

# **SUBMISSION TO WHO'S SECOND PUBLIC HEARING ON PUBLIC HEALTH INNOVATION AND INTELLECTUAL PROPERTY**

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## **1. THE INNOVATION PARTNERSHIP**

The Innovation Partnership (tIP) is an independent, not-for-profit consultancy based in Montreal, Canada. Drawing on cutting-edge academic research and offering full legal services, tIP helps decision-makers develop and implement intellectual property policies which foster innovation, improve access to new products and support scientific infrastructure. tIP advises public and private entities, cultivates its own policy-oriented research projects, offers executive training, and works as a trust builder in order to find common ground among stakeholders with divergent interests.

## **2. THE DRAFT GLOBAL STRATEGY AND PATENT POOLING**

The Draft global strategy on public health, innovation and intellectual property (A/PHI/IGWG/2/2) identifies actions to be taken in relation to transfer of technology, including the promotion of “patent pools of upstream and downstream technologies”. Indicators for this action are twofold: “(1) Meeting convened to review and discuss patent pool models with consensus conclusions and (2) Evaluations made of new patent pools and their effectiveness.”

At present, policymakers do not know not only whether a patent pool is would be consistent with national and international law, but also if such a pool is likely to be effective in reaching the goal of access to needed medicines. This submission evaluates the likelihood of success for a medicines patent pool and outlines general guidelines that governments and non-governmental actors may wish to keep in mind to ensure the legal and practical effectiveness of any pool.

## **3. METHODOLOGY**

This submission is a summary adapted from a more complete report prepared by tIP. In conducting the full report, the tIP team conducted formal interviews with three representatives from the non-governmental community, four from the R&D and generic pharmaceutical industries and four from international governmental organizations, in addition to various informal consultations. The tIP team also conducted a preliminary review of patent families relating to seven chosen anti-retroviral viral (ARV) pharmaceutical compounds (*Efavirenz*, *Lamivudine*, *Lopinavir-Ritonavir Heat Stable*, *Ritonavir Heat-Stable*, *Atazanavir/ Ritonavir*, *Tenofovir*, and *Abacavir*) in eight countries (India, Kenya, Brazil, South Africa, Thailand, Cameroon, Mali and Nigeria).

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<sup>1</sup> This report represents the views of its authors only and does not, therefore, necessarily represent those of any institution nor any of the individuals interviewed in conjunction with the preparation of this report. The authors wish to thank Julia Carbone, Karen Durell and Elisa Henry for their contributions to the research. The authors can be reached at [Richard.Gold2@mcgill.ca](mailto:Richard.Gold2@mcgill.ca); [Jean-Frederic.Morin@mcgill.ca](mailto:Jean-Frederic.Morin@mcgill.ca); and [Tina.Piper@mcgill.ca](mailto:Tina.Piper@mcgill.ca).

#### 4. PATENT POOLING IN THE PHARMACEUTICAL SECTOR

There is no precise definition of a patent pool. In general, a patent pool occurs when numerous patent-holders collect a series of patents that relate to the use of a particular technology. This collective holding is designed to ensure that all the patents in the pool can be efficiently licensed, usually in pre-defined packages, to those making, using or selling the pooled technology. Those wishing to access these technologies can purchase a non-exclusive licence at a given royalty rate.

Patent pools have often been established to address situations of market failure. For example, the airplane, sewing machine and radio patent pools of the first half of the 20<sup>th</sup> century began as a response to strategic behaviour from patent-holders which blocked the development and sale of new products. More recently, patent pools have been used by companies wishing to establish a common technological standard, including for DVD technologies. We have also seen the development of pools aimed to serve public rather than commercial interests. This social-entrepreneurial approach is evident in the SARS pool that brought together public research agencies, a government department and industry so as to facilitate the development of a vaccine.

A patent pool could greatly simplify the licensing process related to medicines and would likely provide a means to encourage increased access. The creation of a Atazanavir/Ritonavir combination, for example, would require, in the absence of a pool, that each manufacturer undertake the time-consuming investment of negotiating with and individually licensing each patent held by each patent holder (figure 1) A patent pool would provide a way to simplify the licensing process and reduce transaction costs and overhead (Figure 2). Patent-holders would need only to issue a single licence to the pool and the pool would, in turn, need only issue standard licensing agreements to manufacturers rather than multiple licences covering different anti-retrovirals.

