Why now and what are the key issues?
- What is the potential public health impact?

It is important to note that the Call for proposals is broader than the three potential opportunities discussed in section 2.2 and 3; these should be considered as examples. They are not intended to be prescriptive, but to illustrate some of the questions Unitaid would want to see answered.

3. Review of potential opportunities

Potential opportunities 1 (improving patent examination) and 2 (Patent Opposition Facility) both work within the existing patent system; they aim to assist patent offices in improving the examination of patent applications and in enhancing the quality of patents that are granted. The discussion below (Why now and what are the key issues?) applies to both opportunities.

Why now and what are the key issues?

Both potential opportunity 1 and 2 would address the same challenge: the granting of additional (secondary) patents on minor variations of existing products "that have no additional therapeutic value and display limited inventiveness".[3]

The potential negative effect of such patents is widely acknowledged:

- A joint publication by WHO, WIPO and WTO noted that these patents "can be used to prolong patent protection in an inappropriate manner, thus creating a negative effect on access to medicines, as well as on further innovation".[6]
- The European Commission has noted that "filing numerous patent applications for the same medicine (forming so called "patent clusters" or "patent thickets") is a common practice ... [A]n important objective of this approach is to delay or block the market entry of generic medicines".[4]
- The Commission on Intellectual Property, Innovation and Public Health (CIPIH) referred to this problem as "evergreening". The CIPIH noted that "evergreening can occur in a number of ways but typically ... arises when companies file and obtain patents, subsequent to the original patent, on other aspects of the same compound or reformulations of the original compound ... [S]trategies include a similar but different dosage form such as capsules rather than tablets, salts, esters, or crystals (polymorphs) of the same product or other changes dependent on the ingenuity of the formulators and the lawyers".[5]

[3] Promoting Access to Medical Technologies and Innovation: Intersections between public health, intellectual property and trade. Geneva: WHO, WIPO and WTO. 2012.

[4] Pharmaceutical Sector Inquiry: Final Report. Brussels: European Commission. 2009.

[5] Public health, innovation and intellectual property rights. Report of the Commission on Intellectual Property Rights, Innovation and Public Health. Geneva: World Health Organization. 2006.

It is worth noting that generic companies may also file applications for secondary patents (with the aim to prevent competition from other generic suppliers).

Some examples of secondary patents that are relevant to Unitaid's work can be found in Box 1. These examples show that time-to-impact can be.

Box 1. Secondary patents for HIV medicines can delay access

The main patent of the HIV medicine nevirapine expired in 2010. However, a secondary patent on nevirapine hemihydrate was applied for, several years after the main patent application. In the countries where it has been granted, this patent – which can block liquid (paediatric) dosage forms of nevirapine – generally lasts until 2018.
A further secondary patent, on extended release formulations of nevirapine, will expire only in 2028.

Other examples of WHO-recommended HIV medicines whose main patent has expired, but with secondary patents currently still in force are abacavir (main patent expired in 2010), and efavirenz and ritonavir (main patents expired in 2013).

In the absence of voluntary licenses or the use of TRIPS flexibilities, these secondary patents can today hamper access to the respective medicines – even though (as mentioned) their main patents have expired several years ago. Yet to have prevented the granting of most of these patents, action should have been taken in the early or mid-2000s.

3.1 Potential opportunity 1: Increase patent quality through improving examination and sharing best practises

Inventions qualify for patent protection if "they are new, involve an inventive step and are capable of industrial application".[6] But while the TRIPS Agreement establishes these criteria, countries have the freedom to set their own standards. Because countries have different standards, the same patent application may be approved in some countries, and rejected in others.

By applying high standards during the examination of patent applications, fewer unmerited secondary patents would be granted. This, in turn, would prevent that such patents hamper access, once the main patent has expired.

The CIPIH recommended that governments "take action to avoid barriers to legitimate competition by considering developing guidelines for patent examiners on how properly to implement patentability criteria".[8] More recently, the UN Secretary General's High Level Panel on Access to Medicines also noted that "the application of public health-sensitive guidelines in country patent offices may be an important policy tool to improve health technology access",[10] and recommended supporting governments "to apply public health-sensitive patentability criteria".[7]

The ***activities*** that could be undertaken by a potential project would aim to expose patent examiners to different standards of patentability and to their public health consequences. This could be done through a variety of mechanisms, such as policy dialogues or workshops

[6] TRIPS Agreement, Article 27.1.

[7] Report of the United Nations Secretary-General's High Level Panel on Access to Medicines: Promoting innovation and access to health technologies. 2016.

where best practices are shared and where a range of examples are reviewed and discussed. These fora could also facilitate exchanges and dialogues between the health sector and patent examiners. By increasing their awareness about the (potential) public health impact of low quality secondary patents, patent examiners can be sensitized to the importance of thorough examination and of ensuring patent quality.

