



Preliminary Legal Review of Proposed Medicines Patent Pool

Prepared by TIP for UNITAID

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Disclaimer

This report represents the views of its authors only and does not, therefore, necessarily represent those of the WHO, UNITAID, its board, TIP nor any of the individuals interviewed in conjunction with the preparation of this report. It should be noted that this report has not been reviewed by the legal department of the WHO for conformity with its mandate, policies and procedures.

This report represents a general legal analysis of a Medicines Patent Pool and should not be taken as specific legal advice applicable in any particular country. Local legal advice should be sought before implementing such a pool.

This report is restricted to examining the feasibility of a patent pool for anti-retroviral medicines and thus does not discuss alternatives to the pool – for example, a substantial increase in aid to purchase medicines, direct licensing of patents outside a pool structure, clearinghouses or the creation of a prize system to encourage the development of new products. It is therefore not intended to compare and contrast the advantages and disadvantages of different approaches to ensuring access to these medicines.



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None of the authors of this report is affiliated with any person who has a direct or indirect interest in the patents discussed nor are they directly associated with any of the major stakeholders in UNITAID. Neither TIP nor the authors have received any financial contribution or other benefit from the holder of any anti-retroviral medicine patent.

Executive Summary

This report provides a preliminary review of the legal feasibility of establishing a Medicines Patent Pool targeted at HIV/AIDS anti-retroviral medicines. We conclude that there is no legal reason that would prevent the establishment of such a 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.

A Medicines Patent Pool is designed to address the fact that patent-holders are not producing either the fixed-dose combinations (FDCs) or the new formulations required by developing countries and that anti-retrovirals are not affordable in those countries. The preliminary evidence available suggests that both of these issues are real and worth addressing. A Medicines Patent Pool would be especially well adapted to addressing the production problem. 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. We recommend that more evidence be collected in the very near future on cost reductions and the level of use of FDCs and new formulations.

Given the range and diversity of stakeholders involved with anti-retrovirals, it will be easiest to build consensus around the need for a Medicines Patent Pool if the pool is tailored to target a proven need. To ensure political feasibility, we recommend that the Medicines Patent Pool should initially restrict its mandate to that area where the broadest consensus concerning the need for the pool exists, i.e. developing FDCs and new formulations that would otherwise not be available.

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, it offers numerous practical advantages to patent holders, generic producers, governmental authorities in exporting and importing countries, and more importantly, for people in need of medicines.

A pool based on non-voluntary licensing (requiring compulsory licences or government use) could be created but it would be more complex and would raise international and national legal issues. For example, the pool would have to comply with the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs) that permits countries to grant compulsory licences to produce anti-retroviral medicines while imposing certain conditions. National laws present a greater challenge to a Medicines Patent Pool using compulsory licences or governmental use as several WTO members do not use the flexibilities offered under the TRIPs agreement. These challenges, though serious, would not prevent the creation of a pool.

However, a Medicines Patent Pool based solely on compulsory licences would not be workable as it would not allow the pool sufficient voice to ensure quality and access. 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 get 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.

To best ensure voluntary participation in a Medicines Patent Pool, the advantages of doing so will have to be communicated to patent-holders. Among other advantages, the establishment of a patent pool offers industry both a way to avoid bad publicity and to gain positive news coverage. In addition, the Medicines Patent Pool may result in greater and more reliable sources of revenue. UNITAID should also consider the possibility of using its Fund to offset research and development costs involved in demonstrating the safety and efficacy of FDCs and new formulations. The result of this effort would provide many of the benefits of a public-private partnership. By co-funding development of medicines specifically adapted to developing country needs, the UNITAID Fund would reduce the investment necessary for any manufacturer to enter the field.

Should UNITAID or another agency decide to further examine the implementation of a Medicines Patent Pool, a strategic plan has to be developed that considers practical, business and legal issues. Once the legal and business risks and advantages are researched, the sponsor can begin to actually establish the pool by incorporating the not-for-profit corporation and appointing its Board of Directors, its managers and an expert to evaluate patents within the pool. The pool will next need to define basic licensing terms and royalty rates for licences and negotiate memoranda of understanding with sponsoring organizations. Then the pool will have to negotiate with patent holders to obtain voluntary licences necessary to manufacture, sell, and import selected medicines. After a reasonable period of time, if a patent-holder does not wish to participate, the pool may need to consider asking countries to issue compulsory licences over medicines. Once patents have been licensed into the pool, the not-for-profit corporation will need to license the pooled patents to manufacturers, importers and sellers of the medicines. After setting up the pool, the Board of Directors should work with the sponsor to develop criteria to assess the functioning of the patent pool and its contribution to public health.

Summary of Recommendations

1. To ensure its political feasibility, the Medicines Patent Pool should initially restrict its ambit to that area where the broadest consensus concerning the need for a pool exists: fixed-dose combinations (FDC) and new formulations otherwise unavailable.

Before Setting up a Pool

2. An analysis should be conducted incorporating the experience of medicine manufacturers and suppliers to establish current and expected needs for FDCs and new formulations.
3. Further research should be conducted on how the pool could reduce the cost of FDCs and new formulations. This would involve examining manufacturing costs, tariffs and taxes, transportation costs, royalties, and final retail prices of medicines licensed through a pool.
4. A more complete review of the patent landscape should be performed in participating countries to conclusively identify FDCs and formulations that are combinations of inventions patented by different patent-holders. This will require on-site examination of patent records in some countries as well as translators.
5. A thorough analysis of staffing, space, infrastructure and operation needs and their cost should be completed. Insulating pool staff through secondment from UN agencies should be investigated in cooperation with the legal services departments of the various potential contributing UN agencies.
6. Business and legal risk should be assessed through in-depth review of national law, especially in the fields of competition, contract, and pharmaceutical product regulation.

Setting up the Pool

7. A Swiss not-for-profit corporation or association should administer the pool.
8. The corporation administering the Medicines Patent Pool should enter into memoranda of understanding with sponsoring organizations led by the WHO on behalf of itself and UNITAID. Other potential sponsors include UNAIDS, UNCTAD and WIPO.
9. Sponsoring organizations and the UNITAID Board should each appoint one member to the corporation's Board of Directors. In addition, one member of the Board should be selected from among NGOs and another from the research-based pharmaceutical companies. These latter two appointments should be individuals with personal practical experience in licensing or health delivery.

Managing the Pool

10. The pool should seek the assistance of its sponsoring organizations, external consultants and non-governmental actors to draft standard licence agreements provide technical assistance to countries and manufacturers, and to monitor quality standards of medicines.
11. Standard licence agreements should be prepared in consultation with research-based and generic pharmaceutical companies. The licence terms must include royalty rates that permit the effective provision of medicines at affordable rates and take into account the different attributes of manufacturing and importing countries.
12. The pool should appoint an independent expert to ensure that the patents licensed into the pool neither compete nor are likely to be invalidated.



13. Additional benefits for patent holders to voluntarily license their invention and for generic companies to participate in the pool should be identified by expanding the group of people interviewed. The pool and UNITAID should also consider offsetting research and development costs involved in demonstrating the safety and efficacy of medicines.

1. Introduction

A Medicines Patent Pool is a mechanism to overcome market failures in the production of needed medicine combinations and new formulations as well as a means to ensure that markets function to meet the overall economic and social needs of countries granting patents over medicines. The pools would accomplish this by collecting a group of patents held by different companies which relate to the manufacture, sale and distribution of needed anti-retroviral medicines (and potentially other medicines that meet significant public health concerns) in developing countries. In doing so, the Medicines Patent Pool reduces transaction costs, overcomes private strategic uses of patents, and overcomes competition concerns in order to more efficiently produce medicine combinations that are formulated to meet the needs of the developing world, particularly those difficult to treat through existing medicinal formulations.

This report provides a preliminary review of the legal feasibility of establishing a Medicines Patent Pool targeted at HIV/AIDS anti-retroviral medicines. While it does not assess the desirability of establishing such a pool in comparison with other proposals, it nevertheless suggests that a pool is not only legally feasible but, if properly constructed, well adapted to placing anti-retroviral medicine **combinations** and **new formulations** on developing world markets at an **affordable** price.

1.1 Overview of the Proposal for a Medicines Patent Pool

This review is based on a proposal submitted by Médecins sans frontières (MSF) to the government of France and to UNITAID on June 6, 2006. The note is attached as Appendix A to this report. While other proposals to create more elaborate patent pools exist, this report only examines the feasibility of the Medicines Patent Pool as described in the note.

1.1.1 Goals and Structure of the Medicines Patent Pool

There are two principal goals to a Medicines Patent Pool: 1) To put fixed-dosed anti-retroviral combination medicines (FDCs) and new formulations of existing medicines adapted to developing countries on the developing world market; 2) and to increase competition in the market for anti-retroviral medicines so as to lower prices through market forces.

Given the long-term side effects of and resistance to existing therapies, new anti-retroviral combinations and targeted formulations offer renewed opportunities to treat HIV/AIDS. These combination therapies bring together existing and/or new medicines to facilitate treatment. For example, new formulations of existing and new medicines could better target the needs of children who often receive adult doses. There have been isolated cases of cooperation between pharmaceutical companies in developing new FDCs, for example, Bristol-Myers Squibb, Gilead Sciences and Merck & Co. offer a once-daily single tablet

containing *Efavirenz*, *Emtricitabine* and *Tenofovir* in the United States¹ and have applied to market the pill in Europe² and in developing countries.³ There remains, however, a substantial unmet need for these medicines.⁴ One can speculate as to the reasons why this is so. These include: i) current business models are not adapted to the need for FDCs or new formulations; ii) that, due to drug lifespans and market conditions in developing countries, these medicines offer low rates of return on investment (ROI); iii) strategic behaviour by patent-holders to protect markets for their existing products; and, iv) competition law concerns that arise when competitors cooperate. For the most part, the FDCs that are available were produced and sold by generic manufacturers in developing countries where no patents existed. Since 2005, those developing countries with manufacturing capacity have amended their patent laws so as to cover medicines, including anti-retroviral medicines. Patents cover the most promising anti-retroviral medicine combinations and formulations in most manufacturing countries studied for this report: Brazil, India and South Africa (see Table 1).

Table 1

Patents over Target Medicines in Countries with Manufacturing Capacity

Medicine	India	Brazil	South Africa
<i>Efavirenz</i>	Yes	Yes	Yes
<i>Lamivudine</i>	No	No	Yes
<i>Lopinavir-Ritonavir</i>	Yes	Yes	Yes
Heat stable <i>Ritonavir</i>	No	Yes	Yes
<i>Atazanvir/Ritonavir</i>	Yes	Yes	Yes
<i>Tenofovir</i>	Yes	No	Yes
<i>Abacavir</i>	Yes	Yes	Yes

A Medicines Patent Pool provides a targeted mechanism to address this failure to meet the need for these new combinations and formulations. It would do so by placing the ability to authorize manufacture of patented medicines, including combinations and new formulations, in one or more developing countries for sale within those countries and for import into other developing countries in the hands of a single entity. Without this authorization, it would not be possible for entities other than the patent-holder to carry out these activities where patent rights exist. Further, the pool could provide financing (for example, through the UNITAID Fund or the Global Fund) to create new markets, offset research and development costs of

¹ U.S. Food and Drug Administration, *Press Release: FDA Approves the First Once-a-Day Three-Drug Combination Tablet for Treatment of HIV-1*, July 12, 2006 available online at: <http://www.fda.gov/bbs/topics/NEWS/2006/NEW01408.html> (last accessed July 13, 2007).

² Gilead Sciences, *Press Release: Bristol-Myers Squibb, Gilead Sciences and Merck & Co. Submit Marketing Authorisation Application for ATRIPLA (TM) to European Medicines Agency*, October 9, 2006 available online at: http://www.gilead.com/wt/sec/pr_913213 (last accessed July 13, 2007).

³ Merck & Co., *Press Release: Merck & Co, Inc. to Distribute ATRIPLA in Developing Countries*, February 16, 2007, available online at: http://www.merck.com/newsroom/press_releases/corporate/2007_0216.html (last accessed July 13, 2007).

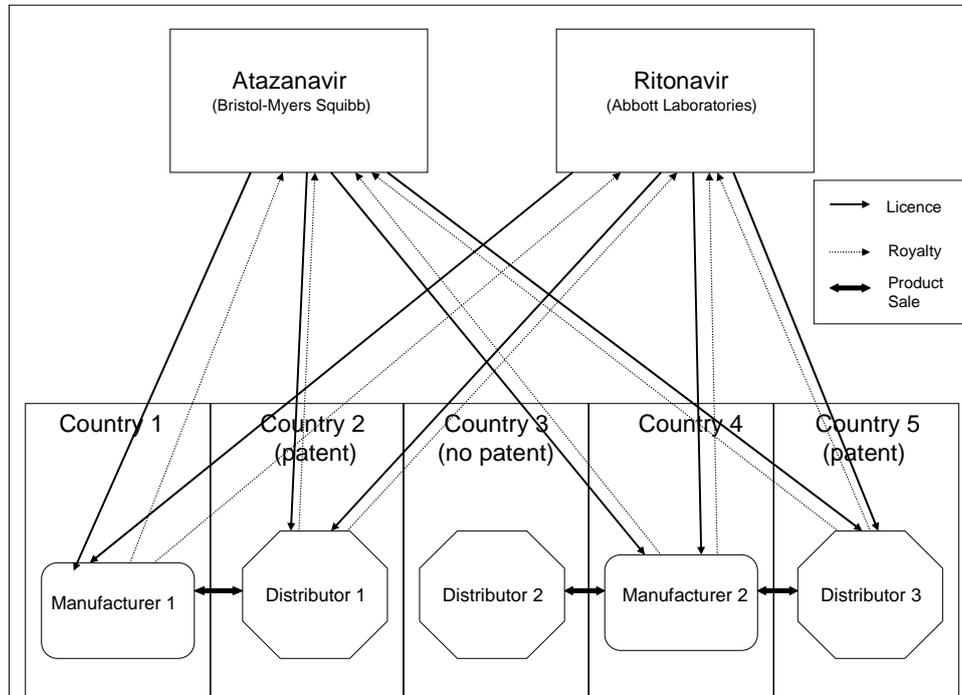
⁴ We note that the US Food and Drug Administration has approved two other FDCs – epzicom (abacavir/lamivudine) and truvada (tenofovir disoproxil/emtricitabine) – but these were by a single company and not two or more companies..

clinical research, and share the results of that research among manufacturing companies in the pool so as to lower costs and thus increase ROI. This could provide opportunities for both generic companies and generic affiliates of research-based pharmaceutical companies to enter the market on an equal basis.

Without a patent pool, coordination of the right to manufacture and sell combinations and new formulations of anti-retroviral medicines for developing countries is costly and time consuming. While patent rights are obviously not the only hurdle to the manufacture and distribution of combinations and new formulations of anti-retrovirals, they are a factor, particularly in countries with the ability to manufacture them. This means that individual agreements have to be negotiated with all concerned patent-holders, a timely process with no norms as to reasonable royalty, term or countries covered. In the example of an Atazanavir/Ritonavir combination, each of the patent-holders would need to individually license each manufacturer and distributor (Figure 1). This is not only complicated, but is time-consuming and requires a significant investment in simply negotiating and managing the various licences.

A Medicines Patent Pool would provide a way to simplify the licensing process and reduce transaction costs and overhead (Figure 2). Patent-holders would need to issue only one licence, to the pool, instead of a licence to each manufacturer and distributor. The pool, in turn, would need to issue only one licence to each manufacturer rather than multiple licences covering different anti-retrovirals. The pool would also use standard licensing agreements, reducing transaction costs and harmonizing royalty rates, countries covered and general responsibilities. Further, the pool would be in a position to impose quality standards and monitor compliance with those standards through the use of appropriate licensing terms. The pool could also be easily adapted to new formulations and combinations.

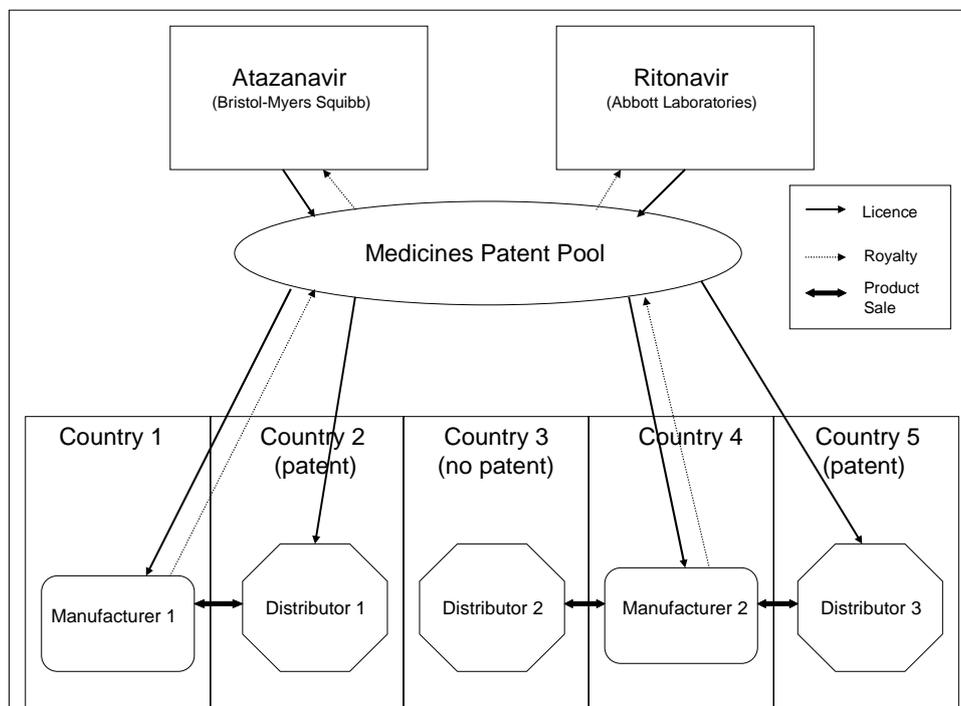
Figure 1
Example of an Atazanavir/Ritonavir Combination without a Pool



A Medicines Patent Pool could be global or regional in scope. The pool should encompass a sufficiently large number of people to take advantage of economies of scale and ensure exports of the medicines to those countries needed them. In practical terms, this means that the pool has to include both manufacturing and importing countries. A national pool or one restricted to only least-developing countries would not, practically speaking, generate the benefits required.

We note, however, that no one mechanism can be counted upon to address all concerns related to the availability and accessibility of anti-retroviral medicines. Generally, a multi-pronged strategy is best suited to address such complex issues. For example, policies to support technology transfer, innovation systems and technology regulation also help to ensure the continued development of new medicines needed to treat HIV/AIDS. Further, ensuring political stability and a well-functioning health care system, as well as reducing corruption, are important ingredients to achieving desired health outcomes. Nevertheless, a patent pool can be an important component of an overall strategy.

Figure 2
Example of an Atazanavir/Ritonavir Combination with Pool



1.1.2 Target Medicines and Sample Countries

For the purposes of this preliminary review, we examined the legal feasibility of a pool for the manufacture of the following medicines (the ‘Target Medicines’): *Efavirenz*; heat-stable *Ritonavir*; *Tenofovir*; *Lamivudine*; *Abacavir*; a combination of *Lopinavir* with heat-stable *Ritonavir*; and a combination of *Atazanavir* with *Ritonavir*. Of these, the most significant for the treatment of HIV/AIDS in developing countries are the combinations of heat-stable *Ritonavir* with *Lopinavir* and *Ritonavir* with *Atazanavir*. While there are no generic versions of heat-stable *Ritonavir* on the market, there are generic versions of *Lopinavir* and *Atazanavir* available in some countries.

Since the home base of any pool is likely to be Switzerland (for practical, not legal reasons), we examine its laws as well as those of the following representative set of countries in which manufacture and/or sale of the medicines will likely occur: India; Kenya; Brazil; South Africa; Thailand; Mali; Cameroon; and Nigeria.

1.2 Mandate for the Review

UNITAID requested that The Innovation Partnership (TIP) – see Appendix B – prepare a report that would accomplish the following:

- Undertake a preliminary legal analysis of the proposed patent pool;
- Assess the feasibility of the proposed patent pool;
- Provide recommendations with regard to major potential risks and impediments and propose possible mitigating strategies; and,
- Propose a work plan for future steps leading to the establishment of the patent pool (including areas that would require more in depth analysis or investigation).



UNITAID instructed TIP to include the following in its analysis:

- The use of voluntary licensing to the patent pool and any legal and practical issues that may arise;
- The use of compulsory licensing to the patent pool consistent with international trade agreements, and any legal and practical issues that may arise; and,
- Regulatory issues that would need to be addressed in order for manufacturers to utilize the essential patents. This could include, for example, pre-qualification requirements, regulatory barriers to competition and international trade requirements.

As part of its review, TIP conducted formal interviews with three representatives from the non-governmental community, four from the R&D and generic industry and four from international governmental organizations, in addition to various informal consultations. While these interviews cannot be expected to generate the full spectrum of opinions within any of these communities, they do provide useful insights into the benefits and drawbacks of any potential Medicines Patent Pool.

This report, as the outcome of the requested review, divides its analysis into three parts, discussed below: The international and domestic legal environment (Part 2); The legal and practical issues related to the implementation of the patent pool (Part 3); and, A proposed work plan should a sponsor decide to implement the patent pool (Part 4).

2. Legal and Practical Context for a Medicines Patent Pool

In this Part, we provide an overview of the legal context in which a patent pool would be created and operated. We start, in Part 2.1, with basic principles concerning patents and patent pools. This is followed, in Part 2.2, with international law, which sets up the general framework within which countries develop their national laws. In Part 2.3, we discuss national laws in four areas: patent law, competition law, contract law and the law relating to product liability. In Part 2.4, the report looks specifically at whether patents exist over the Target Medicines in the sample countries reviewed.

2.1 Patents and Patent Pools

Patent Basics

A patent is a legal right granted by a state to a person under its domestic laws that give that person the ability to prevent others from making, using, selling or importing an *invention*. An invention is, for the purposes of patent law, a thing or way of doing something that involves human intervention. Pharmaceutical products are inventions. In fact, countries grant patents over pharmaceutical products, ways to make them and, in some countries, how to use them to treat certain conditions. In return for the patent granted, the patent-holder discloses the invention, agrees to refrain from using the patent right in an anti-competitive way and accepts that the State may permit others to use the invention under certain circumstances. Countries grant patents to facilitate the commercial development of inventions by giving inventors and their employers a way to make money by doing so.

Patent-holders can exercise their patent rights in one of three ways. First, the patent-holder can itself make, use, or sell a product or service incorporating an invention while preventing all others in the same country from doing so. Second, the patent-holder can, under a contract (called a licence), promise not to prevent a particular company (an exclusive licence) or assortment of companies (non-exclusive licences) from making, using, selling or importing the product or service. That is, these other companies can themselves make, use or sell the product or service within the country knowing that all others are prevented from doing so. Normally, the company receiving permission to use the patent pays a percentage of sales or revenues (called a royalty) to the patent-holder in return for the licence. Third, a patent-holder can decide not to make, use or sell a product incorporating the invention nor permit anyone else to do so. This may, in certain countries, result in the patent being revoked or, more frequently, for the country issuing the patent to permit others to use the invention without authorization from the patent-holder (a compulsory licence).

A licence is not required to resell a medicine purchased in the same country (called patent exhaustion). Thus, a third party distributing medicines purchased in the same country does not need to obtain a licence to do so. It is only when the third party buys in one country but distributes the medicines in another that a licence may be needed. Those countries that permit importation without a licence as long as the product was legally on the market with the consent of the patent-holder in that other country allow 'parallel importing' or 'international exhaustion'. Other countries only permit importing from countries within the same trading

group (such as the European Union) under 'regional exhaustion'. Those that do not allow importation at all follow a principle of 'national exhaustion'.