Figure 1: Example of a combination without a Pool

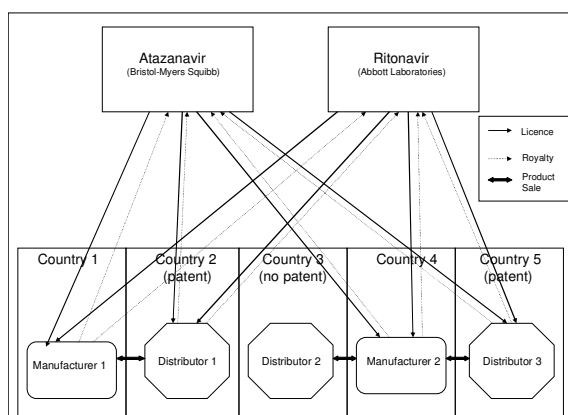
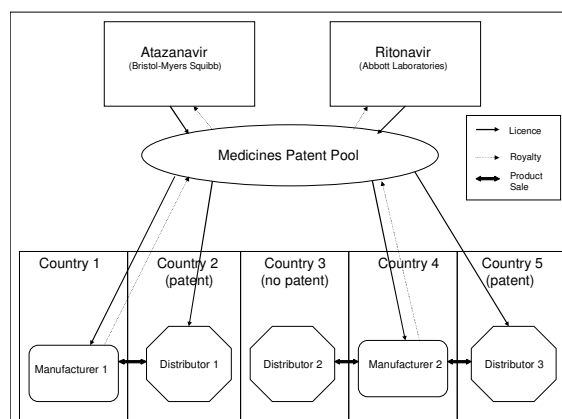


Figure 2: Example of a combination with Pool



Proponents of patent pools for pharmaceutical products suggest that the pooling will: 1) Foster the development of new combinations or formulations that meet developing world specific needs, for example heat-resistant formulas or child-appropriate doses; and 2) Reduce prices for medicines through increased competition. Preliminary evidence available suggests that both of these issues are real and worth addressing. A pool would be especially well adapted to addressing the production problem. Industry has not been able to adequately address the need for new combinations or formulations despite the evidence of the need in developing countries. A patent pool provides a way to overcome this deficiency by lowering transaction costs and avoiding strategic behaviour that may block access.

The capacity of the pool to address the second problem of affordability is less certain. While a pool would likely lessen the costs of medicines through increased competition, it is unclear how significant those cost reductions will be. In addition, a pool aimed at increasing competition for existing medicines would encounter greater resistance from both patent-holders and their governments. One of the most important objections likely to be forwarded by patent holders is the loss of competitive advantage they would experience in developing countries by creating future generic competitors. This risk may be sufficiently important as to discourage voluntary participation in the pool.

Another worry voiced by industry representatives is that a patent pool would likely expand beyond the products and countries initially captured in a pool's mandate. Specifically, industry representatives indicated concern that the pool may expand to cover lucrative product lines in the cancer and heart disease fields. One way to address this concern and encourage the voluntary participation of patent holders in a patent pool would be to establish clear, up-front criteria for inclusion of products and countries in the pool. We suggest that it would be easier to build consensus if the pool is tailored to target a proven need for new formulations rather than at strictly cost reduction.

## **5. INTERNATIONAL AND NATIONAL LEGAL ISSUES**

The most significant instrument of international law related to the development of any potential medical/biotech patent pool is the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs). Its Article 31 provides that a country may give to itself or to a generic producer the right to use, make, sell or import the invention (a so-called government use or compulsory licence). It does not restrict the grounds under which a compulsory licence could be granted but lists a number of general requirements, including a reasonable royalty to the patent-holder. Usually, a first attempt to negotiate a voluntary licence is necessary but a country can dispense with this requirement when it faces a national emergency, a situation of extreme urgency or to meet a public non-commercial use including a public health need.

In 2003, WTO members waived article 31(f) in respect of pharmaceutical products. A country can grant a compulsory licence for the production and export of pharmaceutical products predominantly for another country if a number of conditions are met. To avoid products manufactured in this manner being diverted to high-income countries, they need to be clearly packaged or labeled differently from the original pharmaceutical products.

Article 31(e) of TRIPs requires that compulsory licences should be non-assignable. Given that the word "assignable" has a particular legal meaning, involving a complete divestiture of the licence, the better view of the law is that Article 31 authorizes a country to grant a compulsory licence to a pool, which can then be sub-licensed to manufacturers.

Overall, we find that the TRIPs Agreement does not create any substantial hurdles to the viability of a patent pool. In fact, TRIPs would permit more flexibility in the construction of a medicines patent pool than the national patent laws of several nations studied. Indeed, there are cases where national laws might be more of a blockage to the development of a medicines/biotech patent pool than international agreements. In Kenya, Nigeria, and Brazil, for example, compulsory licences must be limited to the domestic market and do not include a right to sub-license. In several countries, it is unclear if the effective use of a compulsory license would be undermined by exclusivity on data submitted for marketing approval.