3.1.1 What is the potential public health impact?

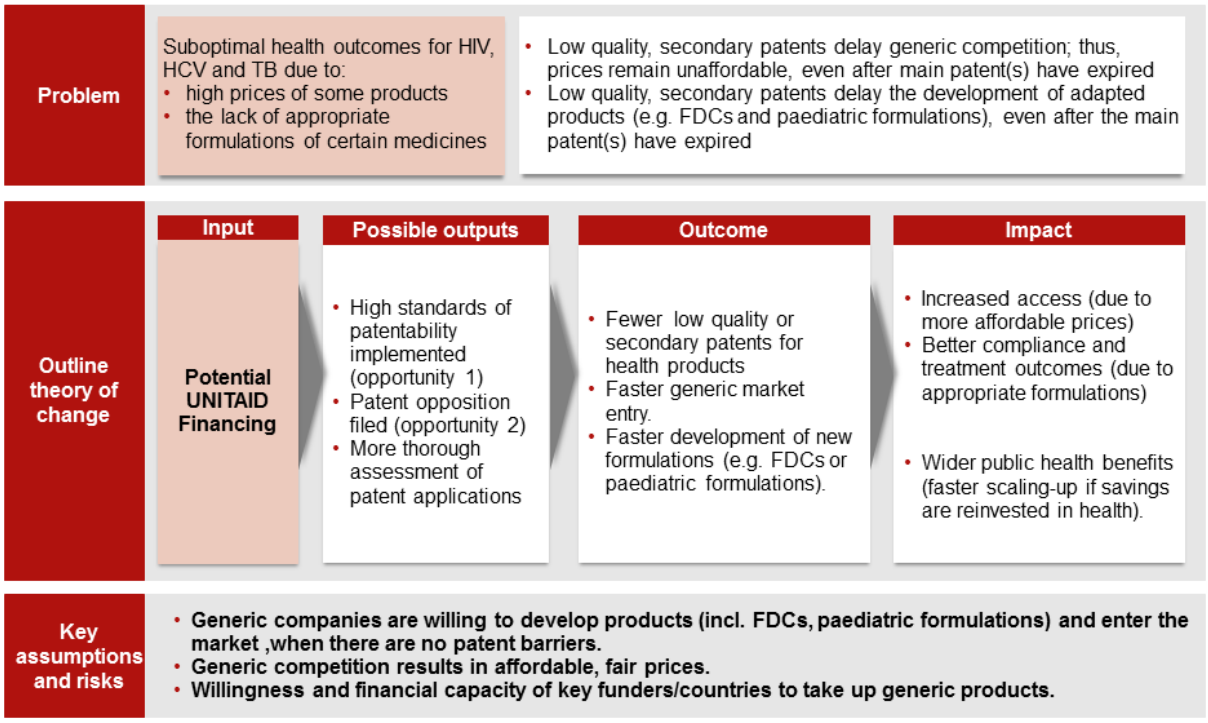
Supporting the implementation of high standards during patent examination would help ensure patent quality and could be an important way to prevent the formation of unnecessary barriers to access. Though a long-term strategy – see Box 1 – its impact can be significant.

A Unitaid-funded project reported encouraging early results due to preventing just two low-quality secondary patents in a single project country (albeit via a different mechanism). This indicates that there is scope for considerable savings. If re-invested in health, this would boost efforts to scale up access to key health products.

This approach could benefit all disease areas, and lead to a structural, sustainable solution. Moreover, a project of this nature is expected to require relatively limited investment, while the return on investment – though long term – could be very substantial.

To ensure optimal project scope and design, proposals would be expected to indicate the rationale or criteria for selection of target countries.

Figure 1. Theory of change, potential opportunities 1 and 2



3.2 Potential opportunity 2: Patent Opposition Facility

Unitaid already funds two projects that use the mechanism of patent oppositions – notably pre-grant oppositions – in five countries. Pre-grant oppositions (called "observations" in the European Patent Convention) allow third parties to submit information and evidence to the

patent office, in order to assist the patent office in its examination of a given patent application. This can help to improve the quality and thoroughness of the examination of the concerned patent application.

Patent oppositions are (human) resource intensive, since they have to be drafted and filed on a patent-by-patent and country-by-country basis (though an opposition filed in one country may serve as the basis for an opposition to a similar patent application in other countries). There currently is no sustainable system for conducting patent oppositions. Nor is there a guaranteed, long-term source of funding for patent oppositions that focus on public health priorities.