Patent Pools

There is no precise definition of a patent pool. In general, a patent pool involves collecting a series of patents that relate to the use of a particular technology so that they can be efficiently licensed to those making, using or selling that technology.⁵

Historically patent pools have been established to build airplanes, sewing machines and radios. These pools, particularly those created in the first half of the 20th century, arose from the need to overcome strategic behaviour from patent-holders that blocked the development and sale of a new product. For example, in the airplane industry, the two main competing patent-holders, Curtiss Company and the Wright Company, could not agree on how to license one another so that somebody could build an airplane. Under government pressure, the pool (the Manufacturer's Aircraft Association) was established comprising the companies with important patents related to the airplane. Similarly, in the radio industry, the Associated Radio Manufacturers was created to pool, by corporate merger rather than by licence, all patents related to the radio industry. This pool was later dismantled for being anti-competitive, but in the early years, it provided a means to overcome the problem of patents blocking commercialization.

Modern patent pools arise where companies wish to establish a common technological standard for an industry. For example, DVD player manufacturers wished to assure that all DVD manufacturers and DVD reader and recorder manufacturers used the same standard. These pools are pro-competitive in that they create the possibility of producing new technologies, such as DVDs and MPEGs, that, absent the pool, would have been difficult.

More recently, we see the development of pools aimed at overcoming transaction costs in order to serve public, rather than commercial, interest. This social-entrepreneurial approach is evident in the SARS patent pool that brought together public research agencies, a government department and industry so as to facilitate the development of a SARS virus vaccine.⁶

Once patents are brought into the pool, they are licensed out to others in pre-defined packages. For example, the DVD 6C pool suggests 14 packages covering different uses of the technology such as DVD players, DVD recorders and so on.⁷ That is, anyone wishing to access the technology represented by the pool can purchase a non-exclusive licence to use all of the patents within the package at a given royalty rate.

The Medicines Patent Pool, as proposed by MSF, differs in important respects from previous or existing patent pools. In particular, to the extent that the Medicines Patent Pool aims at licensing products that, despite being expensive, are available in the relevant markets, it does not follow past or current trends. In this area, the pool would not so much overcome

⁵ See Geetruï Van Overwalle, Esther van Zimmerman, Birgit Verbeure and Gert Matthijs, "Models for facilitating access to patents on genetic inventions" (2006) 7 Nature Reviews Genetics 143 for a discussion of various modes of collaboration. See also Jeanne Clark, Joe Piccolo, Brian Stanton, Karin Tyson, "Patent Pools: A Solution to the Problem of Access in Biotechnology Patents?" USPTO (December 5, 2000).

⁶ See E. Richard Gold, "SARS genome patent: symptom or disease?" (2003) 361 The Lancet 2002.

⁷ See <http://www.dvd6cla.com/list.html> (last accessed July 13, 2007).

transaction costs or strategic behaviour but would aim, instead, at encouraging competition in the market through generic competition. Thus prices would fall to a level at which anti-retroviral medicines are more accessible. On the other hand, while this aspect of the Medicines Patent Pool differs from both the older airplane-type pools and the newer DVD pool, it bears some similarity to the SARS pool in that it aims at serving the public interest through social entrepreneurship rather than through strictly furthering commercial interests.

2.2 International Legal Framework

International law establishes basic principles that apply to how countries implement their national laws, including their patent laws. International law deals with the law between countries and therefore, except for some rare cases, has no direct effect on individuals. Individuals, including patent-holders, patients, manufacturers and distributors are therefore directly subject to *national* and not *international* law. Nevertheless, a quick overview of international law is helpful as it sets out the boundaries within which countries can create and enforce their laws. This is particularly important as sometimes countries impose obligations on themselves and those working within those countries that are not required under international law. As we will illustrate, this occurs frequently in the realm of patent law where countries do not use all of the flexibilities offered by international law to tailor their patent system to internal economic and social goals.

The most significant instrument of international law for the purposes of the present review is the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs).⁸ While patent law is national in reach (each country has its own patent law), TRIPs sets minimum requirements with which all WTO member countries' patent laws must comply. Consequently, it is important to determine whether TRIPs creates any hurdles – once carried over into national law – for the viability of a Medicines Patent Pool. We conclude that it does not. In fact, TRIPs would permit more flexibility in the construction of a Medicines Patent Pool than the laws of several of the sample countries allow.

TRIPs currently applies to all Member States of the WTO except, in respect of pharmaceuticals, to least-developed countries (LDCs) that have until 2016 to fully comply with the Agreement. As many of the beneficiaries of the proposed pool will be people living within LDCs, it is worth noting that, even among these countries, there is substantial variation in their level of compliance with WTO requirements. As with many other developing countries, most LDCs do not take advantage of the flexibilities provided in TRIPs with respect to promoting access to medicines. In fact, some of these laws would need to be amended to allow a Medicine Patent Pool to be its most effective. Nevertheless, given the low patenting rate in LDCs and given industrial policies of many patent holders, this does not legally or practically undermine the feasibility of a Medicines Patent Pool in the sample countries used for this preliminary review.

⁸ *Legal Instruments-Results of the Uruguay Round*, Agreement on Trade-Related Aspects of Intellectual Property Rights, 15 April 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex IC, 33 I.L.M. 81, 1994.

TRIPs contains important statements that apply to a Medicines Patent Pool (see Appendix D for some of its key provisions). It sets out general principles that inform the interpretation of its language and the ways individual countries may choose to implement its rules within their domestic legislation. Two of these principles are of particular importance. First, countries are entitled to implement their obligations in a manner that balances the interests of both technology developers and users so as to achieve overall social and economic welfare (Article 7) and, in particular, to protect public health and promote sectors of vital interest (Article 8(1)). Further statements by WTO Ministers in 2001 support the right of member countries to take a flexible approach to the implementation of their TRIPs obligations in light of their health needs.

The TRIPs Agreement requires countries to provide patent protection over pharmaceutical products for 20 years (Articles 27(1) and 33). It also provides transition measures so that countries newly expanding their patent systems to pharmaceuticals must extend that protection to pharmaceutical inventions deposited with the country after January 1995 (Article 70(8)). The impact of the above is that those countries that currently have the greatest ability to manufacture generic versions of the Target Medicines must now both provide patent protection over pharmaceutical products and grant patents over eligible products submitted since 1995. As noted in Appendix C and in Table 1, these include patents covering most of the Target Medicines.

Patents come with inherent limits, recognized in several parts of TRIPs (See Table 2). The limit most applicable to the present analysis is Article 31, which 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). The TRIPs agreement does not restrict the grounds under which a compulsory licence could be granted but lists a number of general requirements. Among them, the government or third party must pay 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 need⁹.

Table 2
Legal options to export medicines without the consent of the patent holder¹⁰

Basis	Comments
No patent	Some non-WTO members and LDCs do not offer patents over medicines and industry does not apply for patents in every WTO member, especially those such as India which did not offer patent protection for medicines in 1994. In these cases, no licence would be needed to either manufacture or export. Licensing will be required only for distribution in importing countries in which patents exist.
Parallel importation	TRIPs leaves each WTO member free to establish its own regime for exhaustion

⁹ Richard Gold and Danial Lam, “Balancing Trade in Patents: Public Non-Commercial Use and Compulsory Licensing” (2003) 6 The Journal of World Intellectual Property 5.

¹⁰ Brook Baker, *Analysis and Response to WTO Action Regarding Paragraph 6 of the Doha Declaration on the TRIPs Agreement and Public Health*, for United Nations Millennium Development Goals (MDGs) Project, Task Force 5: Infectious Diseases and Access to Essential Medicines, Sub-Group Access to Essential Medicines, January, 27, 2005.

(TRIPs, Art. 6)	without challenge. Consequently, it is possible for a country with an international exhaustion doctrine to buy and import patented medicines, without the consent of the patent holder, if the medicines were originally put on the market with the consent of the patent-holder or – under a liberal interpretation of the TRIPs Agreement – produced under a compulsory license.
Insufficient manufacturing capacity (August 2003 Decision)	An increasing number of countries, including Canada, India and China, are implementing the WTO decision of August 30, 2003 to authorise the issue of a compulsory license for export to countries with insufficient manufacturing capacity. Additional conditions apply, including a notification from importing countries and special packaging or labeling.
Anti-competitive practices (TRIPs, Art. 31k)	TRIPs provides an exception for the predominately-for-the-domestic-market rule in cases of anti-competitive practice. A country can thus issue a compulsory licence for the production and exportation of medicines, in certain circumstances, on the ground of excessive prices, discriminatory pricing or refusal to license.
Non predominant quantity (TRIPs, Art. 31f)	When the importing country does have sufficient manufacturing capacity and no anti-competitive practice exists, a compulsory licence must be authorized predominantly for the supply of the domestic market. While the word 'predominantly' is not defined, it most likely means domestic consumption of just over 50% of production. Therefore, countries with a large internal market can still export a significant quantity of medicines.
General exception to rights conferred (TRIPs, Art. 30)	Some have suggested that TRIPs Article 30 could be interpreted to read that patent-holders do not have exclusive rights to prevent third parties from making, using and selling patented medicines when these medicines are exported to developing countries with insufficient manufacturing capacity. However, this interpretation is disputed by most specialists and faces a high risk of challenge at the WTO. Critics are likely to suggest that the exception is not limited, unreasonably conflicts with the exploitation of a patent, or unreasonably prejudices the legitimate interests of the patent owner.

Until recently, and except in case of anti-competitive practices, compulsory licences could only be authorized predominantly for the supply of the domestic market of the country authorizing this use. This restriction on exportation of medicines to third countries led to great controversy. In a decision of August 30, 2003,¹¹ WTO members agreed that a country can allow for the production and export of medicines predominantly for another country if a number of conditions are met, including a lack of manufacturing capacity in the importing country.¹² To avoid medicines manufactured in this manner being diverted to high income countries, medicines produced under this mechanism need to be clearly packaged or labeled differently from the original medicine. Developing countries operating under a regional trade agreement may export products to other developing countries under the same trade agreement without a notification.

¹¹ General Council, Implementation of paragraph 6 of the Doha Declaration on the TRIPs Agreement and public health, September 1, 2003, WT/L/540.

¹² It is unclear whether, to obtain such a compulsory licence, the manufacturer must first attempt to negotiate a licence with the patent-holder. Since such use will usually be to satisfy a health emergency or a public non-commercial use in the importing country (Article 31 of TRIPs does not restrict emergencies or public use to the country issuing the compulsory licence), no such negotiations would seem necessary. Nevertheless, in a review conducted by the Canadian government of countries permitting the issuance of such compulsory licences, all required evidence of prior but failed negotiations. Industry Canada, *Canada's Access to Medicines Regime: Consultation Paper*, available online at: http://camr-rcam.hc-sc.gc.ca/review-reviser/camr_rcam_consult_e.pdf (last accessed July 15, 2007), Annex B.

A country issuing a compulsory licence must ensure that the licence is limited to addressing the particular need that justified it, is non-exclusive and is not assignable. Given that the word “assignable” has a particular legal meaning (involving a complete divestiture of the licence), a country should be able to issue a compulsory licence to a pool that the pool can then sub-license (that is, permission to manufacture and/or distribute can be granted by the pool to another) if that is permitted by national law. There is an argument that the *Paris Convention for the Protection of Industrial Property*¹³ would prevent sub-licensing, but it is generally accepted that Article 31 of TRIPs provides an additional ground for granting a compulsory licence that goes beyond anything set out in the *Paris Convention*.¹⁴

The bottom line is this: to the extent that the Medicines Patent Pool relies on voluntary licenses, TRIPs is not relevant. If the pool will rely on compulsory licenses, in whole or in part, the TRIPs Agreement provides specific requirements for the exporting and importing countries. Nevertheless, the TRIPs Agreement is quite flexible and authorizes the issuance of a compulsory licence to a patent pool that could then issue sub-licences to manufacturers and distributors. However, as the next section will show, national laws are often more restrictive.

2.3 Overview of Patent and other Laws in the Sample Countries

While TRIPs offers significant flexibility in establishing a pool through compulsory licences national laws limit that flexibility significantly. We provide, in this Part, a brief review of the laws, including patent laws, that are most relevant to the creation and operation of a Medicines Patent Pool in the sample countries listed in Part 1.1.2. We provide a more in-depth review of these laws in Appendix E.

2.3.1 Patent Laws

Patent laws in all the sample countries on the whole comply with TRIPs though enforcement may not. Many countries, however, go beyond TRIPs requirements and fail to explore the flexibilities that that Agreement provides. Because of this, countries differ in the content of their patent laws. Furthermore, while the law may set out certain requirements, actual practice may expand or contract those requirements.

Criteria for Patentability

To be patented, an invention must be novel, involve an inventive step and have an industrial application.¹⁵ In most countries, the patent office examines patent applications to ensure they meet these requirements. In South Africa, however, the examination requirement is not met and patents are, in practice, merely registered. Similarly, Nigeria does not conduct any

¹³ Notably Article 5A(4) which states as follows:

A compulsory license may not be applied for on the ground of failure to work or insufficient working before the expiration of a period of four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever period expires last; it shall be refused if the patentee justifies his inaction by legitimate reasons. Such a compulsory license shall be non-exclusive and shall not be transferable, even in the form of the grant of a sub-license, except with that part of the enterprise or goodwill which exploits such license.

¹⁴ See Gold and Lam, *supra*, note 9 at 21-22.

¹⁵ See Article 27(1) of TRIPs. In some countries, such as the United States and Canada, the criteria appear under the names novelty, non-obviousness and utility.

substantive examination of patent applications. One can expect this to result in a larger number of invalid patents in these two countries than in countries with active application examination.

Methods of Enforcement

All sample countries provide two civil remedies for patent infringement:

1. An injunction against the infringing activity (which may include the destruction of infringing goods and equipment); and,
2. An accounting of profits or a payment of the actual damages suffered by the patent-holder.

These remedies are not mutually exclusive and criminal penalties may also apply. In all countries, an infringement action may be defended by showing either that no infringement took place or that the patent is invalid (that is, that the patent does not actually meet the criteria of novelty, industrial application and inventiveness). Some perceive the enforcement efforts of certain of the sample countries – for example, Brazil, Thailand and India – as being low.

Compulsory Licensing Provisions

The aspects of national law that most affect the potential shape of a Medicines Patent Pool (at least one that relies to some extent on compulsory licences) are the laws related to compulsory licensing, the conditions of these licences and the ability to import drugs manufactured in another country under such licenses. Table 3 summarizes the situation in the sample countries.

Table 3
Comparison of Availability of Compulsory Licence in the Sample Countries

Country	Compulsory licence for national emergency/public health needs	Compulsory licence for importation	Compulsory licence for abuse of a dominant position/anti-competitive conduct	Compulsory licence for production for export
Brazil	YES	<ul style="list-style-type: none"> • In the case of a compulsory licence for abuse of a dominant position, so long as the patent-holder has consented to production in the exporting country and so long as time constraints are respected • In the case of national emergency/public interest where needs 	YES	NO

		cannot be met by domestic production		
India	YES	NO, unless declared in the public interest.	YES	YES
Thailand	YES	<ul style="list-style-type: none"> • Law is silent on the question of importation under a compulsory licence • The Director General of the Patent Office has ultimate authority to set the terms of compulsory licences except in the case of national emergency or war where it is the Prime Minister, with the approval of the Cabinet who has this power. 	YES	Compulsory licences must be used predominantly to supply the domestic market.
Nigeria	Yes (Government declaration)	No importation is permitted under a compulsory licence unless the government declares certain drugs exempt from the country's compulsory licensing rules for reasons of public health, national defence or the protection of the Nigerian economy.	Yes	No explicit scheme for exportation.
Kenya	YES	In the case where the public interest, in particular, national security, nutrition, health, environmental conservation, or the development of another vital sector of the national economy so requires, or where the Managing Director of the Patent Office determines that the manner of exploitation of an invention by the owner of the patent or its licensee is not competitive, the Minister in charge of the industrial property office may authorize by written order importation to satisfy	YES	Use of compulsory licences must be limited to supplying the domestic market.

		the need. Sections 80(1A) and 80(1B) also provide that the Minister in charge of the industrial property office may also issue a compulsory licence to a third party to import a molecule or substance without compensation to the patent-holder.		
South Africa	YES	Section 15C of the 1997 amendments to the <i>Medicines and Related Substances Control Act</i> ¹⁶ allows the Minister of Health to determine the conditions under which drugs may be imported as parallel imports. However, the <i>Patent Act</i> ¹⁷ stipulates that it is the Commissioner of the Patent Office who normally determines the terms of compulsory licences.	YES	No explicit scheme, however, no explicit requirement that products manufactured under a compulsory licence be limited to supplying the domestic market.
Cameroon	YES (through an administrative enactment, subject to the same requirements as the non-voluntary licensing regime).	NO	YES	No explicit program for export. However, there is no limitation on the use of compulsory licences to only satisfy the domestic market. The courts set the terms and conditions of the licence.
Mali	YES (through an administrative enactment,	NO	YES	No explicit program for export. However, there is no

¹⁶ Medicines and Related Substances Control Act as revised by the Medicines Amendment Act No.90 of 1997 [1997 Amendments to the Medicines and Related Substances Control Act].

¹⁷ Patents, Act (Consolidation), 26/04/1978 (1996), No. 57 (No. 49)

	subject to the same requirements as the non-voluntary licensing regime).			mention of use of compulsory licence to only satisfy domestic needs and it is left to the Court to set the terms and conditions.
Switzerland	YES	NO	YES	A compulsory licence is principally awarded to supply the domestic market.

All sample countries have compulsory licensing provisions to meet the needs of the domestic market. Countries generally provide for compulsory licences in cases of national emergency, patent dependency (to make use of one patented invention, one needs access to another patented invention), where the patented article is not widely available to the public at an accessible cost (that is, the public interest is not met) and for anti-competitive conduct by the patent-holder. Other grounds include failure to work locally. The particular restrictions and conditions that an applicant must meet in order to receive such a licence vary depending on the country. Table 4 summarizes these conditions.

Table 4
Conditions for Obtaining Compulsory Licences in the Sample Countries

	Authority issuing compulsory licences	Sub-licensing of a compulsory licence	Other limitations on scope of compulsory licence
Brazil	<ul style="list-style-type: none"> • The Intellectual Property Office (INPI) grants compulsory licences with terms proposed by the applicant, with an opportunity for the patent-holder to challenge those terms • In the case of a compulsory licence granted in respect of a national emergency or the public interest, the Minister responsible for the subject matter sets the terms with the resulting licence 	No sub-licensing permitted.	<ul style="list-style-type: none"> • There must be no reasonable explanation as to why the patent-holder has not met demand • Only non-exclusive licensing permitted

	being an act under the Federal Executive Power		
India	Applications for a compulsory licence are made to the Controller General of Patents, Designs and Trade Marks.	Legislation is silent on the issue of sub-licensing.	The Controller General of Patents, Designs and Trade Marks sets the terms of the licence.
Thailand	Requests for compulsory licences are made to the Director-General of the Department of Intellectual Property.	No assignment but no explicit rule concerning sub-licensing.	<ul style="list-style-type: none"> • Applicant must show an effort to obtain a licence from the patent-holder, having proposed conditions and remuneration reasonably sufficient under the circumstances but unable to reach an agreement within a reasonable period • Scope and duration of the licence is limited • Licensing must aim predominantly at supplying the domestic market
Nigeria	The court decides whether a compulsory licence may be granted and, if the parties cannot agree on the terms, the court may proceed to fix the terms (including adequate royalties having regard to the extent to which the relevant invention is to be worked) which is deemed to constitute a valid contract between the parties.	No sub-licensing permitted.	<ul style="list-style-type: none"> • Applicant must show an attempt to negotiate with the patent-holder • Licences must be non-exclusive • The licence may contain additional restrictions
Kenya	The licence is issued by the court on terms set by the court.	No sub-licensing permitted.	<ul style="list-style-type: none"> • Applicant must show that tried to negotiate a licence with the patent-holder on reasonable terms over a reasonable time frame (except in situations of national emergency or by

			<p>order of the Minister in charge of industrial property)</p> <ul style="list-style-type: none"> • Non-exclusive licences only • Limited in scope and duration • Limited to supplying local market
South Africa	<ul style="list-style-type: none"> • The application for a licence is made to the registrar and it is the Commissioner of Patents who sets the terms of the license • In the case of a compulsory license (for the supply of affordable medicines) under the 1997 amendments to the <i>Medicines and Related Substances Control Act</i>, it is the Minister of Health that sets the conditions 	<ul style="list-style-type: none"> • There is no mention of sub-licensing in the legislation. The Commissioner of Patents or the Minister of Health has the discretion to determine the conditions of a compulsory licence • The license is non-transferable if it is being granted for failure to work the patent invention 	<ul style="list-style-type: none"> • The Commissioner of Patents sets the terms of the compulsory licence issued under the <i>Patent Act</i> (1996) and will consider the risks undertaken by the licensee, the research and development undertaken by the patentee and the subject matter of the patent • In the case of a compulsory licence (for the supply of affordable medicines) under the 1997 amendments to the <i>Medicines and Related Substances Control Act</i>, it is the Minister of Health who sets the conditions • If the compulsory licence is being granted for failure to work the patented invention on a commercial scale or to an adequate extent, the licence must be non-exclusive and non-transferable (otherwise the licence may be exclusive)
Cameroon	<ul style="list-style-type: none"> • The Civil Court issues the compulsory licence and sets its terms • A minister may, through 	The beneficiary of a compulsory licence may not, without the consent of the patent-holder, grant any third party permission to perform	<ul style="list-style-type: none"> • Proof that the applicant attempted to obtain a licence from the patent-holder but has not received one on reasonable commercial

	<p>administrative enactment, issue a compulsory licence for public health (among other reasons) and this enactment will determine who benefits from the licence as well as its scope and terms. If these terms cannot be agreed upon with the patentee, the civil court will set the terms</p>	<p>any of the acts that he or she is authorized to perform under the licence.</p>	<p>terms</p> <ul style="list-style-type: none"> • Proof that the applicant is capable of working the invention
Mali	<ul style="list-style-type: none"> • The Civil Court issues the compulsory licence and sets its terms • A minister may, through administrative enactment, issue a compulsory licence for public health (among other reasons) and this enactment will determine who benefits from the licence as well as its scope and terms. If these terms cannot be agreed upon with the patentee, the civil court will set the terms. 	<p>The beneficiary of a compulsory licence may not, without the consent of the patent-holder, grant any third party permission to perform any of the acts that he or she is authorized to perform under the licence.</p>	<ul style="list-style-type: none"> • Proof that the applicant attempted to obtain a licence from the patent-holder but has not received one on reasonable commercial terms • Proof that the applicant is capable of working the invention
Switzerland	<p>The courts determine the scope and terms of compulsory licences.</p>	<p>Sub-licensing only permitted as part the sale of that part of the enterprise in which the underlying patent is worked.</p>	<ul style="list-style-type: none"> • Applicant must first try to negotiate a licence with the patent-holder (except in cases of national emergency) • The licence is principally awarded for supplying the domestic market. • The scope and duration of licenses are limited

			<p>to the purposes for which they were granted.</p> <ul style="list-style-type: none"> • The patent-holder is entitled to equitable remuneration (as decided by the court) taking into account the facts of the particular case and of the economic value of the licence.
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Brazil, Thailand and South Africa all have experience in granting compulsory licenses or using the threat of a compulsory license to lower drug prices. Requests for compulsory licenses are either made to the courts (as in Mali, Cameroon, Nigeria, Kenya and Switzerland) or to a government agency (Brazil, Thailand, South Africa and India). This means that it may not always be up to the government as to whether and on what terms a compulsory licence is granted. In South Africa, the Minister of Health has considerable discretion as to the terms to include in a compulsory licence granted to encourage the supply of affordable medicines (under the 1997 amendments to the *Medicines and Related Substances Control Act*).