It is possible that the way that patents are licensed and used in a patent pool might be considered anti-competitive. Generally, competition law requires that pools not contain competing patents

(that is, alternative patents that give the same result) or invalid patents (or patents at a significant risk of being held invalid). It will therefore be necessary that the pool avoid so-called ‘me too’ drugs and concentrate on medicines that are not substitutes for one another but that serve different purposes. Competition law also requires that all patent-holders who license into the pool be treated equally and that none are able to pick and choose which patents they contribute to the pool. To ensure equality, patent pools often set a fixed royalty rate per patent without a substantive analysis of how much the patent contributes to the pool.

Overall, there is no legal reason that would prevent the establishment of a medicines pool. While some legal hurdles will have to be cleared, the pool’s feasibility will rest more on mobilizing political will than on avoiding legal pitfalls.

## **6. ENCOURAGING VOLUNTARY PARTICIPATION**

A medicines patent pool would likely be built on one of three approaches to gathering the required licenses: 1) A strictly voluntary licence approach; 2) A mixture of voluntary and compulsory licenses with compulsory licenses only being used if a voluntary approach has been exhausted; or, 3) The application of compulsory licenses to patent holders who do not immediately volunteer to join the pool.

All stakeholders interviewed agree that it would be best to establish the pool under voluntary licences from patent-holders. Such a pool raises no significant international or national legal issues. In addition, this approach would be easier politically, as patent holders and governments would be less likely to resist a pool that relied on voluntary participation. It would also be easier administratively, as the voluntary license approach eliminates the need for individual national governments to establish different licensing arrangements in each territory.

A pool based on non-voluntary licensing would be more complex and could raise international and national legal issues. Moreover, a pool based solely on compulsory licences would not be workable. The participating countries would issue licences to the manufacturers and distributors operating within those countries over patents held in those countries. The manufacturers would pay a royalty to the patent-holders directly, without passing through the pool. The royalty rates payable to patent-holders would depend on each country’s compulsory licence terms for production and sales within those countries. The pool, no longer coordinating licensing, would have insufficient leverage to monitor manufacturing quality, distribution and royalty collection and distribution to provide a significant value-added to the licensing process.

A more realistic approach would be a pool of mixed voluntary and compulsory licences. As long as the mixed pool has a sufficient percentage of voluntary licences, it would have sufficient leverage to administer the pool. The grant of one or more compulsory licences could create an additional pressure to obtain voluntary licences for some patent holders, with the risk that other patent holders may be reluctant to licence their medicines if they know that their voluntary licences will be supplemented by compulsory licences.

An optimally effective medicines patent pool should start with a goal of obtaining voluntary contributions. If the pool is unable to gather the required licences using the voluntary approach, pool administrators can contemplate invoking the use of compulsory licensing. It could do this either by directly applying for compulsory licences in those countries where sub-licensing is permitted or by encouraging manufacturers and distributors to apply for them themselves.

To best ensure voluntary participation in a medicines patent pool, pool organizers will need to communicate the advantages of voluntary participation to patent-holders. These advantages

include 1) Opportunities to show how the current patent system is not a barrier to access to medicines by voluntarily participating in a medicines patent pool; 2) Opportunities to blunt criticism for the lack of action in making medicines available in developing countries or even to insulate patent-holders from criticism by transferring the pressure to the patent pool; 3) Opportunities to garner positive publicity including praise and congratulations from international organizations, government leaders, and NGOs ; 4) Opportunities to gain more reliable sources of revenue and develop new markets, especially if a major sources of funding (international organisations, governments, private foundations, or prize funds) commit to buying drugs produced under the pool or to offset research and development costs involved in demonstrating the safety and efficacy of new formulations.

To encourage voluntary participation in a medicines patent pool, organizers will also need to ensure that high-income countries are excluded from the pool and that export/manufacture in developing countries is tied to a royalty regime which reflects the recipient country's Human Development Index (HDI). In many cases, this model will result in revenues for patent holders from otherwise untapped markets. This HDI-tied approach may also provide higher revenues than patent holders are currently receiving under compulsory licences.

## **7. CONCLUSION**

Our analysis of the feasibility of the patent pool leads us to the conclusion that the pool could be a promising component of an overall strategy to ensure access to needed medicines. While some legal hurdles will have to be surmounted, the pool's feasibility will ultimately depend on the mobilization of sufficient will from relevant stakeholders, including governments and international organizations. Since the pool will operate best with the cooperation of patent-holders, considerable effort should thus be placed on encouraging voluntary participation in the pool. We recommend that more evidence be collected in the very near future on the desirability and feasibility on patent pooling.