A "self-financing" system for patent opposition could be envisaged. Beneficiaries of patent oppositions (generic suppliers, government procurement agencies and/or donors) could contribute a percentage of their gains or savings to a Patent Opposition Facility in order to finance future oppositions.

The idea of a "self-financing" Patent Opposition Facility is attractive from the perspective of sustainability: once the envisaged Facility exists and is functioning, there would be no need for continued external/donor funding for patent oppositions. However, there are significant questions, including how to avoid "free riders" (companies, countries or procurers that benefit but do not contribute financially) and how to ensure a focus on products that are important from a public health perspective (rather than commercially interesting products).

There also are questions whether a self-financing mechanism can indeed be realized; for example, generic manufacturers' willingness to participate may be diminished by (bilateral) agreements with originators.

Furthermore, there are questions on what the hosting arrangements would be, how to operationalize such a Facility, what initial investment would be required and whether it is indeed feasible to create a sustainable Patent Opposition Facility.

The ***activities*** that would be undertaken by a potential Patent Opposition Facility would fall in two categories:

1. Legal and technical work to prepare, submit and follow up on patent oppositions. This could involve expert consultations and review of medical and clinical literature to identify at an early stage the products that would be important from a public health perspective. Subsequently, the patents and – importantly – the relevant patent applications pertaining to such products would have to be identified in the jurisdictions of interest. Once identified, research and consultation with chemical and pharmaceutical experts may be required to establish if there are solid grounds for an opposition and, if so, to draft the opposition. Finally, the opposition would need to be filed in jurisdiction(s) of interest, and follow up will need to be assured (e.g. appearing at hearings, preparing responses to the counter-arguments from the patent applicant).
2. Devising and implementing an equitable system to collect financial contributions from beneficiaries, in order to finance future patent oppositions.

3.2.1 What is the potential public health impact?

Like potential opportunity 1, pre-grant oppositions normally are a long-term strategy. Their impact can be substantial: a Unitaid-funded project reported encouraging early results due to just two pre-grant oppositions, in a single project country.

The Theory of Change for a Patent Opposition Facility would be similar to that for potential opportunity 1 (see Figure 1).

3.3 Potential opportunity 3: A "Platform" or "Policy laboratory"

A third, potentially interesting opportunity relates to support for a Platform or the creation of a Policy Laboratory. Such platform or policy laboratory would provide rapid but limited support for a variety of IP-related activities, aimed at increasing access to medicines. It could for example focus on providing technical assistance, facilitating information sharing and coordination, or on providing financial support (through small sub-grants) to competent (civil society) actors. A combination of some of these could also be envisaged.

The platform or policy laboratory would de facto act as a "rapid response facilitator": when need arises, it would be in a position to quickly provide technical or financial support – of limited magnitude – to enable local actors to respond quickly to challenges related to IPR and access to medicines in countries.

The platform or policy laboratory could support the use of a variety of TRIPS flexibilities, and could potentially also provide support for law reform and/or raise awareness about the implications of TRIPS-plus provisions or commitments. A range of actors, including academia and civil society advocates, could implement these.

A wide range of ***activities*** could be undertaken or supported, depending on the actual scope of any potential project, including e.g.:

1. Technical and/or financial support to implement TRIPS flexibilities (e.g. for drafting and submitting patent oppositions);
2. Financial and/or technical support for a policy dialogue on IPR and public health;
3. Impact assessment for a possible introduction of a TRIPS-plus measure (e.g. data exclusivity);
4. Sharing information and experiences, between sectors or between countries;
5. Legal analysis of a proposed amendment of the patent law;
6. Documenting how supported activities have catalysed change and capturing lessons learned.

The optimal scope of a platform or policy laboratory would need to be defined and justified.

Furthermore, there are outstanding questions, including regarding who could implement such a platform or policy laboratory; the host would need to have both sufficient administrative capacity as well as a good understanding of the technical issues. Moreover, to function well, there would need to be consensus on – or at least sufficient support for – the proposed host organization.

3.3.1 Why now and what is the issue?

A platform or policy laboratory could potentially address a range of issues, depending on scope. The scope of work would need to be clarified, with a strong rationale; only thereafter can a meaningful assessment be made.

3.3.2 What is the potential public health impact?

The ideas discussed in this section encompass a range of actions that implementation of this opportunity might entail. It is therefore difficult to estimate the potential public health impact (or detail a Theory of Change).

One important and likely role of the proposed platform or policy laboratory would be to advocate for reinvesting any savings – whether from activities undertaken/funded by the platform or policy laboratory or undertaken by any other (Unitaid-funded) project – back into scaling up access. Thus, platform or policy laboratory could play a key role in efforts to scale up access to treatment and care.