In most countries (Thailand, Kenya (except in the case of national emergency or on order by the Minister in charge of industrial property), Mali and Cameroon, Nigeria and Switzerland (except in cases of national emergency), the applicant must demonstrate that negotiations to licence the patent from patent-holder failed. Further, a compulsory licence (except in the case of national emergency) will usually only be granted after three years from the grant of the patent.

In Kenya and Brazil, compulsory licences must be non-exclusive, tailored in scope and duration to the need addressed and limited to the domestic market, with no right to sub-license. Thailand also requires that the licence be limited in scope and duration and that production be primarily for the domestic market. While Nigeria also explicitly prohibits sub-licensing, Thai, Indian and South African law does not mention sub-licensing (although Thai law prohibits assignment). Cameroon and Mali only allow for sub-licensing when the patent holder consents. In Switzerland, while the court ultimately sets licence terms, the licence must also be limited in scope and duration and include reasonable remuneration to the patent-holder. Swiss law does not permit sub-licensing of compulsory licences except in conjunction with the sale of that part of the enterprise in which the patents are involved.

In order for non-manufacturing countries to benefit from a patent pool based on compulsory licences, the countries would have to have the ability to import under the compulsory licence. In Mali and Cameroon, though a minister of the government can issue a compulsory licence on such terms as he or she determines compulsory licences cannot be issued to import a medicine. These constraints lessen the eventual flexibility of a Medicines Patent Pool although they do not undermine it. In all other sample countries, while importation is generally not permitted under compulsory licences, special provisions exist to allow

governments to waive this restrictions in situations of national emergency or public health crisis. For example, in Nigeria, a minister of the government can exempt certain drugs from the restrictions contained in the country's compulsory licensing rules for reasons of public health, thus permitting the importation of medicines. Otherwise, licences granted under the country's compulsory licensing rules cannot be used to import. Similarly, in Kenya, the Minister in charge of industrial property can issue a compulsory licence to make or import a molecule or substance. However, the government introduced legislation that would considerably reduce its ability to do so by requiring the consent from patent-holders for importation.¹⁸ If this law were to pass, a patent pool based on compulsory licences would not function in Kenya to the extent that patents over the imported medicines exist in that country. We note, however, that none of the Target Medicines seem to be subject to Kenyan patents.

In addition to compulsory licenses to meet national needs, India provides for compulsory licensing for the manufacture and export of patented pharmaceutical products. Section 92 of India's *Patent (Amendments) Act, 2002* provides for compulsory licensing for the manufacture and export of a patented pharmaceutical product to any country having insufficient or no manufacturing capacity in the pharmaceutical sector. In such a case, the country to which the drug is to be exported must also, if a patent exists in that country, issue a compulsory licence to allow importation of the product. While the other sample countries do not have explicit schemes to manufacture for export under a compulsory licence, Thailand, South Africa, Switzerland, Mali and Cameroon do not explicitly outlaw production for export. The laws of these countries, however, often contain the provision that the production under the compulsory licence be principally aimed at satisfying domestic needs.

In addition to compulsory licences, government use provisions are a second vehicle used to satisfy public health needs. In Kenya, the government may order that a patent be exploited by any government agency or other actor, subject to the payment of compensation, to meet the public interest or to end an anti-competitive practice by the patent-holder. Nigerian law also has a government use provisions in the case of war and national emergency. Brazil permits the government to use inventions in the case of national emergency, public non-commercial use or public interest (including public health). If the government contracts with third parties to exercise the right, this must be done through a bidding process. If the product cannot be manufactured domestically, the licence permits importation.

With the exception of Nigeria and Kenya, all countries require that the patent-holder be compensated for government use of a patent. While the general rule in Kenya is that compensation must be paid to the patent-holder, no compensation is required in those cases where the Minister in charge of industrial property issues a compulsory licence to produce or import a medicine (that is, a molecule or substance). As previously noted, this exception may be eliminated if current amendments to the Kenyan patent legislation pass. Where compensation is payable, it takes the form of the payment of fixed royalties or as determined by the courts. In Kenya, the tribunals set the terms of the compulsory licence in order to ensure fair compensation and respect for competition laws. For compulsory licences based on patent dependency, all countries require that the original patent-holder be provided with a

¹⁸ See Owino Opondo, "Kenya: Amendments Bill Fails Public Interest Test", *The Nation*, July 22, 2007 available online at: <http://allafrica.com/stories/200707230386.html> (last accessed July 26, 2007).

cross-licence of the dependant patent on reasonable terms. Some countries, such as India, place a cap on royalty payments. The use of any patent in respect of a medicine or drug may not exceed 4% of the net ex-factory sale price in bulk of the patented article.¹⁹

Parallel Importing

Most sample countries allow the parallel importation of patented pharmaceuticals (purchasing medicines in another country for importation to take advantage of lower prices) provided they are willingly placed on the market by the manufacturer in the exporting country. This means that, as long a medicine within the pool is manufactured and sold in one country with the consent of the patent-holder in that country, no licence will be required to import and sell it within these sample countries. In its *Industrial Property Law*, however, Brazil does not accept the importation of products sold elsewhere without the consent of the patent-holder. Nevertheless, Brazil has taken the position internationally that parallel importation is one way in which it intends to meet its health needs. Kenya is considering amendments to its patent legislation that would require the approval of the patent-holder before importation can take place.²⁰ Nigeria imposes the additional requirement of government approval (e.g. declaration that certain drugs may be imported) before parallel importation can take place. Depending on the country of export, government approval may also be required in Cameroon and Mali before parallel importation can take place. In Switzerland, parallel importation of pharmaceutical products is not currently permitted. Nevertheless, this rule has been a subject of great discussion and is under review. Consultations on the subject came to an end on June 30, 2007. The conclusions have yet to be released.

In short, this analysis indicates that a Patent Pool for the Target Medicines is legally feasible in all of the sample countries. However, we note that if a patent had existed on the Target Medicines in Mali and Cameroon, these countries could have only participated in the pool if the pool was based on voluntary licences or if the medicines were manufactured by the countries themselves. This is because neither country permits compulsory licences for the importation of medicines despite the flexibilities offered by TRIPs.

This review also points out that the idea that the ideal form of a Medicines Patent Pool – in which those compulsory licences that are awarded are given directly to the pool for sub-licence to manufacturers and distributors – is not possible. The law in Brazil and Kenya, for example, prohibit the issuance of compulsory licences that can be sub-licensed. Once again, these countries have imposed limitations on themselves that do not exist under international law. As a result, while some countries may be able to issue compulsory licenses directly to a Medicines Patent Pool, others will not.

2.3.2 Competition law

While patent laws are relevant to determining the contents and operation of a Medicines Patent Pool, other laws, particularly competition (or anti-trust) law, will also affect how the pool should structured. While patents are not themselves considered anti-competitive, it is

¹⁹ *Patents Act* 1970, 39/1970, Section 100.

²⁰ See Opondo, *supra*, note 18.

possible that the way they are licensed and used in a patent pool are might be. We therefore discuss the application of competition law to both licence agreements and to patent pools.

1. Licence Agreements

As a general rule, licence agreements increase innovation and product development. Even exclusive licences – under which only one person can make the product – are normally acceptable under competition law. Nevertheless, they can cause concern in certain cases. For this reason, the law in several of the sample countries provide what may and may not be included in licence agreements. For example, in both Mali and Cameroon, licences may not impose obligations on the person licensing the invention that attempt to extend the patent-holder's right beyond the time period and the scope of activity covered in the patent.

In Switzerland, the *Federal Act on Cartels and other Restraints on Competition*²¹ provides that the Competition Commission may examine any restrictions contained in agreements for anticompetitive conduct where that restriction is felt in Switzerland. Consequently, a licence agreement with restrictions that affect the Swiss market could be considered anti-competitive even if the agreement was not entered into in Switzerland. Nevertheless, Swiss competition law exempts the exercise of patent rights from anticompetitive scrutiny except where the agreement includes import restrictions based on patent rights. As a result, the Competition Commission may examine agreements with parallel import restrictions.

Swiss competition law provides for a mechanism to exempt an agreement that would otherwise be considered anticompetitive if the agreement is necessary to safeguard a compelling public interest. This could provide an important safeguard for the creation of the pool in Switzerland in case it is ever reviewed as being anti-competitive in some respect.

Given the above and assuming that the Medicines Patent Pool will be established in Switzerland, the agreements that the patent pool enters with the patent-holders should be drafted in a manner that does not produce anti-competitive concerns within Switzerland. If they do, the exception for public benefit could potentially be invoked.

2. Patent Pool Arrangements

Patent pools are generally designed to facilitate access to technology and encourage production by preventing blocking or hold-up situations (one patent-holder preventing others from using a component that is a necessary part of a larger product). As suggested in Part 2.1, a Medicines Patent Pool offers to do exactly that with respect to FDCs and new formulations of anti-retroviral medicines. Pools can, however, in certain circumstances, be anti-competitive. Anti-competitive pools may contain competing patents as opposed to necessary patents and weak or invalid patents as opposed to strong ones. This may extend monopoly power and create cartels. Potentially anti-competitive pools are typically subject to increased regulatory scrutiny and remedial government action.

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 be constructed in such a way that it not include competing products but only products that are independently

²¹ RO 1996 546.

necessary. The pool should therefore avoid so-called 'me too' drugs and concentrate on medicines that are not substitutes for one another but that serve different purposes. **Further, the pool should appoint an independent expert to ensure that the patents licensed into the pool are neither competing nor likely to be held invalid.**

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. That is, a patent-holder must contribute all relevant patents. 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. At a practical level, this avoids individual negotiation over the terms with any particular patent-holder, thus ensuring the goal of equality. Standard-form agreements should, therefore, be the rule for licensing patents into the pool. These agreements should include the same licensing provisions, the same country scope and the same payment structure (for example, royalty rates linked to the Human Development Index of the recipient country). Obviously, the terms of the licences must be such as to allow the pool to meet its goals.

In Switzerland, patent pools are subject to competition scrutiny. Consequently, a patent pool will only be valid so long as its benefits (particularly economic efficiency) outweigh any negative effects on competition. Article 5.2 of the Swiss Act states that an agreement is deemed justified on economic efficiency grounds where it is necessary in order to reduce distribution or production costs, improve products or processes, promote research or dissemination of technical or professional know-how, or to exploit resources more rationally provided that the pool agreement will not eliminate competition. In addition, Article 8 of Chapter Two of the Act exempts agreements affecting competition where the agreement is necessary to safeguard a compelling public interest. However, in order to benefit from this exemption, the patent pool must apply to the Federal Council.

The patent pool will also have to address competition law concerns in the other countries where it will have an impact on the market. In Brazil, for example, Article 54 of the *Competition Act* specifies that any agreement that limits open competition or that result in the control of relevant markets for certain products or services must be submitted to the Administrative Council for Economic Defense (CADE) for review within 15 days of the agreement being signed. Thai and Kenyan competition law grants the competition commission the power to review any agreement that limits competition. It is notable that in South Africa, while competition law may come into play, the patent pool could apply to have the agreement exempt from the competition law because it is in the public interest. Cameroon and Mali do not appear to have any enforceable competition law at this time but are, however, in the process of developing harmonized policies.

2.2.3 Contract law

All sample countries have some form of contract law and mechanisms for contract enforcement. Properly drafted patent pool agreements will be enforceable in all sample countries. However, judicial and enforcement resources may be limited in some cases.

The laws of Nigeria, Kenya and Brazil require that patent licence agreements be registered with the government in order to be valid. Further, the laws of certain of the countries,

including Nigeria, Kenya and Thailand provide that licence agreements must meet certain conditions such as fairness of royalty payments, scope of rights and term of licence. Cameroon and Mali also include provisions covering permissible terms in licence agreements, for example, in relation to scope and duration. Restrictions in the laws of other countries relate to anti-competitive concerns such as tying and other restrictions. There is no reason to believe that a Medicines Patent Pool would have difficulty complying with these standards.

2.2.4 Liability for defective products/ regulation of drugs

The patent pool must also be conscious of liability for defective products as well as regulatory requirements for drug production and registration. This type of liability normally falls on manufacturers rather than on patent-holders or patent pool administrators (although there may be exceptions). However, the more active the pool is in establishing and enforcing manufacturing standards, the higher the risk that the pool itself could attract liability. This is a normal business risk and is usually addressed through the purchase of insurance.

In all sample countries, a manufacturer may be liable for defective products that harm consumers. While the laws in Thailand, Cameroon and Mali are considered to be underdeveloped in this area, in all countries with existing legislation, monetary damages are limited to the physical harm suffered by the consumer. In Cameroon, liability remains in the civil law while in Mali liability may be penal in nature.

Both South Africa and Thailand are considering legislation that would significantly increase the financial liability of manufacturers. The laws in India, Kenya and Nigeria as well as the proposed laws in South Africa and Thailand include criminal penalties (including imprisonment) for pharmaceutical defects causing severe injury.

In addition to liability for defective products, all sample countries require approval of all new medicines put onto those countries' markets. In most countries, generic versions of medicines already on the market can obtain approval more rapidly than a new medicine. For example, in South Africa, anyone who wishes to sell a medicine must register the medicine with the government and receive a registration certificate. Medicines on the WHO's Essential Medicines List obtain fast-track registration. In addition, South African law provides that the Minister of Health may allow a medicine that is identical in composition, meets the same quality standard and is intended to have the same proprietary name as that of another medicine already registered in South Africa, even if the importer is not the holder of the registration certificate for the drug.

With this review in mind, one can conclude that there is nothing in the national laws of the countries examined that would prohibit the establishment and operation of a Medicines Patent Pool. Nevertheless, it will be necessary for the pool and its manufacturers to meet the requirements of each country's laws including registration of medicines as well as licence agreements with government authorities.

2.3 Preliminary Review and Comparison of Patent Families Issued in Respect of the Target Medicines in the Sample Countries

We conducted a preliminary review of patent families relating to the Target Medicines (see Appendix C for the methodology of our review and our conclusions). In conducting this review, we used publicly available electronic information available in English. Before a Medicines Patent Pool could actually be put in place, a more complete review of the patent landscape in participating countries will be necessary.

In this preliminary review, we used patent families to identify relevant patents or patent applications. Patent families are the full set of issued patents and patent applications related to a particular medicine. Often patents granted for the same medicine in multiple countries will be related to each other, sometimes stemming from a single priority filing, such as a Patent Cooperation Treaty (PCT) patent application filing. Further, multiple patents and patent applications may be filed relating to aspects and uses of a single pharmaceutical component within a single country. Recognizing the role of patent families allows an understanding of the complete picture of the patent situation in an international context. However, it is important, for the purposes of this review, to remember that it is only necessary that one patent be granted in a given country over a pharmaceutical compound to prevent manufacturing from occurring without first gaining a licence from the patent-holder.

In general, our review indicates that patents exist in countries with the manufacturing capacity to make the two most important combination therapies: heat-stable Ritonavir with Lopinavir and Ritonavir with Atazanavir, (see Table 1). On the other hand, in most importing countries, we cannot find evidence of patents or patent applications. (Of course, as is explained in Appendix C, this does not necessarily mean that patents do not exist in these countries.) This indicates that the most significant contribution of the Medicines Patent Pool will be in providing the right to manufacture and sell medicines rather than to grant the right to import and distribute. Most of the importation can likely take place without need for a licence due to the absence of patents in the affected countries. This will need to be verified on a by-country and by-drug basis as suggested in the work plan set out in Part 4 of this report.

3. Analysis of the Medicines Patent Pool

It is clear from the above review of international and national law that it is legally feasible to establish a Medicines Patent Pool. The pool's feasibility will rest more on mobilizing political will than on clearing the legal hurdles.

While this report focuses on the legal feasibility of a Medicines Patent Pool, in Part 3.1, we briefly consider factors relating to the desirability of the pool. We follow this, in Part 3.2, with a discussion of the licence structure of the pool and the role of the entity administering the pool. In Part 3.3, we examine the legal aspects of the entity that administers the pool. We then turn to an examination of how to encourage voluntary participation in the pool (Part 3.4) before analyzing the best ways to deploy compulsory licences if they turn out to be necessary (Part 3.5). We then turn to three technical but critical issues: determining the countries whose laws apply to the pool (Part 3.6), the liability of the pool and its directors and officers (Part 3.7), and licence terms (Part 3.8).

3.1 Brief Overview of Factors Affecting Desirability of a Medicines Patent Pool

The desirability of a Medicines Patent Pool rests on the answer to three questions. First, is there really a problem that needs addressing through a pool or otherwise? Second, if there is such a problem, should a Medicines Patent Pool form part of the solution to that problem? Third, if so, how can one ensure that patent-holders, countries, donors and non-governmental actors working in the field participate in the pool? We briefly discuss these in turn.

Is There a Problem?

The two problems identified in the MSF proposal are: 1) that there is a market failure in that patent-holders are not producing combination therapies and formulations that the market in developing countries demand; and 2) that anti-retroviral medicines are unaffordable in developing countries.

As to the first point, it is clear that FDCs and targeted formulations are not available in sufficient quantity on the market. If combinations and new formulations represent the vast majority of medicines actually deployed and needed in developing countries, then it would appear that a patent pool aimed at producing FDCs and new formulations aimed at targeted audiences (such as children) might be an appropriate approach to correcting this market failure.

MSF indicates that almost 85% of all the treatments they offer in developing countries are fixed-dose combinations (FDCs).²² These are, in fact, medicines that are not being offered by patent-holders but by generic producers in developing countries. Generics could offer FDCs cheaply because, until recently, no patents existed for pharmaceutical products in those countries. Given that patents now exist in many developing countries with manufacturing capabilities, the production and sale of new generations of FDCs is a major concern. As with

²² Médecins sans frontières, *Too Little for Too Few: Challenges for Effective and Accessible Antiretroviral Therapy*, Briefing Document, XVI International AIDS Conference, Toronto, August 2006.

the airplane industry, a patent pool over anti-retroviral treatments would open up – or at least permit the continuation and growth – of an entire line of products that would otherwise be unavailable. The pool would provide a tailored tool to overcome entry barriers (such as fragmented markets and competition law concerns) and strategic behaviour (as was the case prior to the airplane pool) by unblocking patents so that new FDCs and targeted formulations can be produced to satisfy a significant market need.

While the data supplied by MSF is a good starting point, **we recommend that further investigation be conducted, drawing on the experience of other organizations supplying anti-retroviral therapies, to determine the present need for FDCs and new formulations as a percentage of all anti-retroviral medicines used, as well as their expected use in the future.** We also recommend that the study assess what percentage of current and anticipated FDCs are combinations of medicines patented by the same patent-holder and what percentage are combinations of different holders. Given MSF's experience and the lack of ambiguity in its data, we suggest that this study can be completed quickly.

Should a Pool be Part of the Solution?

To properly address this question, one should recall the types of problems that patent pools have successfully addressed before. As discussed in Part 2.1, patent pools are well designed to address two types of problems. First, pools have been used to overcome a failure to produce products for which there was a clear market need. The airplane patent pool, for example, overcame the reticence of the two patent-holders that had been blocking airplane manufacture. Second, pools are useful in industries in which the technological standards actually permit the formation of the industry. Patent pools relating to DVDs and MPEGs fall into this category.²³

The difference between these two uses of patent pools is that, in the second, the push for a pool comes from industry. Industry sees the pool as a necessary foundation upon which to develop and sell products in the market. Due to competition law concerns, competing companies must be careful about the way they interact so as not to be accused of price fixing or keeping new entrants out of the market. The pool provides a systematic way to regulate the relationship between industry players in a way that avoids anti-competitive concerns.

In the first set of patent pools (e.g. the radio and airplane pools) the push for the pool often comes from government which sees a public benefit to the development of a particular product. To realize this benefit, government puts pressure on industry – including, on occasion, through the threat of compulsory licences – to participate in the pool. Each company is acting strategically with respect to its patents. It does not want to create competition for its existing products, it wants to extract a higher value from its patent than is objectively reasonable and so on. Thus the price of the combined product would have to be far above market tolerance in order to give all players what they demand. In such circumstances, no one patent-holder is willing to ask for less since otherwise its competitors will gain at its expense. Thus, no solution can be found by the parties acting in isolation. Through intervention of a third-party, usually the government, it is possible to arrive at a fair

²³ See Robert Merges, "Institutions for Intellectual Property Transactions: The Case of Patent Pools" (1998) University of California at Berkeley (1998) for a discussion of various kinds of patent pools.

solution for all patent-holders while maintaining a reasonable price for the final product. In short, the government is able to ensure that all patent-holders accept less for the benefit of all.

Patent pools are more suited to the first of the two problems identified, the failure to address a market need because of blocking patents (as opposed to the failure to provide medicines at affordable prices).²⁴ Industry has not been able to adequately address the need for FDCs nor for targeted formulations (for example, pediatric formulations) despite the evidence of the need. A patent pool provides a way to overcome this deficiency by applying sufficient government pressure to induce patent-holders to negotiate licences. When complemented by funding for research and development costs associated with these FDCs and formulations, the pool can provide positive incentives for development of these medicines.

It is unlikely that industry will embrace government intervention at first. However, by overcoming the strategic behaviour of all patent-holders, industry may actually benefit from the pool in the long term. This is especially true if funding is available for research and development. New products and new revenue sources come into being. From a governmental point of view, complementing the patent system with a patent pool better meets economic and social goals.

The capacity of the pool to address affordability is less certain. While a pool will likely lessen the costs of medicines through increased competition, it is unclear how significant those cost reductions will be and whether there are better tools to specifically target costs. These other tools could include, for example, advance purchase commitments, the establishment of a prize fund, the creation of purchasing groups among purchasing countries and other non-governmental actors, formal price controls and so on. **We recommend that further research be conducted to evaluate the performance of a Medicines Patent Pool in reducing costs, especially in comparison with other methods.** This would involve examining manufacturing costs, tariffs and taxes, transportation costs, royalties, and final retail prices of medicines licensed through a pool.

Thus a Medicines Patent Pool is part of the solution to the problem of the failure to produce FDCs and targeted formulations. Whether a pool is also capable of addressing affordability is a question that will need to be considered once better data are available.

How to Encourage Participation in the Pool?

Given the range and diversity of stakeholders with respect to anti-retroviral medicines – patients, physicians, patent-holders, generic producers, governments, governmental organizations and non-governmental organizations – it will be easiest to build consensus around the need for a Medicines Patent Pool in those areas in which a pool most clearly targets a proven need.

Following the analysis above, **a Medicines Patent Pool focused on FDCs and new formulations of particular need to developing countries offers the best chance of acceptance by stakeholders.** While one may expect patent-holders to initially resist the pool as they have historically, this resistance will be weaker and likely shorter-lived if the pool

²⁴ See, for example, Carl Shapiro, “Navigating the Patent Thicket: Cross Licences, Patent Pools and Standard-Setting” (March 2001) University of California at Berkely.

targets certain medicines. At a second stage, the pool, once it demonstrates its management and financial expertise, could be extended to other anti-retroviral medicines.

A Medicines Patent Pool aimed at increasing competition for existing medicines will encounter greater levels of resistance from both patent-holders and governments. To obtain government support, it will be important to demonstrate the effectiveness of a pool in reducing costs. To obtain patent-holder support, the pool will need to demonstrate added value. Providing a consistent revenue stream is only part of this added value. Other sources of value can be found in demonstrating licensing expertise in developing countries, ensuring the sharing of important manufacturing and health data, monitoring quality of production, helping to undermine counterfeit medicines through clear and consistent labeling and tracing obligations and collecting and distributing royalties.

3.2 Licence Structure

The simplest licence structure for a Medicines Patent Pool is one based on voluntary licences. Through the licence arrangements, the pool simplifies negotiation by using a separate standard licence with each patent-holder, manufacturer and distributor. The licences would address such issues as royalty formulas, countries covered, quality standards and monitoring and sharing of know-how. This will greatly reduce transaction costs and administrative overhead while increasing transparency. Other advantages of voluntary licences include the ability to establish the pool earlier with reduced difficulty and lower cost. The risk of this approach is that one or more patent-holders may refuse to participate, putting the entire pool at risk.

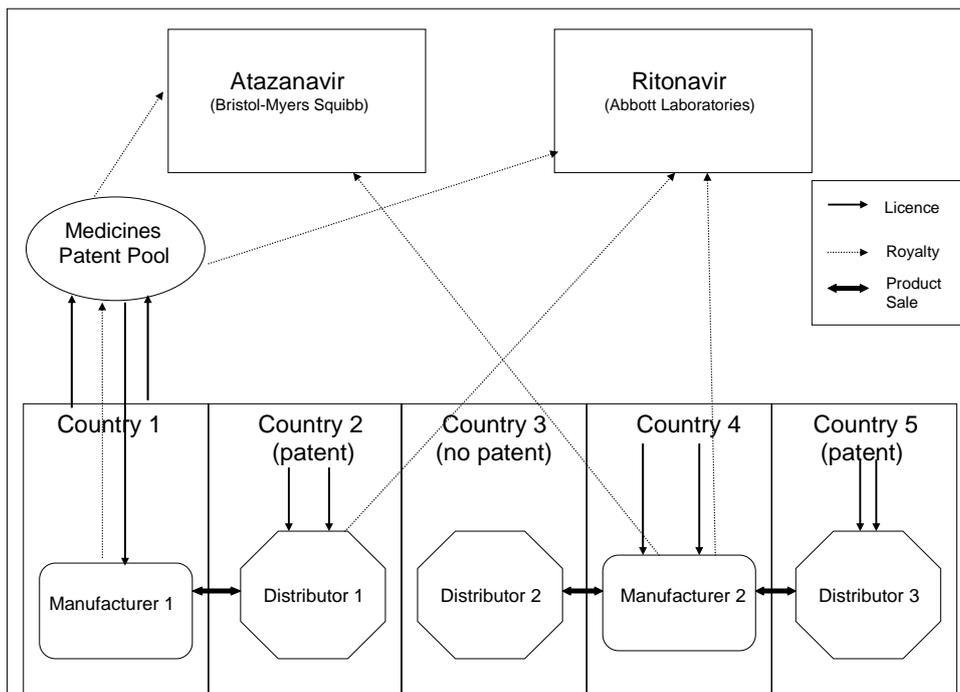
On the other hand, it may be that access to manufacturing know-how is not important to the pool and that participating countries would be willing to quickly issue compulsory licences. The compulsory licensing approach offers the certainty that all patents will be available to manufacturers and distributors. Compulsory licensing would also offer insurance in the eventuality of one or more patent-holders refusing to negotiate, slowing down negotiations or demanding licensing terms that deviate from the standard licensing terms contained in other agreements. Compulsory licensing's advantages come with several disadvantages, however, including likely delays, a lack of uniformity in licence terms, political pressure on developing countries, coordination between compulsory licenses in manufacturing countries and importing countries, restrictions on quantity and duration, and a lack of the direct contribution of know-how about manufacturing processes from industry.

We do not believe that a Medicines Patent Pool based solely on compulsory licences would be workable (Figure 3). This is due to the fact that, as previously outlined, many countries' national legislation does not exercise the flexibilities available in TRIPs (particularly the ability to issue compulsory licences with rights of sub-licensing). Thus, many if not most compulsory licences would be issued directly from countries to local manufacturers and distributors rather than to the pool for sub-licensing. In this case, the Medicines Patent Pool would not, in fact, be a pool but would become an organization providing technical assistance to countries and manufacturers. 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.

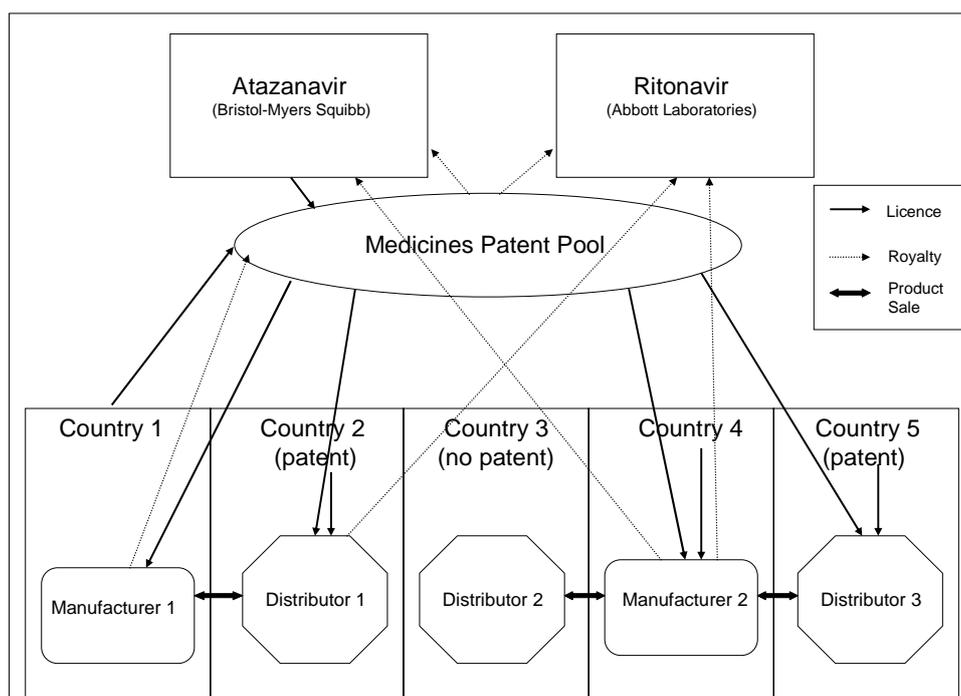
We recognize that, in its proposal, MSF suggested that the pool would enter into memoranda of understanding (MOUs) with the governments of participating countries. MSF suggests that one term of this MOU would be that the country would issue a compulsory licence on request to any manufacturer or distributor in that country on standard terms established by the pool. We do not think this solution is workable. First, it is unclear whether countries would sign an MOU with the pool. As we discuss in the next Part, we suggest that the pool be established as an independent not-for-profit corporation or association. It would be unlikely that governments would sign a binding MOU with such an entity. Second, it is unclear whether governments can, in fact, bind themselves through an MOU with an independent pool. This is a constitutional question for each country that is linked to the principle of sovereignty. Third, the executive branch of government is often not the one to actually set compulsory licence terms. In some countries, an independent agency or the judiciary determines these terms. Therefore, the government often cannot, as a practical matter, ensure compliance with an MOU. At best, the pool could suggest a form of compulsory licence for governments and agencies to consider but would not be able to ensure compliance with that form. This could lead to significant gaps that undermine the integrity of the effort.

Figure 3
Example of Compulsory Licences Only Arrangement



A more realistic approach is a pool of mixed voluntary and compulsory licences (Figure 4 and Table 5). As long as the pool has a sufficient percentage of voluntary licences, we estimate in the range of at least two out of three, it would have sufficient leverage to administer the pool. Between voluntary licences and compulsory licences issued to the pool for sub-licence, most royalties would pass through the pool. Further, through the voluntary licences and sub-licences of compulsory licences, the pool could impose quality standards and monitor performance adequately to ensure the integrity of the project. Nevertheless, as there is no way to ensure all would be the same or even always compatible, there would still likely be disparities between compulsory licences as well as between compulsory and voluntary licences. A mixed pool will still face delays in coordinating compulsory licences and be more difficult to administer. It is, nevertheless, feasible as long as the number of compulsory licences is kept low.

Figure 4
Example of a Mixed Pool



One problem with a mixed pool is the willingness of patent-holders to participate in it, given the inconsistent ‘message’ of voluntary and compulsory licensing. Our interviews with a sample of industry representatives indicate that they are of the view that patent-holders would be significantly less likely to voluntarily license their patents to the pool if there existed a significant threat of the issuance of a compulsory licence. Although clearly permitted by international and domestic law and invoked in countries across the world, industry nevertheless views compulsory licensing as an illegitimate taking of their patents. Given this, there is a risk that patent-holders will resist participation in a Medicines Patent Pool that includes compulsory licences. On the other hand, representatives from a sample of non-governmental organizations believe that without the threat of compulsory licenses, the pool

would have no leverage to ensure that all necessary patents are contributed to the pool. In their view, a real threat that countries would issue compulsory licences is necessary to convince patent-holders to voluntarily license their patents into the pool.

Table 5
Pros and cons of voluntary and compulsory approaches

	Complete voluntary approach	Mixture of voluntary and compulsory licences	Complete compulsory approach
Pros	The standardisation of licences will reduce transaction and administrative costs and increase transparency	The pool will still have licences to administer while additional pressure will exist to push for voluntary licences on reasonable conditions	Licences will be issued on terms that are reasonable from a governmental point of view
Cons	It may be difficult to obtain licences from all patent-holders if they feel the incentives are insufficiently high	The pool will face serious administrative difficulties and may lose the trust of patent holders	The pool will have insufficient leverage to provide a significant value-added to the licensing process

In this context, a frequently-asked question is whether to pursue 1) a strictly voluntary approach to licensing, 2) a mixture of voluntary and compulsory licenses, 3) or raise the possibility of compulsory licensing from the beginning. We think that this question is misguided. It is impossible to make a clear *a priori* evaluation of which option would best meet the goals of the sponsoring agency. It would be ill-advised for the sponsoring agency to completely dismiss the possibility of compulsory licences for two reasons. First, neither the sponsor nor the pool has the power to prevent countries from issuing compulsory licences. Second, it would be unwise for the pool to undercut its bargaining power by rejecting the use of compulsory licences even in extreme cases (for example, to discipline one rogue patent-holder when the remainder of patent-holders has issued voluntary licences).

A Medicines Patent Pool should likely start, as a first step, on the basis of obtaining voluntary contributions to the pool. If this does not result in the pool being able to meet its goals, the pool should contemplate, as a second step, 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 these licences.

There may be one alternative that avoids both voluntary and compulsory licences, at least for manufacturing: have all manufacturing occur within either a non-WTO member country or in a LDC with manufacturing capacity that has yet to implement the TRIPs requirement to provide patents over pharmaceutical products. We have not conducted a search for such a country although one of our interviewees suggested Bangladesh and the Bahamas. The advantage of this approach would be that no licence would be needed to manufacture or export medicine to another country. The disadvantage is that the role of the Medicines Patent Pool would be limited to licensing distribution in importing countries in which patents exist. As noted in Part 2.3, there are few patents on the Target Medicines in the studied importing countries for which compulsory licences would need to be issued. This means that the pool would have little or no leverage in standardizing licence terms and medicine quality. This



approach would, however, permit production of medicines at least until 2016 when the country would have to comply with TRIPs.

3.3 Possible Organisational Structures of a Medicines Patent Pool

There are four organizational issues involved with setting up a Medicines Patent Pool. First, there is the question of which organisation(s) are best positioned to sponsor the creation of the pool. The second is whether the pool should be created within the sponsoring organization or should be a separate not-for-profit corporation. Third, the pool administrator would need to be identified. Fourth, internal management of the pool will need to be addressed.

Sponsoring Organisation

There are several conceivable sponsors for a Medicines Patent Pool. These include UNITAID, the WHO, the WIPO, UNCTAD, UNAIDS, or a consortium of non-governmental organizations. While in theory any of these could act as sponsor, it is important to look at each organisation's mandate. UNITAID has a mandate to help provide essential medicines to developing countries and, through contributions from multiple governmental and philanthropic donors, has the resources to finance the implementation of the pool and research and development to bring FDCs and new formulations to market. Nevertheless, UNITAID has no distinct legal personality and operates through the aegis of the WHO. The WHO has a clear mandate over health and has conducted work in the area of intellectual property, innovation and health but is not directly responsible for delivery of medicines. WIPO has expertise in intellectual property but none in product delivery nor in determining which medicines are most needed. UNCTAD's mandate over trade and development includes trade in medicines but is not directed specifically to health. UNAIDS, which itself is cosponsored by a number of United Nations agencies, focuses on developing leadership and advocacy, strategic information and technical support, tracking monitoring and evaluation, civil society engagement and mobilization of resources in relation to HIV/AIDS. While it plays an important role in the social processes surrounding the efforts to prevent and treat HIV/AIDS, it does not directly seek to provide medications to those who need them. Many non-governmental organizations are active in delivering HIV/AIDS medicines in developing countries but lack the trust of patent-holders.

While the mandate of all of these organizations covers different aspects of the patent pool, UNITAID's specific focus on finding mechanisms to deliver HIV/AIDS medications and the availability of the UNITAID Fund to support its activities suggests that it should take a lead role in sponsoring the creation of a Medicines Patent Pool. Ideally, however, as many of the other agencies as possible should contribute their expertise to the pool's creation and operation.

Corporate Structure of the Pool

Whichever organization eventually leads the effort to create a Medicines Patent Pool, we suggest that the pool itself should be legally and functionally independent from its sponsor. There are several reasons for this. First, the question of access to anti-retroviral medicines is highly politically charged. Management of the pool by an independent corporation may

insulate the pool from some of the politics surrounding access to medicines. Second, the pool will need to be flexible, adjusting arrangements as it gains experience. It will also need to be completely transparent about its finances so that those paying royalties know how they are collected and patent-holders know how they are distributed. This would be difficult within any large organization. Third and perhaps most important, the licence agreements entered into by the pool need to be legally enforceable against it by patent-holders, manufacturers and distributors. UNITAID itself has no legal capacity to enter into agreements. Other UN organisations, including WHO, WIPO, UNCTAD and UNAIDS, are immune from any legal process unless expressly waived.²⁵ Similarly, their staff is immune from legal processes.²⁶ UN organisations are extremely reluctant to enter into any agreement that would waive their immunity. Given this, it would be impossible to have a UN organization administer the pool since it would not accept the enforceability of its licence agreements in national courts. While the UN does provide for an alternative dispute resolution process,²⁷ this is unlikely to be sufficient to make the pool operational.

An independent entity outside of the United Nations systems could provide a useful way to both manage the pool and to ensure a political connection with the sponsoring agencies. In order to maintain links between the pool and its sponsor(s), we recommend that this entity enter into an MOU with the sponsoring organisation(s). While UNITAID may take the lead role in establishing the pool, it would be the WHO that actually signs the MOU on its own behalf and on behalf of UNITAID, given UNITAID's lack of legal personality. We also suggest that UNITAID approach other agencies, such as UNAIDS, UNCTAD and WIPO, to also enter into MOUs with the pool. Under these MOUs, **each of the sponsoring agencies could be given the opportunity to appoint one member to the Board of Directors.**

Pool Administration

Patent pools are generally administered in one of two ways: i) a pool administered by one of the patent-holders; or ii) a pool administered by an independent body. We examine each in turn.

The simplest administration mechanism is to have one member of the pool act as the pool administrator. All other patent-holders would then license their patents to the pool administrator who would, in turn, license the pooled patents to third parties. For example, Philips acts as the pool administrator for the DVD Patent Pool, a pool of developers of DVD-players, recorders and drives.²⁸ Similarly, the DVD 6C patent pool – consisting of DVD audio, video, ROM and RAM players and recorders – with nine separate patent-holders – is administered by Toshiba Corporation.²⁹

²⁵ *Convention of the Privileges and Immunities of the United Nations*, United Nations, Treaty Series, vol. 1, p. 15, Section 2.

²⁶ *Ibid*, Section 18.

²⁷ *Ibid*, Section 29.

²⁸ The DVD pool began when Sony and Philips announced that they would form a patent pool, with Philips as the licensor. Eventually Pioneer Electronics joined the others.

²⁹ Toshiba offers licences on packages of the patents within the pool at fixed rates per package. These rates are provided on the pool's Internet page <http://www.dvd6cla.com/royaltyrate.html>.



The second approach is to have the pool managed by an independent party. This is the case, for example, with the pool relating to video players using MPEG standards – managed by the MPEG Licensing Authority (MPEG LA). In this case, the administrator receives licences from all patent-holders and manages the licensing of the pooled patents to users. The administrator is a neutral party with no patents itself.³⁰

We recommend that the second approach, independent administration, best meets the objectives of a Medicines Patent Pool. While having one of the patent-holders administer the pool is simple, it is ill-suited to the Medicines Patent Pool because it is far from clear which party could play the role of Philips or Toshiba. The only possible candidate is a major patent-holder willing to take on responsibility for the pool, a situation that seems highly unlikely. On the other hand, an independent pool administrator offers the opportunity to provide transparency and neutrality to the licensing process.

Given that political and practical links with its sponsoring organization will be important to the success of a Medicines Patent Pool, we suggest that the pool administrator be established in Switzerland under the laws of that country. Further, to ensure the neutrality of the administrator, we recommend that it take the structure of a not-for-profit association or corporation. This entity would be governed by a Board of Directors that would set general policy and be managed by officers on a day-to-day basis. The entity would be able to enter into legally binding agreements with patent-holders, manufacturers and distributors that are enforceable through legal processes in the countries involved. It would be able to establish transparent financial reporting and be held responsible for any failure to do so.

Internal Management of the Pool

While the exact internal structure of a Medicines Patent Pool will depend heavily on how it is established and its role, we briefly outline one structure that we suggest offers flexibility and low cost.

Depending on its exact mandate, a Medicines Patent Pool could be responsible for the following activities:

- Preparation of standard form licence agreements with each of the patent-holders, manufacturers and distributors;
- Managing and enforcing licence agreements with patent-holders, manufacturers and distributors;
- Collection of royalties from manufacturers;
- Distribution of royalties to patent-holders;
- Preparation of financial statements;
- Technical assistance to countries on regulatory and licensing matters;

³⁰ The MPEG pool began through an agreement between nine patent-holders to combine the patents needed to meet an international standard. Under the agreement, the patent-holders licensed all their essential patents to a central administrative body, MPEG LA. MPEG LA then took on the responsibility of licensing the patent portfolio to third parties that then manufactured products. MPEG LA also provided expert advice on patent valuation procedures, a process to determine what patents should be added to the pool and a procedure for settling disputes. See Merges, *supra* note 23 for a discussion of the MPEG patent pool.

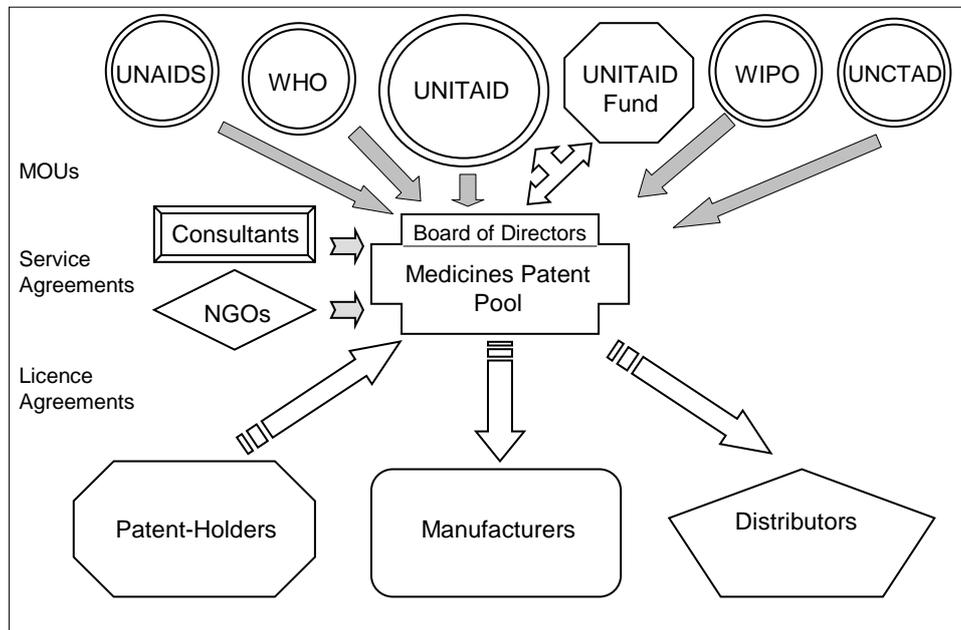
- Technical assistance to manufacturers on compliance with the WHO Prequalification Programme and national regulatory requirements;
- Monitoring, reporting and enforcement of quality standards for the manufacture of products;
- If included, funding of research and development (including clinical research);
- The sharing of research results among manufacturers; and,
- Reporting to sponsoring organization(s).

We recommend that the Medicines Patent Pool provide some of these functions internally and rely on outside parties to provide the rest. In particular, the pool should directly manage and enforce licence agreements, collect and distribute royalties, prepare financial statements, report and enforce quality standards, provide funding for research and development, share research results and report to the sponsoring organization(s). The pool should seek the assistance of its sponsoring organization(s), external consultants and non-governmental actors to prepare the licence agreements, provide technical assistance to countries and manufacturers and monitor quality standards. If the Medicines Patent Pool is established as we suggest in this Part, it will operated as set out in Figure 5.

If this recommendation is accepted, we suggest that the internal management of a Medicines Patent Pool would be small with a low overhead. For example, the pool may be able to be administered by the following staff members:

- A Chief Operating Officer, in charge of overall day-to day management of the pool who would report to the pool's Board of Directors;
- Two Vice Presidents, one in charge of the Legal Department and one in charge of accounting and country liaison who would select outside contractors and support the Chief Operating Officer;
- Two legal experts (in addition to the Vice President (Legal)) who would be responsible for entering into licence agreements (using the standard forms developed) and monitoring legal compliance with those agreements as well as general contracting with contractors, non-governmental organizations and agencies for the delivery of services;
- Two accounting officers responsible for collecting and distributing royalties as well as financial reporting;
- Three liaison officers (located in the pool's headquarters) to work with governments in each of the regions of Africa, the Caribbean and Latin America, and Asia; and,
- Three to four administrative staff.

Figure 5
Management of a Medicines Patent Pool



As noted, the actual staffing of the Medicines Patent Pool will, however, depend on its structure, the responsibilities allocated to it and the extent to which it relies on outside contractors, non-governmental organizations and UN agencies to assist it in providing services. **We recommend that a more thorough analysis of staffing, space, infrastructure and operations needs and costs be conducted prior to implementation of a Medicines Patent Pool.**

3.4 Methods to Encourage Voluntary Participation

Whichever approach a Medicines Patent Pool eventually takes to the issue of compulsory licensing, both our analysis and our interviews strongly demonstrate the preference for a pool constructed on the highest percentage of voluntary licences as possible. Ideally, all licences within the pool would be issued on a voluntary basis.

To best ensure voluntary participation in a Medicines Patent Pool, the advantages of doing so will need to be communicated to patent-holders. One of the main advantages for the industry would be a strong policy win by demonstrating that the patent system (without the need of compulsory licences) is not a barrier to access to medicines. It is no secret that industry has been heavily criticized in the press and by some non-governmental actors for its actions in making essential medicines available in developing countries. These criticisms have labeled industry interventions, from enforcement of patents to the donation of medicines, as being, at best, unsustainable to being, at worst, harmful and greedy. While industry obviously rejects these characterizations, they remain a leitmotif of current debates.

The establishment of a patent pool offers industry both a way to avoid this publicity and to gain positive news coverage. The patent pool insulates patent-holders from decisions about the manufacturing, distribution and cost of medicines. Thus, if there is criticism of how

medicines are being distributed – which is almost inevitable but likely less pronounced than before the pool– it will be aimed at the pool itself rather than at the patent-holders. While not encouraging for a pool manager, this may be a tangible benefit of voluntary participation in the pool. In addition, participating in the pool offers patent-holders (and particularly early members) an opportunity to garner positive publicity, such as favourable news coverage and congratulations by organizations such as the WHO, government leaders and even NGOs. These are important benefits to a voluntary participation in the pool.

UNITAID should also consider offsetting research and development costs involved in developing new combinations and formulation and demonstrating the safety and efficacy of existing FDCs. If this feature is incorporated into the Medicines Patent Pool, we suggest that the pool become a partner organization of UNITAID to which Fund payments can be made. The pool would then administer these funds by providing funding to manufacturers or third parties to conduct the necessary research on combination possibilities, new formulations, bioequivalence and biosafety. All research results would belong to the pool (protected as a trade secret) but would be distributed under licence to all manufacturers. Thus the research results would be a public good administered by the Medicines Patent Pool. This option offers both research-based and generic pharmaceutical companies the opportunity to obtain a reasonable return on investment (ROI) on the manufacture and distribution of these medications, providing many of the benefits of a public-private partnership. By co-funding development of medicines specifically adapted to developing country needs, the UNITAID Fund would reduce the investment necessary for any manufacturer to enter the field. Combined with better publicity, the possibility of a better ROI may lead certain companies that have moved out of conducting research in the HIV/AIDS field, such as Novartis, to return to it.

As noted by Pfizer's Chief Medical officer at a June 2007 OECD high-level forum in Noordwijk in the Netherlands, the pharmaceutical industry's current business model does not work. He suggested that far from being the exception to the way that the pharmaceutical industry conducts its business, public-private partnerships are the industry's future. The establishment of a Medicines Patent Pool, with funding provided by the UNITAID Fund to offset some of the research costs involved with putting FDCs and new formulations on the developing world market, would provide industry with an opportunity to explore these models further and to demonstrate its willingness to adapt to current market needs.

A side benefit of this approach is that it would strengthen the bargaining power of the Medicines Patent Pool. Since all data collected through the funding mechanism described above would belong to the pool, all manufacturers, including research-based pharmaceutical companies, would pay more to the pool to obtain access to that data.

In addition to this, the Medicines Patent Pool may result in higher and more reliable sources of revenues. At present, it is difficult to project the size of the actual developing world market for FDCs and new formulations of anti-retroviral medicines. This uncertainty undermines the confidence of pharmaceutical companies in entering into developing world markets.³¹

³¹ For example, Novartis expanded production of its anti-malarial drug, Co-Artem, based on what turned out to be inflated demand estimates provided by the Malaria Medicines and Supply Services of the WHO. See Prashant Yadav, Kirsten Curtis and Neelam Sekhri, *Background Paper: Mapping and Realigning Incentives in*



Through its purchasing power and working through its partners, such as the Clinton Foundation, UNITAID can provide a higher level of certainty to the market than currently exists. The pool can therefore act as a resource to manufacturers, including research-based pharmaceutical companies, that will enable them to better anticipate market demands. This is an important incentive to voluntary participation in a Medicines Patent Pool since only voluntary participants would receive this information.

Smaller companies such as Gilead Sciences, a US-based biopharmaceutical company, are more likely to see the benefits of participating in the pool than are larger companies. This is because smaller companies are often more flexible and more willing to experiment with novel business models than large companies with established structures and ways of doing business. Gilead has, for example, already non-exclusively licensed many Indian-based generic companies to produce its patented *Tenofovir* DF medicine for HIV/AIDS for sales in low-income countries. This model provides Gilead with a steady revenue source without having itself to expand production facilities while also facilitating access to its medicine. Nevertheless, Gilead's approach has not been without its critics. Knowledge Ecology International has challenged the company's licensing model as anti-competitive.³²

Despite these advantages, there are also reasons why a patent-holder would not wish to participate in a Medicines Patent Pool. One of the most important of these includes a loss of competitive advantage in developing countries by creating future competitors for the patent-holders. This is because those most likely to manufacture the medicines under the pool will be able to build expertise that would provide them with an advantage in the world market. This risk may be sufficiently important as to discourage voluntary participation in the pool.

Another worry voiced by industry representatives is that the Medicines Patent Pool could expand beyond anti-retroviral medicines. Specifically, industry is concerned that the pool may expand to cover lucrative product lines in the cancer and heart disease fields. While the Medicines Patent Pool as proposed is limited to anti-retrovirals, if the pool is successful, our interviewees believe that there will be a push to expand the pool to other medicines. They are not opposed to this as long as limits are placed on the expansion. One way to do so is by establishing clear criteria for inclusion within the pool up front along with appointing respected experts to determine whether a particular medication falls within the criteria.

A related concern is that the pool will include even high-income countries or undermine revenue sources in the higher-income developing countries. This can be easily countered by specifically excluding high-income countries from the pool (as suggested in the MSF note proposing the creation of the pool) and by instituting a royalty regime in which royalty rates are tied to the recipient country's Human Development Index. Therefore, higher income developing countries would pay higher royalties than would LDCs. In many cases, this

the Global Health Supply Chain, Centre for Global Development, available online at: <http://www.cgdev.org/doc/DemandForecasting/RealigningIncentives.pdf> (last accessed: July 14, 2007) at p. 10 who conclude that deviations between projections and actual sales have so far (in the early stages) been "extremely high."

³² See Knowledge Ecology International, *KEI request for investigation into anticompetitive aspects of Gilead Voluntary Licenses for patents on Tenofovir and Emtricitabine* available online at: <http://www.keionline.org/misc-docs/ftcgilead12feb07.pdf> (last accessed: July 14, 2007).

revenue stream will likely be higher than payments made under current compulsory licences and would otherwise consist of untapped markets.

3.5 Use of Compulsory Licenses to Ensure Contributions

If the voluntary approach does not produce desired results, it will need to be determined, at a second stage, whether compulsory licences are required. Three sets of compulsory licences would be required to operate the pool as follows:

1. In each country where there are patents covering the medicine and where manufacturing is to take place predominantly for the domestic market the government would need to issue a compulsory licence either, (i) to the **manufacturers** of the medicine for the **manufacture and sale of the medicines**; or (ii) if compulsory licences can be issued with the right to sub-license, to the Medicines Patent Pool for sub-licensing to manufacturers (depending on the relevant national law). The licence would be non-exclusive and the patent-holder would get reasonable royalties³³. A country issuing a compulsory licence predominantly for its own market could permit the export of some of the medicines without further permission.
2. In each country in which manufacturing is to take place primarily for export, the government would need (depending on national law) to issue a compulsory licence either (i) to the **manufacturers of the medicine for the manufacture, sale and export of the medicines**, or (ii) if compulsory licences can be issued with the right to sub-license, to the Medicines Patent Pool for sub-licensing to manufacturers. The country would need to wait for a request from an importing nation before doing so and the medicines would need to be differentially packaged or labeled.
3. In each country in which medicines are to be imported from another country (and in which there are patents covering the medicine), the government would need to notify the TRIPs Council (under the August 30, 2003 decision) and would need to issue a **compulsory licence permitting the import and sale of the medicines** within that country. Depending on national law, this compulsory licence would either be issued to (i) the importer or (ii) if compulsory licences can be issued with the right to sub-license, to the Medicines Patent Pool for sub-licensing to importers. Under the 2003 WTO Decision, there is no obligation for the importing country to provide compensation to the patent-holder for this licence.

As noted earlier, the process of obtaining compulsory licences is more complex than that involving only voluntarily licences. With strong coordination and assistance, this need not necessarily delay implementation of the pool but it does require more thought and effort. In order to operate through compulsory licences, the pool would have to undertake the following steps:

- a) Identify the countries in which manufacturing and importation will take place.
- b) Determine whether patents covering the desired medicines exist in those countries.

³³ What is a reasonable royalty depends on national law as there are no widely accepted standards.

- c) For each country in which manufacturing will take place for the domestic market (and in which a patent exists), the government of that country would need to issue a compulsory licence as described in point 1 above.
- d) For each country that will import the medicine and in which a patent exists, the government of that country will need to notify the TRIPs Council and to issue the compulsory licence as described in point 3 above.
- e) For each country that will manufacture medicines predominantly for export (where patents exist over the medicine), the government will need to issue a compulsory licence as described in point 2 above.

While it will be more difficult, in the case of compulsory licences, to rely on standard form licence agreements since many are needed and the national laws permitting these licences differ, the Medicines Patent Pool could help streamline the process of obtaining compulsory licences by designing standard model compulsory licences for manufacturing, for manufacturing and export and for importing medicines that countries can adapt to their local laws. In addition, the pool could speed up the process of obtaining compulsory licences by providing assistance to national governments on how to modify their laws to permit such licences and to develop procedures to quickly issue such licences. If appropriately managed, the pool can significantly reduce time delays and lack of standardization.

One long-term advantage of a patent pool based on compulsory licences is that it will assist transfer of technology and manufacturing know-how to developing country manufacturers. In the long term, this could result in greater competition and, presumably, a lowering of prices. This is a long-term goal, however, and is likely to be regarded unfavourably by existing pharmaceutical companies.

3.6 Applicable Legal Jurisdictions Under Which Licenses are Issued to the Medicines Patent Pool

The Medicines Patent Pool will operate in three sets of countries: a) the country that is home to the administrator of the pool; b) the countries in which medicines are manufactured; and c) the countries which import and buy medicines.

The law of the country in which the pool is set up will apply to the organization of the pool, the liability of directors and competition issues. As noted earlier, this is likely to be Switzerland. Since the pool will not itself operate outside its home country the laws of other states should not, in theory, apply (we assume that the pool itself will carry on no direct manufacturing or sales function). This will only be true, however, if the pool carries out no activity beyond collecting and issuing licences and royalties in its home state.

There are two sets of rules that may apply to the manufacture of medicines: those of the country in which manufacturing occurs and, indirectly, the laws of the country to which the medicines will be exported. The laws related to contracts, competition law, regulation of pharmaceutical products, patents and liability of the country in which manufacturing will occur apply directly to the manufacturer. The laws regulating the production and sale of pharmaceutical products of the importing nation will also apply to the entity importing those products who is likely to be the manufacturer. The manufacturer will be bound by the rules

applicable to the production and sale of pharmaceutical products in both its home country and the country to which the medicines will be exported.

All sales of the product in the recipient country will be governed by that country's set of laws. Thus, in addition to regulations covering the sale of pharmaceutical products, the competition laws, product liability laws and patent laws apply to those importing and selling medicines within the country.

3.7 Liability of Directors, Officers and Donors to the Medicines Patent Pool

There is a risk – small but worth addressing – that the directors and managers (and donors if they dictate how licences are to be distributed) of the Medicines Patent Pool could be held liable for the faults of the manufacturers the pool licences. This could happen, for example, if the pool selected a manufacturer that it knew or should have known, would manufacture defective products or if it failed to sanction a manufacturer that did not meet the quality standards agreed upon by the pool and the manufacturer. In this case, there is a risk that the pool and perhaps its Board of Directors, managers and (less likely) its donors could be held to be liable for harm done.

According to Swiss law (in which, for present purposes, we presume the Medicines Patent Pool will be located), directors and managers will be personally liable for their own wrongful acts or omissions while acting in their official capacity for the pool. This could, conceivably, expose the directors and managers of the pool to patent infringement, contract and product liability issues as the manufacturers and distributors of the medicines licensed by the pool where the directors and/or the managers take an active role in supervising production or distribution of medicines. Donors are likely to face liability only if the donor takes an active part in making decisions about whom to license out of the pool.

This type of risk is not unusual in manufacturing and licensing situations. It can be addressed and limited in four ways. First, given the immunity of UN agencies and of their employees, it may be possible to limit liability of the pool's staff by seconding UN employees under a MOU. **We recommend that the possibility of insulating pool staff through secondment be further investigated with the legal services departments of the various potential contributing UN agencies.** Second, the pool should ensure that appropriate mechanisms exist to ensure the supply of high quality and safe pharmaceuticals to all participating countries. This would involve contracting for monitoring services with a reputable company and by requiring that company to indemnify the pool for any loss due to a failure to appropriately monitor manufacturers licensed by the pool. Third, manufacturing and distribution licences should require the manufacturer or distributor to indemnify the pool for any problem and to purchase insurance to cover this. Fourth, the pool should itself purchase insurance to cover its, its directors' and its managers' risks.

3.8 Form of Licences With the Medicines Patent Pool

It will be critical to the operation of the patent pool that basic licensing terms and royalty rates for voluntary licences (and compulsory licences to the extent possible) be standardized. There are two reasons for this, one legal and one practical. From a legal point of view, the



Medicines Patent Pool must be implemented so as to avoid any competition law concerns. While a Medicines Patent Pool aimed at providing access to developing country patients may not seem to raise competition concerns, if the pool is not established in a transparent, objective and equal fashion, it may nevertheless fall afoul of competition law. In addition, from a practical point of view, it will not be feasible for the pool administrator to negotiate different forms of licence with each patent-holder, particularly as the scope of the pool expands. **Thus, for both legal and practical reasons, it is essential to set a standard form of licence into and out of the pool.**

Given the above, licences into the pool should be non-exclusive, encompass all countries within the reach of the pool, cover manufacturing, export, import and sale of the medicines and include a royalty regime that is standard and fair, such as by taking into account the level of development of the recipient country. Individual negotiations with patent-holders threatens to not only undermine the functioning of the pool but may give rise to competition concerns if one or a group of patent-holders obtains more favourable terms than do others. The practice of existing pools demonstrates that best practice is to pay a royalty that is standard for all patents and not to engage in a review of the particular importance of each patent within the pool. Further, patent-holders should not be permitted to licence some but not all of their relevant patents as this may lead to undue advantages. Therefore, all patent-holders participating in the pool should license all relevant patents (as determined by an expert committee) on a fixed royalty regime on a non-exclusive basis. The pool could consider the approach in Canada's essential medicines regime of tying the licence fees to the Human Development Index with a resulting royalty depending on the level of human development in the country of final sale.³⁴

³⁴ The calculation would be as follows: $(1 + [\text{the number of countries on the UNHDI list}] - [\text{the importing country's rank on the HDI list}]) / [\text{the number of countries on the UNHDI list}] * 0.04$.

4. Work Plan for Future Action to Implement a Medicines Patent Pool

Should it be decided to further examine the implementation of a Medicines Patent Pool, there will be a need to develop a strategic plan that takes into account the practical, business and legal issues involved with setting up and running the pool. In this Part, we briefly survey the issues that this plan would need to examine.

4.1 Steps to Address Legal and Business Risk

We have already recommended that, prior to any decision to establish a Medicines Patent Pool, research should be conducted on the costs of anti-retroviral medicines, on the need for FDCs and new formulations, on the costs of setting up and operating a Medicines Patent Pool, and on the possibility of insulating pool staff through secondment from UN agencies. In addition, we recommend conducting an in-depth review of patent families (Part 4.1.1.) and a thorough analysis of national law (Part 4.1.1)

4.1.1 Methodology to Conduct In-Depth Review of Patent Families

It is critical to assess the patent landscape before deciding which medicines to include in the pool and in which countries to manufacture the medicines. The landscape would consider which patents over which medicines exist in what countries. We provide a preliminary review of patents that apply to the Target Medicines in Appendix C. This review is based on publicly available information. **To develop a full picture concerning which medicines are patented where, it will be important to conduct a more thorough review of patents in each country in which manufacturing or sale is likely to take place.** This will require an examination of each country's patent register which often can only be done in person at the country's Patent Office. The examination should be conducted by a patent agent who is familiar with the language of patent claims. Ideally, that person would work with local experts who can provide a more subtle analysis of the meaning of the claims under domestic law. In conducting the examination of which patents exist, it is important to examine all patents that relate to the manufacture (so-called process patents) or sale of the medicine.

4.1.2 Methodology to Review National Laws

While this report reviewed national laws in general, it will need to be followed up by an in-depth examination of the laws of each participating country. First, it will be necessary to review national regulations applicable to the sale of pharmaceuticals in each country in which the medicines will be sold. Second, a review of the national and regional laws applicable to Switzerland and manufacturing countries will need to be undertaken. Third, it will be important to verify that the laws of the countries in which manufacturing will take place will abide by the decision to have Swiss law govern the contracts, as manufacturers will not necessarily be present in Switzerland. **These in-depth examinations of national laws will need to be undertaken by locally qualified lawyers.**

4.2 Creating the Medicines Patent Pool



Once the legal risks associated with the creation and operation of the pool are known, the pool can actually be set up. This Part examines the issues in doing so.

4.2.1 Incorporation or Creation of the Medicines Patent Pool

If, as suggested, the Medicines Patent Pool be administered by a not-for-profit corporation or association in Switzerland, the pool's sponsor would need to employ a locally qualified lawyer to prepare and file the documents necessary to do so. Article 60 of the Swiss Civil Code provides, for example, for the creation of an association to carry out activities such as those contemplated here. Whether this provides the best level of protection and flexibility will need to be determined in conjunction with a local legal expert.

Once incorporated, the Medicines Patent Pool should enter into a Memorandum of Understanding with the sponsoring organization(s) as illustrated in Figure 5 setting out its roles and responsibilities as well as the political backing of the sponsor(s).

4.2.2. Appointment of Directors and Managers for the Medicines Patent Pool

Once the corporation comes into existence, the sponsor(s) will need to appoint directors to sit on the Board of Directors of the newly formed corporation. These directors should be selected for their ability to understand financial and business practices as they will be responsible for setting the overall management direction of the corporation.

Further, we suggest that sponsoring organizations and the UNITAID Board should each appoint one member to the Board of Directors. In addition, a member of the Board of Directors should be selected from among non-governmental organizations representing patients or physicians and another be selected from among the research-based pharmaceutical companies. We further recommend that these latter two appointments *not* include individuals without personal practical experience in licensing and/or health delivery. By ensuring that the majority of the Directors are appointed by an international organization rather than an advocacy group or a private actor, the risk of conflict among the Directors is reduced.

The directors will, in turn, appoint the managers of the not-for-profit corporation including the Chief Operating Officer of the corporation. These managers have day-to-day responsibility for running the corporation, signing contracts and preparing financial reports. Only the Board of Directors has the authority, however, to set overall priorities and to approve important contracts.

4.2.3 Appointment of an Independent Expert to Review Patents in the Medicines Patent Pool

Under competition law, it is important that only those patents that are necessary for the operation of the pool be included. Given the scope of the Medicines Patent Pool – as covering narrowly defined products – it will usually be fairly obvious which patents are necessary. Nevertheless, we suggest that the corporation's Board of Directors appoint an expert who is independent from any of the patent-holders to assess whether a particular patent is necessary to the operation of the pool. This will be particularly useful if the scope of the pool expands and to ensure that a particular patent-holder contributes all relevant patents into the pool.

4.2.4 Design Mechanisms to Address Liability

Under corporate law, both the directors and the managers may be held liable for not only their own negligence but in some circumstances the negligence of anyone acting on behalf of the corporation. While unlikely given the scope of the expert's duties, it is theoretically possible that the independent expert assessing which patents are necessary for the pool could also be held liable for negligence. Once it is determined whether, through secondment from UN agencies, individual immunity liability can be attained, a decision can be made as to whether to purchase insurance (as is usual in the corporate sector) to protect the directors, managers and the expert against this liability.

4.3 Contribution of Patents to the Medicines Patent Pool

Once incorporated and the directors, managers and expert appointed, the Medicines Patent Pool will need to bring into the pool the set of patents necessary to manufacture, sell, export and import the medicines.

4.3.1 Design Methodology to Determine which Patents Need to be Included in the Medicines Patent Pool

As a first step, the Board of Directors will need to determine which medicines to include in the pool. The Board of Directors should consider establishing an expert group to advise it on these matters. Not only would this provide greater confidence to patent-holders that the pool will not expand to cover all medicines, but it would help address competition law concerns. Medicines selected on the basis of their medical indication should overcome any competition law issue over the inclusion of patents covering medicines for the same disease.

Once the list of medicines has been established, it will be necessary to evaluate which patents in particular will need to be contributed to the pool. The Board of Directors working with the group of experts will need to develop the criteria used to determine which patents are necessary for inclusion within the pool. The criteria should focus on which patents will be engaged in the manufacture and sale of medicines for the purposes of HIV/AIDS treatment.

The independent expert will then actually make the evaluation, on a case-by-case basis, of whether a particular patent fits within the criteria. The expert will also determine whether the contributing patent-holder possesses any other patents that are necessary for inclusion in the pool. This is important as, to comply with competition law, it is necessary that all contributing patent-holders provide a licence to all relevant patents.

4.3.2 Prepare Standard Form Licences

Concurrently with the creation of the list of patents to include within the pool, the Board of Directors should direct the Chief Operating Officer to have prepared the standard form voluntary licence for contribution of patents into the pool. As noted earlier, this standard form licence should be non-exclusive in scope, should include all relevant manufacturing and importing countries and provide for a clear and transparent royalty formula that does not vary from patent to patent. Tying the royalty right to the Human Development Index is one way of achieving fairness, transparency and clarity

The standard form licence agreement should be developed in conjunction with industry experts to ensure that it suits their general needs. **This could be accomplished, we recommend, by first bringing together representatives from both research-based and generic pharmaceutical companies who actually engage in licensing to discuss different licensing models.** Nevertheless, the licence terms – ideally prepared by a neutral party – must meet the needs of the Medicines Patent Pool including uniformity, transparency, royalty rates that permit the effective provision of medicines at affordable rates and royalties that take into account the different attributes of manufacturing and importing countries. Any deviation from this will seriously undermine the feasibility of the pool.

4.3.3 Investigate Mechanisms to Induce the Voluntary Contribution of Patents to the Medicines Patent Pool

The Medicines Patent Pool should work with stakeholders to identify advantages to voluntarily contributing to the Medicines Patent Pool beyond those surveyed in this review. This can be accomplished by expanding the group of people interviewed as part of the preparation of the current report.

As noted in this report, one way to induce voluntary participation in the pool is to provide funding to offset research and development costs. UNITAID or another funding agency will need to decide early on in the process of establishing the pool whether to fund research activities and how this funding will be linked to the pool's operations.

4.3.4 Design Policy Regarding the Issuance of Compulsory Licenses to Obtain Contribution to the Medicines Patent Pool

If the voluntary approach does not induce sufficient participation in the pool, the pool will need to consider whether to rely on compulsory licences to make the Medicines Patent Pool operational. If a compulsory licence is eventually required to operate the pool, each country in which manufacturing will be done will need to issue a licence to either each manufacturer in the country or to the pool (the latter only if sub-licensing is permitted). Each licence will have to be issued in conformity with the domestic law of each the countries and thus may contain different terms and conditions. Similarly, a compulsory licence will be needed from each importing nation to each importer within that country. Countries wishing to import medicines from manufacturing countries in which patents over those medicines exist will need to notify the TRIPs Council of their intention to import as required by the August 30, 2003 WTO decision.

Given the complications involved with using compulsory licences, the Medicines Patent Pool should provide countries with technical assistance on how to manage and issue compulsory licences. This should include providing countries with model language to use in these licences.

4.4 Access to Patents Within the Medicines Patent Pool

In respect of patents licensed into the Medicines Patent Pool, the not-for-profit will need to license the pooled patents to manufacturers, importers and sellers of the medicines. It should also provide technical assistance to manufacturers to apply to the WHO's Prequalification



Programme for the listing of medicines produced through the operation of the Medicines Patent Pool as well as to meet national regulatory requirements.

4.4.1 Preparation of Licence Agreements to Obtain Use of the Pooled Patents

The Chief Operating Officer should have prepared two types of licence agreement: 1) A licence to manufacture and sell a product on a non-exclusive, world-wide (except for high income countries) basis; 2) a licence to import a product into a country and sell it. These licences should be used for voluntarily licensed patents and as a resource by countries issuing compulsory licences. Given that compulsory licences are subject to the particularities of each country's regime, the terms of individual country licences will vary depending on the national laws where manufacturing or importation takes place.

4.4.2 Identify Location of Potential Licensees of Patents Within the Medicines Patent Pool

The Board of Directors should identify, based on the patent analysis described in Part 4.1.1, those countries that have manufacturing capacity but where no or few patents exist. This will simplify the operation of the pool as, in fact, no licences will be required in those countries in which no patent exists. There may, nevertheless, be some benefits to licensing manufacturers in those countries, particularly if patent-holders also provided access to manufacturing know-how that could be useful to the manufacturers. The not-for-profit corporation will need to ensure that all licences to manufacture, export, import or sell the medicines in many countries, including Nigeria, Kenya and Brazil are registered with government authorities.

4.5 Ongoing Management of the Medicines Patent Pool

Once operational, the Board of Directors should work with the sponsor to develop criteria to assess the functioning of the patent pool and its contribution to public health.

4.5.1 Design Method to Monitor the Performance of the Medicines Patent Pool

To do so, the sponsoring organization(s) and/or the Board of Directors should consult with the pool's informal group of experts and other stakeholders to jointly develop metrics that will be used to assess the short, medium and long-term performance of the pool. These metrics should measure the final price of the medications, how many people are reached by the medications, the revenues generated by the pool and the financial and practical sustainability of the pool.

4.5.2 Design Processes to Deal With Claims of Patent Infringement

Despite the best efforts of the Board of Directors of the not-for-profit corporation administering the pool, there will always remain the possibility that some patent-holder will emerge claiming that the operations of the pool or the manufacture of a medicine in a particular country violate its patent. The Board of Directors should develop a defensive strategy to address this risk.



One possible way of addressing this risk is to establish an insurance fund or seek the assistance of donors to provide such a fund (real or virtual) that will be used to defend both the not-for-profit corporation and licensed manufacturers against claims of patent infringement. The fund can be used to defray the costs of defending a legal action and to pay out any amounts in settlement of the infringement suit.

4.5.3 Create Public Relations Strategy and Public Education Programme

In order to obtain all the benefits of the Medicines Patent Pool, including the advantages for patent-holders voluntarily contributing to the pool, it will be necessary to publicize the existence of the pool and to publicize how the pool operates. The sponsoring organization(s) together with the Board of Directors should therefore develop both a public relations strategy whose aim would be to maximize the benefit to voluntary participants within the pool and an education programme to inform the general population about the pool and its benefits.

5. Overall Recommendation

Our analysis of the legal and business feasibility of the proposed Medicines 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. There is no legal reason that would prevent the establishment of a Medicines Patent Pool. While some legal hurdles will have to be surmounted, the pool's feasibility will rest more on mobilizing political will than on legal hurdles. 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.



APPENDIX A MSF NOTE TO FRANCE AND UNITAID

APPENDIX B

TIP AND AUTHOR BACKGROUNDS

TIP is a nonprofit organization based in Montreal dedicated to three goals: first, fostering the development of innovative capacity; second, the dissemination and uptake of inventions and creations that result from this innovation; and third, the development of mechanisms to ensure that benefits derived from innovation are maximized – both regionally and internationally - through the strategic use of intellectual property systems and intellectual property management. It is the Knowledge-to-Action (K2A) partner of the CIPP, a leading university research centre with partners throughout the world investigating how intellectual property (IP) systems can be designed and implemented to achieve desired social and economic outcomes. Both IP Design Solutions and the CIPP operate in both English and French and are equally expert in both common law and civil law systems.

TIP provides capacity-building and consultancy services to governments, NGOs, research organisations and industry. It advises on how best to develop, deploy and employ IP systems to meet social and economic goals. IP Design Solutions draws on the skills, research and network of the CIPP to provide flexible, effective and accountable services to the public and private sectors, primarily in low and medium income countries. This collaboration is based on a Memorandum of Understanding between the two. All revenues of IP Design Solutions are reinvested to expand its programmes.

TIP operates based on the following principles:

- **Equal capability:** We believe that every country and local community can develop an innovative capacity
- **Respect:** We are persuaded that one needs to bring together individuals with different backgrounds and experience to construct a strategy to foster innovative capacity
- **Exchange:** We have found that interdisciplinary, cross-cultural, cross-border interaction and education is critical to developing innovative capacity. These interactions add value to the policy process
- **Neutrality & Independence:** We neither promote nor dissuade the use of IP nor do we advocate for any political party or policy
- **Transparency:** Our operations and governance are transparent to stakeholders, funders and the public.

The authors of the report include the following. The team leader, Dr. Richard Gold, is Canada's leading researcher on intellectual property (IP) and innovation and the Director and co-founder of the CIPP. He is frequently sought out as a consultant to the federal and provincial governments of Canada, the World Health Organization, the World Intellectual Property Organization and the Organisation for Economic Cooperation and Development. Dr. Gold is the leader of an international research project at the CIPP investigating how policy-makers can best deploy IP to ensure access, develop a scientific infrastructure and encourage innovation. Before entering academia, Dr. Gold was a practicing lawyer with significant experience in drafting licensing contracts, joint ventures and services agreements. Prof. Gold



was lead author of a background study for the WHO on gene patents and access to health, was a member of the Scientific Review Panel of the WHO report, *Genetics, genomics and the patenting of DNA*, presented to WHO staff (including staff from the Commission Secretariat) on patents and health and has written many scholarly articles on patents, health and access including one published in the WHO Bulletin in 2004. He was also the expert consultant to the OECD's guidelines on the licensing of genetic inventions and contributed to the MIHR/PIPRA Handbook on Intellectual Property Management on strategies for joint research projects.

Prof. Tina Piper is a professor at McGill University's Faculty of Law and a key member of the CIPP. She is a leading Canadian researcher examining open science platforms including Creative Commons licences, patent pooling and similar innovative approaches to ensure that scientists in both developed and developing countries have access to needed knowledge, tools and products. Prof. Piper is organizing the CIPP's workshop on Access to Biotechnology in East Africa in conjunction with the International Centre for Trade and Sustainable Development.

Dr. Jean-Frédéric Morin is a researcher at the CIPP with an interdisciplinary background in international relations, including a dual PhD in political science and law. He heads the CIPP's project on Canada's Access to Medicines Regime and on Bilateral Trade Agreements in the IP field. Prior to joining the CIPP, he worked as a consultant for Unisféra International Centre and the Institute of International Relations and Sustainable Development. In the last three years, Dr. Morin has published eight peer-reviewed articles on various topics, including international patent lawmaking, international trade governance, and access to medicines.

Karen Durell is a researcher at the CIPP and a patent agent. She is the lead patent analyst on the CIPP's projects on examining models to deploy plant-derived vaccines to treat Hepatitis B in India and has been instrumental in developing IP Design Solutions/CIPP capacity-building courses and exchanges.

Julia Carbone is a researcher at both the CIPP and Duke University's Center for Genome, Ethics, Law & Policy. She is co-investigator on the CIPP's project examining the political context and implications of Myriad Genetic's patenting of human genes related to breast and ovarian cancer.

Elisa Henry is the Executive Director and co-founder of the CIPP with a background in international AND COMPARATIVE law. She has extensive experience in managing large-scale projects, budgets and workshops. Prior to joining the CIPP, Ms Henry was a practicing intellectual property lawyer in France.

APPENDIX C

PRELIMINARY PATENT FAMILY REVIEW

The following information describes the patent family information gathered for each of 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).

Drug/Product Information:

- The brand name information provided is drawn from *The Canadian Compendium of Pharmaceuticals and Specialties* (2006). Details of a brand name ARV product is included to offer representative information of drugs containing the specified pharmaceutical component that are manufactured for sale to the public. The brand name of drugs, the manufacturer and the details of the drugs may differ from country to country.
- The patent information listed directly below the “Patent Information” title is derived from one of the following sources: patent document disclosure; online articles; or the electronic version of the “Orange Book” (<http://www.fda.gov/cder/ob/docs/queryai.htm>).

Patent Search Methodology

An online database of national patents/applications is not available for all of the countries identified and reviewed for our research. This is true of even middle developed countries, such as South Africa. Furthermore, there are problems with some of the available national online patent search resources, for example: language barriers prevent use of some of the existing national online patent resources (e.g. Brazil offers its database in Portuguese); some search tools have limited search options (e.g. India you can only search by title, inventor, application or IP classification); some databases do not available access to the patent/application document; other databases were not accessible (e.g, I could not access the database Thailand offers). Thus, a collection of online resources is utilized in our review to search of the existence of relevant patents in all selected countries, as explained below.

1. PCT Database

- Available at: <http://www.wipo.int/pctdb/en/>
- The review included a search for applications having a national filing in one of the selected countries and either matching the title of the base patent for the drug, if one is identified, or listing the active component (pharmaceutical compound) in the description.
- Patent applications found through this search method were then reviewed to ensure the disclosure is relevant to the ARV drug, and does not merely reference the drug compound in an off-hand manner.

- The eight countries are identified by the following codes in the PCT database: India (IN); Kenya (KE); Brazil (BR); South Africa (ZA); Thailand (TH); Cameroon (CM); Mali (ML); Nigeria (NG).
2. Espacenet Database
 - Available at: http://ep.espacenet.com/advancedSearch?locale=en_ep
 - The review included a search for patents either matching the title of the base patent for the drug, if one is identified, or for patents having the pharmaceutical compound name in the title or abstract of the patent.
 - From this list the patents which are for the pharmaceutical compound (as opposed to those patents that merely reference the pharmaceutical compound) are identified through a review of the disclosure.
 - The patent family listed for each of the patents identified as claiming the pharmaceutical compound were reviewed to identify patents or applications filed in each of the selected countries.
 3. NIC Database
 - Available at: <http://patinfo.nic.in/main.php>
 - The data available in this database includes patent applications filed through the Patent Cooperation Treaty (PCT), patents published by African Intellectual Property Organisation (ARIPO), European Patent Office (EPO), Organisation Africaine de Propriété Intellectuelle (OAPI) and the countries of Argentina, Austria, Australia, Belgium, Brazil, Bulgaria, Canada, Czech Republic, China, Croatia, Cuba, Cyprus, Denmark, Egypt, Finland, France, Germany, Greece, Hong Kong, Hungary, India, Ireland, Israel, Italy, Japan, Kenya, Latvia, Lithuania, Luxembourg, Malawi, Malaysia, Malta, Mexico, Moldova, Singapore, Mongolia, Monaco, New Zealand, Netherlands, Norway, Philippines, Poland, Portugal, Rep. of Korea, Romania, Russia, Spain, Sweden, Slovenia, Slovakia, South Africa, Switzerland, Turkey, United Kingdom, U.S.S.R, U.S.A., Vietnam, Yugoslavia, Zambia and Zimbabwe.
 - The available search parameters are limited in this database to: Title; Inventor; Applicant/Assignee; and I.P. Classification. The patent document cannot be reviewed.
 - The review included a search by Title (using PCT title, or titles known to be utilized in Canada or the US), Inventor (using inventors listed on PCT application or known from Canadian or US patents), Applicant/Assignee (using known manufacturers of the drug).
 - This database searches by set year ranges.
 4. Google Search
 - The review included a search of the Google search engine using a search string comprised of the ARV pharmaceutical compound, the country name and “patent”.
 - In some cases this provided reference to the existence of a patent for the ARV pharmaceutical compound in the relevant country at some point in the past. Where

such information was located and other evidence of a drug patent was not found for a particular country the google search information is indicated in the data-set.

- Please note: Existence of a patent over the drug at one point does not necessarily mean there is still a patent for the drug in the selected country at this time.

General Comments Regarding the ARV Patent Data-Set

- This data-set provided by no means represents all of the patents existing for the selected ARVs in the identified countries. It merely represents what the researcher was able to locate using the available online resources in the time allowed to complete this search.
- It is not possible to produce a complete list because the patent database tools are insufficient to achieve accuracy that such a task requires (e.g. example problems: the databases do not offer full patent information; the databases are not complete; not all countries are included in the databases; etc.).
- Thus, where a country is identified as “No Match Found” this does not necessarily mean that a patent for the ARV pharmaceutical compound is not filed in that nation’s patent office. It merely means that the tools utilized in the search were unable to identify a matching patent.
- In some countries, such as South Africa, there are multiple products for each drug component, thus compiling a complete list of ARV drug patents may provide to be a lengthy task for some countries.
- To obtain a complete list of patents available it will be necessary to ask each country’s patent office to complete a manual search of their patent documents for relevant patents.
- Where relevant, the data-set indicates if a patent is part of a patent family stemming from a PCT application.
- India may be unable to produce a complete listing of relevant patents at this time as it may still be behind in identifying valid patents held nationally due to the black box system imposed as it adopted the TRIPs agreement.
- The identified matching patents are for a use of the drugs on the list. The listed matches do not necessarily identify the primary patent or source of a family of patents for the ARV drug. (This is due in part to the fact that not all the databases utilized provide a copy of the patent document for review. Without this information it is impossible to state with confidence that all of the patents for ARV drugs included in the data-set are the primary patent.)
- South Africa is uniformly included in the countries chosen for national filings from PCT applications. No other selected country has this distinction.

EFAVIRENZ

Brand Name Product Information *

SUSTIVA *Efavirenz*. (manufactured by Bristol-Myers Squibb)

* This information is from *The Canadian Compendium of Pharmaceuticals and Specialties* (2006).

Pharmacology: Efavirenz is a selective non-nucleoside reverse transcriptase (RT) inhibitor of human immunodeficiency virus type 1 (HIV-1). Efavirenz is predominantly a noncompetitive inhibitor of HIV-1 RT. HIV-2 RT and human cellular DNA polymerases α , β , γ , and δ are not inhibited by concentrations of efavirenz well in excess of those achieved clinically.

Patent Information

PCT Application: WO1999/064048

INHIBITORS OF HIV REVERSE TRANSCRIPTASE

India

There is evidence that a patent is issued for this pharmaceutical compound in India.³⁵

Kenya

No Match Found

Brazil

At least one matching patent is issued:

Example match: BR9908810

Filed: December 19, 2000

Title: Formulation of Fast-Dissolving Efavirenz Capsules or Tablets Using Super-Disintegrants

There is a patent for Efavirenz in Brazil. It is held by Merck Sharp & Dohme³⁶ and has been given the brand name Storcrin

South Africa

Multiple matching patents exist

Example match: ZA200004558

Filed: August 31, 2000 (national filing for PCT WO1999/064048)

Title: Inhibitors of HIV Reverse Transcriptase

Thailand

There is a patent for Efavirenz in Thailand. It is held by Merck. The Thai government issued a compulsory license for the patent in December 2006.^{37, 38}

Cameroon

No Match Found

Mali

³⁵ <http://www.i-base.info/wcab/PDF/W-CAB-Mumbai-report-jul05.pdf>

³⁶ <http://www.msnbc.msn.com/id/18490388/> Brazil has decided to ignore Merck's patent on Efavirenz and will manufacture and distribute a generic version of the drug to its population.

³⁷ http://patentcircle.blogspot.com/2007_01_01_archive.html

³⁸ http://www.evb.ch/cm_data/Referat_Jiraporn__e.pdf



No Match Found

Nigeria

No Match Found

LAMIVUDINE

Brand Name Product Information *

3TC *Lamivudine* (manufactured by GlaxoSmithKline)

Pharmacology: 3TC administered orally, in either tablet or oral solution forms, in combination with other antiretroviral agents is indicated for the treatment of HIV-infection. Tablets of 150mg and 300mg strengths are available that contain hydroxypropyl methylcellulose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, sodium starch glycolate and titanium dioxide. Oral solution is available in a 10mg/mL strength that contains the same ingredients as the tablets with the addition of black iron oxide.

Patent Information

PCT Application: W01991/017159

1,3-OXATHIOLANE NUCLEOSIDE ANALOGUES

India

No Match Found

Kenya

No Match Found

Brazil

No Match Found

South Africa

Multiple matching patents exist

Example match: ZA200005922

Filed: October 23, 2000 (national filing for PCT WO/1999/055372)

Title: Homogeneous Pharmaceutical Compositions Comprising Abacavir, Lamivudine and Zidovudine

Thailand

There is evidence that a patent is issued for this pharmaceutical compound in Thailand.³⁹

Cameroon

* This information is from *The Canadian Compendium of Pharmaceuticals and Specialties* (2006).

³⁹ http://www.evb.ch/cm_data/Referat_Jiraporn__e.pdf



No Match Found

Mali

No Match Found

Nigeria

No Match Found

LOPINA VIR-RITONAVIR HEAT STABLE

Brand Name Product Information *

KALETRA *Lopinavir-Ritonavir* (manufactured by Abbott)

Pharmacology: Lopinavir, an inhibitor of the HIV protease, prevents cleavage of the Gag-Pol polyprotein, resulting in the production of immature, non-infectious viral particles. Ritonavir inhibits the metabolism of lopinavir, thereby increasing the plasma levels of lopinavir. The antiviral activity of lopinavir/ritonavir is due to lopinavir.

Patent Information

PCT Application: WO/1992/017176

RETROVIRAL PROTEASE INHIBITING COMPOUNDS

India

There is evidence that a patent is issued for this pharmaceutical compound in India.⁴⁰

Kenya

No Match Found

Brazil

At least one matching patent is issued and is identified as part of the patent family for the “Retroviral Protease Inhibiting Compounds” patent:

Example match: BR1100397
Filed: April 11, 2000
Title: [Compostos para inibir proteases retrovirais](#)

South Africa

Multiple matching patents exist

Example match: ZA 200700101
Filed: January 3, 2007 (national filing for PCT WO/2006/014282)
Title: Prodrugs of HIV Protease Inhibitors

Thailand

* This information is from *The Canadian Compendium of Pharmaceuticals and Specialties* (2006).

⁴⁰ <http://www.i-base.info/wcab/PDF/W-CAB-Mumbai-report-jul05.pdf>



A patent has been issued for Lopinavir-Ritonavir in Thailand. The Thailand government issued a compulsory license for this drug as of January, 2007.⁴¹

Cameroon

No Match Found

Mali

No Match Found

Nigeria

No Match Found

RITONAVIR HEAT-STABLE

Brand Name Product Information *

NORVIR & NORVIR SEC *Ritonavir* (manufactured by Abbott)

Pharmacology: Norvir (ritonavir) is an inhibitor of HIV protease with activity against HIV. Ritonavir is an orally active peptidomimetic inhibitor of both the HIV-1 and HIV-2 proteases. Inhibition of HIV protease renders the enzyme incapable of processing the gag-pol polyprotein precursor which leads to the production of HIV particles with immature morphology that are unable to initiate new rounds of infection. Ritonavir has selective affinity for the HIV protease and has little inhibitory activity against human aspartyl proteases.

Patent Information

PCT Application: WO/1992/017176

RETROVIRAL PROTEASE INHIBITING COMPOUNDS

India

No Match Found

Kenya

No Match Found

Brazil

At least one matching patent is issued and is identified as part of the patent family for the “Retroviral Protease Inhibiting Compounds” patent:

Example match: BR1100397

Filed: April 11, 2000

Title: [Compostos para inibir proteases retrovirais](#)

⁴¹ http://patentcircle.blogspot.com/2007_01_01_archive.html

* This information is from *The Canadian Compendium of Pharmaceuticals and Specialties* (2006).



South Africa

Multiple matching patents exist

Example match: ZA 200601718

Filed: February 27, 2006 (national filing for PCT WO/2005/039551)

Title: Solid Pharmaceutical Dosage Form Comprising an HIV Protease Inhibitor Solid Dispersion

Thailand

No Match Found

Cameroon

No Match Found

Mali

No Match Found

Nigeria

No Match Found

ATAZANAVIR/RITONAVIR

See above for RITONAVIR

Brand Name Product Information*

REYATAZ *Atazanavir Sulfate* (manufactured by Bristol-Myers Squibb)

Pharmacology: Reyataz administered orally in the form of capsules of 150mg or 200mg. Reyataz (atazanavir sulfate) is indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection.

Patent Information

PCT Application: WO/1997/040029

ANTIVIRALLY ACTIVE HETEROCYCLIC AZAHEXANE DERIVATIVES

India

There is evidence that a patent is issued for this pharmaceutical compound in India.⁴²

Kenya

No Match Found

Brazil

* This information is from *The Canadian Compendium of Pharmaceuticals and Specialties* (2006).

⁴² <http://www.i-base.info/wcab/PDF/W-CAB-Mumbai-report-jul05.pdf>



At least one matching patent is issued and is identified as part of the patent family for the “[Antivirally Active Heterocyclic Azahexane Derivatives](#)” patent:

Example match: BR9701877
Filed: September 29, 1998
Title: [Antivirally Active Heterocyclic Azahexane Derivatives](#)
There is an article that suggests that a patent is issued over this drug in Brazil.⁴³

South Africa

Multiple matching patents exist

Example match: ZA 200607466
Filed: Sept. 6, 2006 (national filing for PCT WO/2005/090367)
Title: Prodrugs of Piperazine and Substituted Piperidine Antiviral Agents

Thailand

No Match Found

Cameroon

No Match Found

Mali

No Match Found

Nigeria

No Match Found

TENOFOVIR

Brand Name Product Information*

VIREAD *Tenofovir Disproxil Fumarate* (manufactured by Gilead Sciences)

Pharmacology: Viread (tenofovir disproxil fumarate) is administered orally in the form of a 300mg tablet. Viread (tenofovir disproxil fumarate) is indicated for the treatment of HIV-1 infection in combination with other antiretroviral agents in patients 18 years of age and older.

Patent Information

US Patent: 5,922,695

Antiviral phosphonmethoxy nucleotide analogs having increased oral bioavailability

India

There is evidence that a patent is issued for this pharmaceutical compound in India.⁴⁴

⁴³ <http://news.bbc.co.uk/2/hi/americas/3271031.stm>

* This information is from *The Canadian Compendium of Pharmaceuticals and Specialties* (2006).

⁴⁴ <http://www.i-base.info/wcab/PDF/W-CAB-Mumbai-report-jul05.pdf>



Kenya

No Match Found

Brazil

No Match Found

South Africa

Multiple matching patents exist

Example match: ZA 200505852

Filed: July 21, 2005 (national filing for PCT WO/2004/064845)

Title: Compositions and Methods for Combination Antiviral Therapy

Thailand

No Match Found

Cameroon

No Match Found

Mali

No Match Found

Nigeria

No Match Found

ABACAVIR

Brand Name Product Information*

ZIAGEN *Abacavir Sulfate* (manufactured by GlaxoSmithKline)

Pharmacology: Abacavir is a nucleotide analogous reverse transcriptase inhibitor. Abacavir is metabolized intracellularly to the active moiety, carbovir 5'-triphosphate (TP), a potent, selective inhibitor of HIV-1 and HIV-2, including HIV-1 isolates with reduced susceptibility to zidovudine, lamivudine, zalcitabine, didanosine and veirapine. In vitro studies have demonstrated that its mechanism of action in relation to HIV is inhibition of the HIV reverse transcriptase enzyme, an event which results in chain termination and interruption of the viral replication cycle. Abacavir shows synergy in vitro in combination with nevirapine or zidovudine. It has been shown to be additive in combination with didanosine, zalcitabine, lamivudine and stavudine.

Patent Information

PCT Application: WO/1988/009332

THERAPEUTIC NUCLEOSIDES

* This information is from *The Canadian Compendium of Pharmaceuticals and Specialties* (2006).



India

There is evidence that a patent is issued for this pharmaceutical compound in India.⁴⁵

Kenya

No Match Found

Brazil

At least one matching patent is issued and is identified as part of the patent family for the “Therapeutic Nucleosides” patent:

Example match: BR9205661

Filed: May 24, 1994

Title: [Antiviral Activity and Resolution of 2-Hydroxymethyl-5-\(5-Fluorocytosin-1-YI\)-1,3-Oxathiolane](#)

South Africa

Multiple matching patents exist

Example match: ZA 200606644

Filed: August 10, 2006 (national filing for PCT WO/2005/077050)

Title: HIV Integrase Inhibitors

Thailand

There is evidence that a patent is issued for this pharmaceutical compound in Thailand.⁴⁶

Cameroon

No Match Found

Mali

No Match Found

Nigeria

No Match Found

⁴⁵ <http://www.i-base.info/wcab/PDF/W-CAB-Mumbai-report-jul05.pdf>

⁴⁶ http://www.evb.ch/cm_data/Referat_Jiraporn__e.pdf

APPENDIX D

KEY PROVISIONS OF THE AGREEMENT ON TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS

Article 7

Objectives

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

Article 8

Principles

1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.
2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

Article 27

Patentable Subject Matter

1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.⁴⁷ Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.
2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or

⁴⁷ For the purposes of this Article, the terms "inventive step" and "capable of industrial application" may be deemed by a Member to be synonymous with the terms "non-obvious" and "useful" respectively.

morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

3. Members may also exclude from patentability:
 - (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;
 - (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

Article 30

Exceptions to Rights Conferred

Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

Article 31

Other Use Without Authorization of the Right Holder

Where the law of a Member allows for other use⁴⁸ of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

- (a) authorization of such use shall be considered on its individual merits;
- (b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme

⁴⁸ "Other use" refers to use other than that allowed under Article 30.

urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;

- (c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;
- (d) such use shall be non-exclusive;
- (e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;
- (f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;
- (g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;
- (h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;
- (i) the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;
- (j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;
- (k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;

- (l) where such use is authorized to permit the exploitation of a patent ("the second patent") which cannot be exploited without infringing another patent ("the first patent"), the following additional conditions shall apply:
 - (i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;
 - (ii) the owner of the first patent shall be entitled to a cross-licence on reasonable terms to use the invention claimed in the second patent; and
 - (iii) the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.

Article 33

Term of Protection

The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date.

Article 70

Protection of Existing Subject Matter

8. Where a Member does not make available as of the date of entry into force of the WTO Agreement patent protection for pharmaceutical and agricultural chemical products commensurate with its obligations under Article 27, that Member shall:

- (a) notwithstanding the provisions of Part VI, provide as from the date of entry into force of the WTO Agreement a means by which applications for patents for such inventions can be filed;
- (b) apply to these applications, as of the date of application of this Agreement, the criteria for patentability as laid down in this Agreement as if those criteria were being applied on the date of filing in that Member or, where priority is available and claimed, the priority date of the application; and
- (c) provide patent protection in accordance with this Agreement as from the grant of the patent and for the remainder of the patent term, counted from the filing date in accordance with Article 33 of this Agreement, for those of these applications that meet the criteria for protection referred to in subparagraph (b).

APPENDIX E REVIEW OF NATIONAL LAWS

	PATENTABLE SUBJECT MATTER	TERM OF PATENT PROTECTION	RIGHTS CONFERRED BY PATENT	ENFORCEMENT PROCEDURES
BRAZIL	<ul style="list-style-type: none"> An invention is patentable if it is novel, involves an inventive step, and has an industrial application. (Industrial Property, Law, 14/05/1996, No. 9.279, (hereinafter IPL) Art. 8.) An object of practical use is patentable as utility model if it is susceptible of industrial application, has a new form or arrangement, and involves an inventive act, that results in functioning improvement in its use or manufacture. (IPL, 14/05/1996, No. 9.279, Art. 9.) <p>Exceptions from Patentability</p> <ul style="list-style-type: none"> Discoveries, scientific theories, and mathematical methods, purely abstract conceptions, commercial, 	<ul style="list-style-type: none"> An invention patent lasts for 20 years and a utility model patent for 15 years from the date of filing. (IPL 14/05/1996, No. 9.279, Art. 40.) The term will not be less than 10 years for an invention patent and 7 years for a utility model patent, beginning on the date of granting, unless the INPI has been prevented from examining the merits of the 	<ul style="list-style-type: none"> A patent confers on its titleholder the right to prevent a third party from, without his consent, producing, using, offering for sale, selling or importing for these purposes: a product that is the object of the patent; a process or a product directly obtained by a patented process. (IPL, 14/05/1996, No. 9.279, Art. 42.) The patent holder is further assured the right to prevent third parties from contributing to the perpetration by others of the acts referred to in this Article.(IPL, 14/05/1996, No. 9.279, Art. 42). 	<p>Infringement (IPL s. 183-186)</p> <ul style="list-style-type: none"> Patent infringement actions must be filed in state court and are tried without a jury. Infringement may be a civil or criminal wrong <p>Civil Penalties</p> <ul style="list-style-type: none"> Damages (value of the lost benefit) or injunction (awarded on a case-by-case basis). <p>Criminal Penalties</p> <ul style="list-style-type: none"> Damages (a fine or compensation equivalent to the value of the lost benefit), an injunction or imprisonment (maximum one year).

	<p>accounting, financial, educational, advertising, raffling, and inspection schemes, plans, principles or methods, literary, architectural, artistic and scientific works, or any aesthetic creation, computer programs, presentation of information, rules of games, surgical techniques and methods, as well as therapeutic or diagnostic methods, for application to human or animal body. (IPL, 14/05/1996, No. 9.279,</p> <p>All or part of natural living beings and biological materials found in nature, even if isolated therefrom, including the genome or germoplasm of any natural living being, and the natural biological processes. (IPL)</p>	<p>application by a proven pending judicial dispute or for reasons of force majeure. (ipl, 14/05/1996, No. 9.279, Art. 40.)</p>		<ul style="list-style-type: none"> • In the case of an injunction, the patentee must demonstrate that they hold a good right (worth protecting) and that without immediate action, the right is likely to be severely damaged.
INDIA	<ul style="list-style-type: none"> • Any invention or technology which has not been anticipated by publication in any document or used in the 	<p>The term is 20 years for any patent that has not expired or ceased to have effect on May 20th 2003, subject to</p>	<ul style="list-style-type: none"> • Where the subject matter of the patent is a product, the exclusive right to prevent third parties, who do not 	<ul style="list-style-type: none"> • Infringement suit cannot be instituted in any court inferior to a district court having jurisdiction to try the

	<p>country or elsewhere in the world before the date of filing of patent application with complete specification, i.e. the subject matter has not fallen in public domain or that it does not form part of the state of the art. (Patents (Amendment) Act, 2005, s. 1.)</p> <ul style="list-style-type: none"> • DNA is patentable as of January 1, 2005. <p>Exceptions</p> <ul style="list-style-type: none"> • Frivolous invention (Patents Act 1970, s. 3 (a); Inventions that are contrary to public order or morality or which cause serious prejudice to human, animal or plant life or health or to the environment. Patents (Amendment) Act, 2002, s. 4 (a); scientific principles or the formulation of an abstract theory or discovery of any living thing or non-living substance occurring in nature. 	<p>the payment of the regulatory fees. Patents (Amendment) Act, 2002, s. 27.</p>	<p>have his consent from the act of making, using, offering for sale, selling or importing for those purposes the product in India. Patents (Amendment) Act, 2002, s. 25.</p> <ul style="list-style-type: none"> • Where the subject matter of the patent is a process, the exclusive right to prevent third parties, who do not have his consent, from the act of using that process, and from the act of using, offering for sale, selling or importing for those purposes the product obtain directly by that process in India. Patents (Amendment) Act, 2002, s. 25. 	<p>suit. Patent Act, s. 104, 1970.</p> <p>Damages</p> <ul style="list-style-type: none"> • A court may grant the following relief: either damages or an account of profits. • The courts may also direct that the goods which are found to be infringing and materials and implement, the predominant use of which is in the creation of infringing goods, shall be seized, forfeited or destroyed, as the court deems fit under the circumstances of the case without payment of any compensation. Patent Act, 1970, s. 108 & Patents (Amendment) Act, 2002, s. 45. • In order to be awarded damages or an account of profit, the infringement must
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	<p>Patents Act 1970, s. 3 (c) & Patents (Amendment) Act, 2002, s. 4 (b); a new form of a known substance which does not result in the enhancement of the known efficacy of that substance; any new property or new use for a known substance or use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant. Patents (Amendment) Act, 2005, s. 3 (d).</p> <ul style="list-style-type: none"> • Substances obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance. Patents Act 1970, s. 3 (e); Arrangement, re-arrangement or duplication of known devices each functioning independently in a known way. Patents Act 1970, 			<p>have been intentional. Patent Act, 1970, s.111.</p> <p>Injunction</p> <p>A patent holder may obtain an injunction in any infringement proceeding Patent Act, 1970, s. 108.</p>
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	<p>s. 3 (f); Methods of agriculture or horticulture. Patents Act 1970, s. 3 (h); Processes for the medicinal, surgical, curative, prophylactic, diagnostic, therapeutic or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products. Patents Act 1970, s. 3 (i) & Patents (Amendment) Act, 2002, s. 4 (d).</p> <ul style="list-style-type: none"> • Plants and animals in whole or any part thereof other than micro-organisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals. Patents (Amendment) Act, 2002, s. 4 (e); Mathematical equations, business methods and computer programs (Patents (Amendment) Act, 2002, s. 4 			
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	<p>(e)); Literary, dramatic, musical or artistic work or any other aesthetic creation including cinematographic works and television productions. Patents (Amendment) Act, 2002, s. 4 (e); A scheme or rule or method of performing mental act or method of playing game. Patents (Amendment) Act, 2002, s. 4 (e); Presentation of information. Patents (Amendment) Act, 2002, s. 4 (e); Topography of integrated circuit. Patents (Amendment) Act, 2002, s. 4 (e); Inventions which are in effect traditional knowledge or an aggregation or duplication of known properties of traditionally known component or components.</p>			
<p>THAILAND</p>	<ul style="list-style-type: none"> • “Any innovation or invention which creates a new product or process, or any improvement of a known 	<ul style="list-style-type: none"> • Invention patents: 20 years from date of filing (PA. art.35) • Petty patents: 6 	<ul style="list-style-type: none"> • Section 36 of the PA defines patent holders’ rights. • Petty patent holders and invention patent holder rights 	<p>Infringement Proceedings</p> <ul style="list-style-type: none"> • In order to enforce patent rights, the patent holder may file a criminal complaint

	<p>product or process.” Patent Act B.E. 2522 (A.D. 1979) amended by Patent Act (No.2) B.E. 2535 (A.D. 1992) and Patent Act (No. 3) B.E. 2542 (A.D. 1999), art. 5 (hereinafter PA).</p> <ul style="list-style-type: none"> • A process is defined as “any method, art or process of producing, maintaining or improving the quality of a product, including the application of such process.” (PA, art.3) 	<p>years followed by two renewable periods of two years each (10 years total). (PA 65<i>septies</i>.)</p>	<p>are identical</p> <ul style="list-style-type: none"> • Where the subject matter of a patent is a product, the patentee has an exclusive right to “produce, use, sell, have in the possession for sale, [offer] for sale or import the patented product.” • Where the subject matter of a patent is a process, the patentee has an exclusive right to “use the patented process, to produce, use, sell, have in the possession for sale, offer for sale or import the product produced by the patented process.” • Only patent holders may use “Thai Patent” or “Thai Petty Patent” on their product, packaging and marketing materials. 	<p>with local authorities or with the Intellectual Property and International Trade Court.</p> <ul style="list-style-type: none"> • Patent cases are heard by the Intellectual Property and International Trade Court and governed by Rules for Intellectual Property and International Trade Cases B.E. 2540 (1997). • Burden (presumption) shifting takes place; “In a civil case in respect of the infringement of the rights of the owner of a patent or petty patent where the subject matter of the patent or petty patent is a process for obtaining a product, if the owner of the patent or petty patent can prove that the defendant’s product is identical or similar to the product obtained by the process under the patent or petty patent, it shall be
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				<p>presumed that the defendant has used the process under the patent or petty patent unless the defendant can prove otherwise.”</p> <ul style="list-style-type: none"> • Remedies are provided for by PA B.E. 2522, Section 77. <p>Sanctions (PA, Chapter IV)</p> <ul style="list-style-type: none"> • Criminal and civil penalties. • Fines and imprisonment up to 2 years and the loss of infringing goods. <p>Damages (PA, Chapter IV)</p> <ul style="list-style-type: none"> • Half of any criminal fines go to the patent holder. • Recovery of criminal fines does not reduce the damages available to the plaintiff in a civil action for infringement. • Damages in civil cases are, “in an amount deemed
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				<p>appropriate by the court, taking into consideration the gravity of the injury including the loss of benefits and expenses necessary to enforce the rights of the owner of the patent or petty patent.”</p> <p>Injunction (PA, Chapter IV)</p> <ul style="list-style-type: none"> • Injunctions are available in cases where, “there is clear evidence that any person is committing or about to commit any act in infringement.” • The granting of the injunction has no impact on the available damages.
KENYA	<ul style="list-style-type: none"> • According to <i>The Industrial Property Act, 2001</i> (hereinafter IPA), s. 2: “invention” means a new and useful art (whether producing a physical effect or not), process, machine, manufacture or composition of 	<ul style="list-style-type: none"> • The standard term is 20 years from the filing date subject to the payment of the annual fees. (ss. 60 & 61 of IPA) 	<p>When a patent is granted for a product the owner can prevent others from:</p> <p>1) making, importing, offering for sale, selling and using the product; (s. 54(1)(a)(i) IPA)</p>	<p>Available Remedies</p> <p>Section 55 of the IPA gives the owner the following enforcement rights in the case of infringement:</p> <ul style="list-style-type: none"> • An injunction against the performance or likely performance of an act that

	<p>matter which is not obvious, or any new and useful improvement thereof which is not obvious, capable of being used or applied in trade or industry and includes an alleged invention.</p> <ul style="list-style-type: none"> • Section 21(1) of the IPA states that: “invention” means a solution to a specific problem in the field of technology. <p>Exclusions from Patentable Subject Matter:</p> <ul style="list-style-type: none"> • “Discoveries, scientific theories and mathematical methods”; (<i>IPA, 2001, s. 21(3)(a)</i>) • “Schemes, rules or methods for doing business, performing purely mental acts or playing games”; (<i>IPA, s. 21(3)(b)</i>) • “Methods for treatment of the human or animal body by surgery or therapy, as well as diagnostic methods practiced in relation thereto, except products for use in any such 		<p>2) stocking such product for the purposes of offering it for sale, selling or using the product; (s. 54(1)(a)(ii) IPA)</p> <p>When the patent is granted for a process the owner can prevent others from:</p> <p>1) making, importing, offering for sale, selling and using the product; (s. 54(1)(a)(i) of the <i>IPA</i>)</p> <p>2) stocking such product for the purposes of offering it for sale, selling or using the product; (s. 54(1)(a)(ii) of the <i>IPA</i>)</p> <p>3) To conclude license contracts (subject to the restrictions contained in the <i>Act</i>). (s. 53(1)(c) of the <i>IPA</i>)</p>	<p>will infringe the patent;</p> <ul style="list-style-type: none"> • A claim to damages from someone who, with knowledge of the patent, performs any of the acts reserved to the owner of the patent without the owner’s consent; • Finally, an owner can claim compensation from someone who performs any of the inventions as if they had a patent, if they had known that the invention was patented or had received written notice to that effect.
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	<p>methods”; (<i>IPA</i>, s. 21(3)(c))</p> <ul style="list-style-type: none"> • “Mere presentation of information”; (<i>IPA</i>, s. 21(3)(d)) • “Public health related methods of use or uses of any molecule or other substance whatsoever used for the prevention or treatment of any disease which the Minister responsible for matters relating to health may designate as a serious health hazard or as a life threatening disease”; (<i>IPA</i>, s. 21(3)(e)) • “Plant varieties as provided for in the Seeds and Plant Varieties Act, but not parts thereof or products of biotechnological processes”; (<i>IPA</i>, s. 26(a)) • “Inventions contrary to public order, morality, public health and safety, principles of humanity and environmental conservation.” (<i>IPA</i>, s. 26(b)) 			
NIGERIA	<ul style="list-style-type: none"> ○ An invention is patentable if it is new, results from inventive activity and is capable of 	<ul style="list-style-type: none"> • S. 7(1) PDA states that a patent will be good for 20 years 	<ul style="list-style-type: none"> • A patent on a product gives the holder exclusive rights to import, produce, sell, or 	<p>Infringement (s.25 PDA)</p> <ul style="list-style-type: none"> • The rights of a patentee are

	<p>industrial application. (s. 1(1)(a) <i>Patent and Designs Act, 1970</i> (hereinafter PDA))</p> <p>Exempt from Patenting</p> <p>Plant or animal varieties, essential biological processes; Inventions whose exploitation would be contrary to public order or morality. (s. 1(4) <i>PDA</i>)</p> <p>-</p>	<p>following the date of filing and subsection (2) makes this term dependent on the payment of annual fees.</p>	<p>stock for sale or use, while a patent on a process gives the holder exclusive rights to apply the process as well as exclusive rights to do any of the previously mentioned acts with products produced by the process. (s.6(1) <i>PDA</i>)</p>	<p>infringed if another person, without the licence of the patentee, does or causes the doing of any act that the patent covers</p> <ul style="list-style-type: none"> • Infringement is actionable at the suit of the patentee • An infringement action may give rise to damages, injunction, accounts or otherwise shall be available to the plaintiff as is available in any corresponding proceedings in respect of the infringement of other proprietary rights. • If a patent has been granted in respect of a process for the manufacture of a new product; and the same product is manufactured by a person other than the patentee, the product shall in the absence of proof to the contrary be presumed to have been manufactured by that process.
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<p>SOUTH AFRICA</p>	<ul style="list-style-type: none"> • Any new invention that involves an inventive step and is capable of being used or applied in trade or industry or agriculture (Patents, Act (Consolidation), 26/01/1978 (1996), No.57(No.49) sec 25(1) (hereinafter PA) • A discovery, scientific theory, mathematical method, a literary, dramatic, musical or artistic work r any other aesthetic creation, a scheme, rule or method for performing a mental act, playing a game or doing business, a computer program and presentation of information is not patentable (PA. sec 25(2)) • Methods of medical treatment and surgery are not patentable (PA. sec11) 	<ul style="list-style-type: none"> • The duration of a patent shall be 20 years from the date of application (PA, sec 46(1)) 	<ul style="list-style-type: none"> • right to exclude other persons from making, using, exercising or disposing of the invention, so that he shall have and enjoy the whole profit and advantage accruing by reason of the invention. (PA, sec 45) 	<p>Infringement (PA. Chapter XI)</p> <ul style="list-style-type: none"> • An infringement action can only be instituted nine months after the seal (publication) of the patent (PA, sec 44(4)) • Infringement may be remedied by an interdict; delivery up of any infringing product or any article or product of which the infringing product forms an inseparable part; and damages (may be calculated on the basis of the amount of a reasonable royalty which would have been payable by a licensee or sub-licensee in respect of the patent concerned). • In any proceedings for infringement the defendant may counterclaim for the
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	<ul style="list-style-type: none"> • Any invention exploitation of which would be deemed to encourage offensive or morally repugnant behavior. • For any variety of plant or animal or any biological processes for the production of plants or animals, not being a microbiological process or the product of any such process 			<p>revocation of the patent and, by way of defence, rely upon any ground on which a patent may be revoked</p> <ul style="list-style-type: none"> • patentee shall not be entitled to recover damages in respect of infringement of a patent from a defendant who proves that at the date of the infringement he was not aware, and had no reasonable means of making himself aware, of the existence of the patent, • A commissioner may make a declaration that the use by any person of any process, or the making or use or sale by any person of any article, does not constitute patent infringement, notwithstanding that no assertion to the contrary has been made by the patentee or licensee, if it is proved- (a) the person attempted
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				<p>and failed to get such a declaration from the patent owner or the exclusive licensee.</p> <ul style="list-style-type: none"> • Remedies exist for groundless threats of infringement proceedings (s.70)
CAMEROUN	Cameroon and Mali both adhere to the Agreement Revising the Bangui Agreement of March 2, 1977, on the Creation of an African Intellectual Property Organization (Bangui (Central African Republic), February 24, 1999)	SEE MALI (<i>Agreement Revising the Bangui Agreement</i>)	SEE MALI (<i>Agreement Revising the Bangui Agreement</i>)	SEE MALI (<i>Agreement Revising the Bangui Agreement</i>)
MALI	<p>Invention</p> <ul style="list-style-type: none"> - Article 2(1) of Annex I of the <i>Agreement Revising the Bangui Agreement</i> (hereinafter the <i>RBA</i>) states: “An invention that is new, involves and inventive step and is 	<p>Duration</p> <p>The duration is 20 years from the filing date of the application, subject to payment of fees. (Art. 9 RBA)</p>	<p>Rights Conferred by the Patent</p> <ul style="list-style-type: none"> - The exclusive right to work the patented invention; - The right to prevent others from working the invention; 	<p>Fines and Criminal Punishment</p> <p>The <i>Revised Bangui Agreement</i> includes states that any infringement will be punished with a fine of 1,000,000 (approx. 2050 US dollars) to 3,000,000 (6150 US dollars) CFA francs (Central African francs) without prejudice</p>

	<p>industrially applicable may be the subject of an invention patent (hereinafter called “patent”).”</p> <ul style="list-style-type: none"> - Article 2(2) RBA states that an invention “may consist of or relate to a product or process or to a use thereof.” <p>Exclusions from Patentable Subject Matter</p> <ul style="list-style-type: none"> - Inventions contrary to morality/public order; - Discoveries and scientific or mathematical theories; - Plant varieties, animal species, or essentially biological processes for the breeding of plants or animals (other than micro-biological processes and the products of such processes); - Rules or methods for doing business; 		<ul style="list-style-type: none"> - For the above two rights, art. 7(3) RBA defines “working” as: “(a) where the patent has been granted for a product: (i) manufacturing, importing, offering for sale, selling and using the product, (ii) holding the product for the purposes of offering it for sale, selling it or using it; <p>(b) where the patent has been granted for a process: (i) using the process, (ii) engaging in the acts mentioned in subparagraph (a) above in relation to a product resulting directly from the use of the process.”</p> <ul style="list-style-type: none"> - Assign the patent, transfer it by succession and enter into license contracts; <p>Right to institute legal proceedings against any person who does the any of the above</p>	<p>to actual compensation of the right holder. (Article 59 RBA) Furthermore, in the case of recidivism, article 59 of the <i>Revised Bangui Agreement</i> establishes a prison sentence of one to six months.</p> <p>However, criminal prosecution under the <i>RBA</i> can only be initiated by the Office of the Public Prosecutor if an injured party complains. (Article 61 RBA)</p> <p>Seizure, Confiscation, Destruction</p> <ul style="list-style-type: none"> - Article 64 RBA allows for patent holders to apply to the courts for a seizure order on infringing materials. - Article 67 RBA establishes a strong enforcement measure as follows: “The confiscation or destruction of recognized infringing objects and, where necessary, that of the implements or tools
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	<ul style="list-style-type: none"> - Purely mental acts; - Schemes, rules, or methods for doing business; - Methods for treatment of the human or animal body by surgery or therapy, as well as diagnostic methods; - Computer programs; <p>Literary and artistic works, as well as any other aesthetic</p>		<p>acts without the patent holder's permission. (All of above contained in article 7 RBA)</p>	<p>specifically intended for their manufacture shall, even in the case of acquittal, be ordered against the infringer, the receiver, the introducer or the retailer.”</p> <p>Criminal Law</p> <ul style="list-style-type: none"> - Malian criminal law contains provisions that address directly infractions against intellectual property. Article 248 <i>Code Pénal</i> (CP) states: “Toute atteinte aux droits d’un brevet ... soit par fabrication de produit soit par l’emploi de moyens faisant l’objet du brevet ... constitue le délit de contrefaçon et est punie d’un emprisonnement de un à cinq ans et d’une amende de 50 000 à 15 000 000 de francs.” (<i>Code Pénal of Mali</i>) [Producing an object or employing a process that is the subject of a patent
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				<p>constitutes counterfeiting and can be punished by a prison sentence of one to five years and a fine of 50 000 to 150 000 Malian francs]</p> <ul style="list-style-type: none"> - Article 249 CP continues: “Les receleurs et ceux qui vendent ou introduisent sur le territoire national un ou plusieurs objets contrefaits sont punis des mêmes peines que les contrefacteurs.” (2) “En cas de récidive, outre l’amende visée à l’article précédent, une peine d’emprisonnement d’un mois à six mois pourra être prononcée.” (<i>Code Pénal of Mali</i>) [Selling or dealing in counterfeit objects attracts the same punishment as that set out for counterfeiters themselves in article 248. A second offense, in addition to the fines of article 248, will be accompanied by
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				imprisonment of one to six months.]
SWITZERLAND	<p>Invention (s.1 of the <i>Federal Law Concerning Patents of Inventions of June 25, 1954 as amended on December 19, 2003</i> (hereinafter FLPI)) Inventions, to be patentable, must be new, involve an inventive step and be industrially applicable. Pharma products are included - all fields of technology.</p> <p>Second Use Article 7c FLPI allows the patenting of known substances when a second use for them is discovered. Following is the full text of the provision:</p> <p>“Les substances ou compositions qui, en tant que telles, sont comprises dans l'état de la technique ou font l'objet d'un droit antérieur, main ne répond pas à ces conditions quant à leur</p>	20 years protection, but can get supplementary protection certificate for medicinal products. Results in 5 more years of protection. (Article 14 FLPI)	<ul style="list-style-type: none"> - A patent includes the exclusive right to use "professionally" the invention: utilization, execution, offering for sale, placing in circulation and importation for such purposes. (Article 8 FLPI) - A patent on a process protection extends to its product. (Article 8 para 3 FLPI) 	<p>Criminal Punishment Article 81 FLPI sets the criminal punishment of patent violation at one year in prison or a fine of 100 000 francs.</p>

	<p>utilisation pour la mise en oeuvre d'un méthode chirurgical ou thérapeutique ou d'une méthode de diagnostic (art. 2, let. b), sont réputées nouvelles dans la mesure où elles ne sont destinées qu'à une telle utilisation.”</p> <p>Subject Matter Excluded from Patentability</p> <ul style="list-style-type: none"> - (a) plant and animal varieties as well as essentially biological processes for the production of plant and animal varieties. However, microbiological processes and products obtained by such processes are patentable; (Article 1(a) FLPI) - (b) inventions the exploitations of which would be contrary to public order or morality; (Article 2(1) FLPI) <p>Examples of this include:</p>			
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	<ul style="list-style-type: none"> ○ procedures for cloning humans; ○ procedures that concern modifying human DNA and germinal human cells. <p>- (c) methods of surgical or therapeutic treatment and of diagnosis applied to the human or animal body. (Article 2(2) FLPI)</p>			
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	RULES ON PARALLEL IMPORTS	COMPULSORY LICENSING PROVISIONS	GOVERNMENT USE PROVISIONS
BRAZIL	<ul style="list-style-type: none"> • Once a product manufactured in accordance with a process or product patent that has been 	<ul style="list-style-type: none"> • A compulsory license may be applied for under certain circumstances. 	<ul style="list-style-type: none"> • There are no specific government use provisions

	<p>introduced onto the domestic market directly by the patentholder or with his consent (s.44 IPL), the right is exhausted</p> <ul style="list-style-type: none"> • Parallel importation of a patented article or process is never a criminal wrong but may be a civil wrong. • In the case of a compulsory license for abuse of economic power, the licensee (compulsory license) who proposes local manufacture shall be assured a period, limited to the provisions of Article 74 IPL, to import the object of the license, provided that it was introduced onto the market directly by the titleholder or with his consent. • In the case of importation to exploit a patent and in the case of importation as provided for in the preceding 	<ul style="list-style-type: none"> • The compulsory license must be exploited within one year of grant or the original patentee can file for cancellation of the license. (IPL 9 279, 1996, Article 74) <p>Abuse of a patent right (or derived economic power) (s.68 IPL)</p> <ul style="list-style-type: none"> • A compulsory license is granted if a patent holder exercises his or her rights in an abusive manner, proven pursuant to law in an administrative or judicial decision. IPL Art. 68. • In the case of a compulsory license for abuse of economic power, the licensee who proposes local manufacture is assured a period, limited to the provisions of Article 74 IPL, to import the object of the license, provided that it was introduced onto the market directly by the patent holder or with his consent. • In the case of importation to exploit a patent and in the case of importation, third parties shall also be allowed to import a product manufactured according to a process or product patent, 	
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	<p>Paragraph, third parties shall also be allowed to import a product manufactured according to a process or product patent, provided that it has been introduced onto the market by the titleholder or with his consent.</p>	<p>provided that it has been introduced onto the market by the titleholder or with his consent.</p> <p>Non-exploitation within Brazil</p> <ul style="list-style-type: none"> • Non-exploitation of the object of the patent within the Brazilian territory for failure to manufacture or incomplete manufacture of the product, or also failure to make full use of the patented process, except cases where this is not economically feasible, when importation shall be permitted. (IPL, Art. 68). <p>Market need</p> <ul style="list-style-type: none"> • A compulsory license may be granted in the case where commercialization does not satisfy the needs of the market. (IPL, Art. 68) <p>Patent dependency</p> <ul style="list-style-type: none"> • There is a situation of dependency of one patent with regard to another; the object of the dependent patent constitutes a substantial technical progress with regard to the earlier patent; and the titleholder fails to reach 	
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		<p>agreement with the patentholder of the dependent patent on the exploitation of the earlier patent. IPL, Art. 70.</p> <p>National emergency / public interest</p> <ul style="list-style-type: none"> • Provided that the patent holder or his licensee does not fulfill the need, a temporary, non-exclusive compulsory license will be granted in cases of national emergency or of public interest, as declared in an act of the Federal Executive Power, (IPL, Art. 71.) • The Compulsory Licensing Decree (Presidential Decree No. 3.201 of October 6, 1999, establishes rules concerning the granting, ex officio, of compulsory licenses in cases of national emergency and public interest provided for in Article 71 IPL) specifies that a condition of impending danger to the public, public health, nutrition, protection of the environment, as well as those conditions of primordial importance to the technological or social and economic development of the country qualify as a national emergency • The Minister of state responsible for the 	
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		<p>subject matter in question performs the act of the Federal Executive Power declaring the national emergency or the need for a compulsory licensing because of public interest</p> <ul style="list-style-type: none"> • The act establishes the term of the license and the possibility of renewal; the terms that the Union offers, particularly regarding the compensation to the titleholder and the obligation of the patent holder, if needed, to transmit necessary and sufficient information to the effective reproduction of the protected object, to the supervision of assembly and further technical and commercial aspects applicable to the case in question. • In order to determine compensation owed to the patent holder, the relevant economic and market circumstances, the price of similar products and the economic value of the authorization will be considered • The exploitation of a patent licensed in accordance with the provisions of the Decree may be performed directly by the government or by contracted third 	
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		<p>parties,</p> <ul style="list-style-type: none"> • In such cases where it might not be possible to fulfill the situations of national emergency or public interest with local production, the product may be imported provided that it was introduced onto the market directly by the patentholder or with his consent. <p>A compulsory license will not be granted when the patent holder :</p> <ol style="list-style-type: none"> 1) justifies the non-use based on legitimate reasons; 2) proves that serious and effective preparations for exploitation have been made; 3) justifies the failure to manufacture or to market on grounds of an obstacle of legal nature; <p>- Compulsory licenses shall always be granted on a non-exclusive basis, and sublicensing shall not be permitted. (art.72 IPL)</p> <p>Conditions and Procedures for grant of Compulsory License (s.73 IPL)</p>	
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		<ul style="list-style-type: none"> • The application for a compulsory license must include conditions of the license • After an application for a license has been submitted, the patent holder is notified and has 60 days within which to submit comments. If no comments are submitted, the proposed conditions are accepted as such. • An applicant for a license who alleges either abuse of patent rights, abuse of economic power or failure to exploit must attach documentation that proves it • If the application is contested, the INPI may conduct the necessary inquiries, including the establishment of a committee, which may include specialists who are not on the staff of that autarky, to arbitrate the remuneration to be paid to the titleholder. • The agencies and entities of direct or indirect, federal, state, and municipal public administration shall furnish the INPI with information as requested for purposes of assisting in the arbitration of the remuneration. 	
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		<ul style="list-style-type: none"> • In the arbitration of the remuneration, the circumstances of each case shall be considered, and it shall consider, necessarily, the economic value of the license granted. • After evidence has been gathered in the case, the INPI will decide whether or not to grant the license within 60 days 	
INDIA	<ul style="list-style-type: none"> • Patent owner has the right to control importation of the patent product/process • Importation of patented products by any person from a person who is duly authorized by the patentee to sell or distribute the product is not considered patent infringement. Patents (Amendment) Act, 2002, s. 58 	<p><i>Compulsory Licence for Export</i> (s.55 Patents (Amendment) Act, 2002)</p> <ul style="list-style-type: none"> • Compulsory licences are available for manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems, provided compulsory licence has been granted by such country or such country has, by notification or otherwise, allowed importation of the patented pharmaceutical products from India. • On receipt of the application, the Controller will grant a compulsory licence 	<p>47. The grant of the patent under this Act is subject to the condition that:</p> <p>(1) any machine, apparatus or other article in respect of which the patent is granted or any article made by using a process in respect of which the patent is granted, may be imported or made by or on behalf of the Government for the purpose merely of its own use; (s.47(1) Patents, Act, 19/09/1970, No. 39 (Patent Act 1970).</p> <p>(2) any process in respect of which the patent is granted may be used by or on behalf of the Government for the purpose merely of its own use s.47(1) Patent Act 1970)</p>

		<p>solely for manufacture and export of the concerned pharmaceutical product to such country under such terms and conditions as may be specified and published by him.</p> <p><i>Compulsory Licences</i></p> <ul style="list-style-type: none"> Any interested person may apply for a compulsory licence, include a licensee (Patents Act, 1970). <p>At any time after the expiration of three years from the date of the sealing of a patent, any person interested may make an application to the Controller alleging that the reasonable requirements of the public with respect to the patented invention have not been satisfied or that the patented invention is not available to the public at a reasonable price and praying for the grant of a compulsory licence to work the patented invention.</p> <p>(2) An application under this section may be made by any person notwithstanding that he is already the holder of a licence under the patent and no person shall be stopped from alleging that the reasonable requirements of the public with respect to the patented invention are</p>	<p>(3) any machine, apparatus or other article in respect of which the patent is granted or any article made by the use of the process in respect of which the patent is granted, may be made or used, and any process in respect of which the patent is granted may be used, by any person, for the purpose merely of experiment or research including the imparting of instructions to pupils; s.47(1) Patent Act 1970)</p> <p>(4) in the case of a patent in respect of any medicine or drug, the medicine or drug may be imported by the Government for the purpose merely of its own use or for distribution in any dispensary, hospital or other medical institution maintained by or on behalf of the Government or any other dispensary, hospital or other medical institution which the Central Government may, having regard to the public service that such dispensary, hospital or medical institution renders, specify in this behalf by notification in the Official Gazette. s.47(1) Patent</p>
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		<p>not satisfied or that the patented invention is not available to the public at a reasonable price by reason of any admission made by him, whether in such a licence or otherwise or by reason of his having accepted such a licence.</p> <p>(3) Every application under sub-section (1) shall contain a statement setting out the nature of the applicant's interest together with such particulars as may be prescribed and the facts upon which the application is based.</p> <p>95.-(1) In settling the terms and conditions of a licence under section 84, the Controller shall endeavour to secure-</p> <p>(i) that the royalty and other remuneration, if any, reserved to the patentee or other person beneficially entitled to the patent, is reasonable, having regard to the nature of the invention, the expenditure incurred by the patentee in making the invention or in developing it and obtaining a patent and keeping it in force and other relevant factors;</p> <p>(ii) that the patented invention is worked to the fullest extent by the person to whom the</p>	<p>Act 1970)</p>
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		<p>licence is granted and with reasonable profit to him;</p> <p>(iii) that the patented articles are made available to the public at reasonable prices.</p> <p>(2) No licence granted by the Controller shall authorise the licensee to import the patented article or an article or substance made by a patented process from abroad where such importation would, but for such authorisation, constitute an infringement of the rights of the patentee.</p> <p>(3) Notwithstanding anything contained in sub-section (2), the Central Government may, if in its opinion it is necessary so to do in the public interest, direct the Controller at any time to authorise any licensee in respect of a patent to import the patented article or an article or substance made by a patented process from abroad (subject to such conditions as it considers necessary to impose relating among other matters to the royalty and other remuneration, if any, payable to the patentee, the quantum of import, the sale price of the imported article, and the period of importation),</p>	
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		and thereupon the Controller shall give effect to the directions.	
THAILAND	<ul style="list-style-type: none"> • Thailand permits parallel importation • The “use, sale, having in possession for sale, offering for sale or importation of a patented product when it has been produced or sold with the authorization or consent of the patentee” is an exception to the patentees exclusive rights, PA, sec 2) 	<p>Compulsory Licensing (sec 45 -52 PA)</p> <p>Non-exploitation</p> <ul style="list-style-type: none"> • Any person may apply to the Director-General for a license, any time after three years from the grant of a patent or four years from the date of application, it appears that the patented product has not been produced or the patented process has not been applied in the country, without any legitimate reason <p>Anti-competitive conduct</p> <ul style="list-style-type: none"> • Any person (after three years of the grant or four years of the application) may apply to the Director-General for a license if it appears, that no product produced under the patent is sold in any domestic market, or that such a product is sold but at unreasonably high prices or does not meet the public demand, without any legitimate reason.” <p>Patent dependency</p> <ul style="list-style-type: none"> • If the working of any claim in a patent is likely to constitute an infringement of a 	<ul style="list-style-type: none"> • Provisions exist for both the civil service (PA, Section 51) and the executive (PA, Section 52) to make use of any patent. • Civil Service, PA, Section 51 “In order to carry out any service for public consumption or which is of vital importance to the defense of the country or for the preservation or realization of natural resources or the environment or to prevent or relieve a severe shortage of food, drugs or other consumption items or for any other public service, any ministry, bureau or department of the Government may, by themselves or through others, exercise any [patent right] by paying a royalty to the patentee or his exclusive licensee [...]and shall notify the patentee

		<p>claim in a patent of any other person, the patentee, desiring to exploit his own patent, may apply to the Director-General for a license under the patent of the other person under the following criteria:</p> <ol style="list-style-type: none"> 1. the invention of the applicant involves an important technical advance of considerable economic significance in relation to the invention for which the license is applied 2. the patentee shall be entitled to a cross-license on reasonable terms 3. the applicant shall not assign his right in the license to other persons except with the assignment of his patent.” <p>Conditions of Compulsory Licenses</p> <ul style="list-style-type: none"> • Compulsory licenses require, “the applicant for a license must show that he has made an effort to obtain a license from the patentee having proposed conditions and remuneration reasonably 	<p>in writing without delay.”</p> <ul style="list-style-type: none"> • Executive, PA, Section 52 - “During a state of war or emergency, the Prime Minister, with the approval of the Cabinet, shall have the power to issue an order to exercise any right under any patent necessary for the defense and security of the country by paying a fair remuneration to the patentee and shall notify the patentee in writing without delay.”
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		<p>sufficient under the circumstances but unable to reach an agreement within a reasonable period.”</p> <ul style="list-style-type: none"> • The patentee or assignee is entitled to remuneration where a compulsory license is granted. • the scope and duration of the license shall not be more than necessary under the circumstances; • the patentee shall be entitled to further license others; • the license shall not be entitled to assign the license to others, except with that part of the enterprise or goodwill particularly of the part under the license; • the licensing shall be aimed predominantly for the supply of the domestic market; • the remuneration fixed shall be adequate for the circumstances of the case. 	
KENYA	Section 58(2) of the <i>IPA, 2001</i> is	<i>Pre-conditions for issuing a compulsory</i>	Use by Government or Third

	<p>read to allow parallel importation of drugs purchased on other markets</p> <p>The section reads: “The rights under the patent shall not extend to acts in respect of articles which have been put on the market in Kenya or in any other country or imported into Kenya.”</p> <p>Section 37 of the <i>Industrial Property Regulations, 2002</i> limits the application of the above section to articles that are “legitimately” put on the market in the foreign jurisdiction.</p>	<p>license</p> <ul style="list-style-type: none"> • Applicant must show that he tried to negotiate a license with the owner on reasonable terms over a reasonable timeframe (<i>IPA</i>, s. 74(1)(a)). This requirement is waived in situations of national emergency or other situations of extreme urgency (s. 74(2) <i>IPA</i>); • Applicant has to guarantee the Tribunal that he will use the invention to remedy the situation which caused the need for the compulsory license. (<i>IPA</i>, s. 74(1)(b)) <p>Grant and Terms of Compulsory License (<i>Industrial Property Act, 2001s. 75</i>) Terms are set by the Tribunal but they should be non-exclusive, limited in scope and duration, limited to supplying the domestic market, do not allow the licensee to grant further licenses and, according to s. 75(2)(e) <i>IPA</i> they should provide for remuneration that is: “equitable with due regard to all the circumstances of the case, including the economic value of the license.”</p>	<p>Persons Authorized by Government s. 80(1) of the <i>IPA</i> provides that the Minister may order that a patented invention can be exploited by any government agency or other actor, subject to the payment of adequate compensation to the patent holder, when these requirements are met:</p> <ul style="list-style-type: none"> a) the public interest, in particular, national security, nutrition, health, environmental conservation, or the development of other vital sector of the national economy so requires; or (b) the Managing Director determines that the manner of exploitation of an invention by the owner of the patent or his licensee is not competitive. <p>Section 80(2) requires that the individual applying have attempted to sign a contractual license with the patent holder, except in cases of national emergency or extreme urgency.</p>
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		<p><i>For Non-Working</i> Four years after the filing date, or three years after the grant of the patent (whichever comes last), anyone can apply for a license to use the patent “on the grounds that a market for the patented invention is not being supplied on reasonable terms” (s. 72(1) of the <i>IPA</i>). However, sub-section (2) of the same article prevents the license from being issued if the patent holder can justify why the market is not being supplied.</p> <p><i>Based on Interdependence of Patents</i> <i>s. 73 of the IPA</i> allows the holder of a later patent to apply for a compulsory license on a previously registered patent if it is required for the working of the later patent and the invention is “a technical advance of considerable economic significance.”</p> <p><i>Cancellation</i> Any interested party can apply for cancellation:</p> <ul style="list-style-type: none"> • If the licensee does not comply with the terms; (<i>IPA s. 77(1)(a)</i>) • If the conditions that led to its issuance have ceased and are unlikely to occur. 	<p>However, under s. 80 there is also a measure that allows for non-governmental actors to exploit a patent without providing compensation:</p> <p>“(1A) Upon exercising the powers conferred upon him under subsection (1), the Minister may, notwithstanding any of the measures set out in this section, authorize by written order the importation, manufacture or supply, or authorize the utilization of any molecule or substance whatsoever by any individual, corporation or society as named or described by any individual, corporation or society as named or described in the order without notice to the patent holder or any other notifiable party, and such order shall remain in force until revoked by the Minister in writing, after giving six months’ prior notice of his intention of such revocation to the party named or described in the order.</p> <p>(1B) An order made under the subsection (1A) shall not require the</p>
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		<p><i>(IPA, s. 77(1)(b))</i></p> <p>Furthermore, if the application is made by the owner of the patent the Tribunal can cancel the license if, two years from its issuance, the licensee has not used the invention to remedy the deficiencies that gave rise to its creation. Terms may also be varied on request of the owner.</p> <p><i>Licenses as of Right</i> <i>Section 79 of the IPA</i> allows the owner of a patent to designate it as being available to license as of right. A current licensee may object to this designation, however, if it would violate a term in the contract between the two. This designation reduces by half the amount of annual fees that the patent holder has to pay.</p>	<p>payment of compensation to the owner of the patent or licence holder or any other party so interested.</p> <p>(1C) The Minister shall, notwithstanding any of the measures set out in this section, authorise the utilisation of any process for the manufacture, sale or supply of any molecule or substance whatsoever by any individual, corporation or society as named or described in the order, and such order shall remain in force until revoked by the Minister in writing, giving six months prior notice of intention of such revocation to the party named or described in the order.”</p>
<p>NIGERIA</p>	<p>- Exhaustion occurs when the product has been lawfully sold in Nigeria, unless the patent makes provision for a special application of the product. (s. 6(3)(b) <i>PDA</i>)</p>	<p>Compulsory Licensing</p> <p>All of the provisions on compulsory licensing are included in Schedule 1 of the <i>PDA</i>. All section numbers below refer to the section of Schedule 1 that the information within which the information is contained. As of 2001, there was no record of these provisions having been used to license a medicine.</p>	<p>Government Use</p> <ul style="list-style-type: none"> ▪ S.15, schedule 1 establishes that where a Minister is satisfied that it is in the public interest to do so, he may authorise any person to purchase, make, exercise or vend any patented article or invention for the service of a government agency

		<p><u>For Non-Working</u> Four years after the filing date, or three years after the grant of the patent (whichever period is later) anyone can apply for a compulsory license on the following grounds (as laid out in s. 1 of the Schedule):</p> <ul style="list-style-type: none"> - The invention is not being worked in Nigeria; - Extent to which an invention is being worked does not meet the demand for such working on reasonable terms; - “(c) that the working of the patented invention in Nigeria is being hindered or prevented by the importation of the patented article; and - (d) that, by reason of the refusal of the patentee to grant licences on reasonable terms, the establishment or development of industrial or commercial activities in Nigeria is unfairly and substantially prejudiced.” <p>The term non-working is defined at the end of Schedule 1 as follows:</p> <ul style="list-style-type: none"> - “14. For the purposes of this Part, references to the working of a patented 	<p>in the Federal Republic.” (s. 15 of Schedule 1 to the <i>PDA</i>)</p> <ul style="list-style-type: none"> ▪ Section 16 further specifies that the authority of a Minister under paragraph 15 of this Schedule may be given before or after the relevant patent has been granted; before or after the doing of the acts in respect of which the authority is given; and to any person whether or not he is authorised directly or indirectly by the patentee to make, use, exercise or vend the relevant article or invention.” - The section 15 powers can also be used in an emergency situation for the purpose of: <ul style="list-style-type: none"> ○ Carrying out a war; ○ Providing supplies and services necessary to the life of the community; ○ Providing supplies and services to maintain the well-being of the community; ○ To support industry;
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		<p>invention are to be construed as references to—</p> <ul style="list-style-type: none"> ○ (a) the manufacture of a patented article; or ○ (b) the application of a patented process; or ○ (c) the use in manufacture of a patented machine, <p>by an effective and serious establishment existing in Nigeria on a scale which is adequate and reasonable in the circumstances.”</p> <p><u>Dependent Patent</u> A compulsory license can be issued to the holder of a patent if another, earlier invention is required for the working of the second. The second invention must have a different industrial purpose and must be an important technological development for this provision to apply. If, however, the second invention does not have a different industrial purpose the license can still be issued as long as the holder of the first invention also receives a license to use the second (cross-licensing). (ss. 2 & 3 of Schedule 1 PDA)</p>	<ul style="list-style-type: none"> ○ To correct an unfavourable balance of trade; ○ To ensure that all resources are used in the way that best serves the interests of the community. (s. 20 of Schedule 1 PDA) <p>- The definition of Minister applicable in this section includes both the Federal Minister of Health and state Commissioners of Health. Furthermore, there is no limitation on to whom the government can designate these powers and, by extension, whom will be exempted from liability under the operation of the provisions.</p> <p>- There are no difficult procedural aspects to the operation of the government use provisions, unlike in other jurisdictions that, for example, require that the order be</p>
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		<p><u>Patent Holder's Response</u> The patent holder can prevent a compulsory license from being issued in the above two scenarios if he or she can show the court that their actions are justifiable in the circumstances. However, "he shall not be held to have so satisfied the court if he merely shows that the patented article is freely available for importation." (s. 4 of Schedule 1, PDA)</p> <p><u>Requirement of Negotiation</u> A compulsory license will not be issued unless the applicant can show that she both attempted to negotiate a licensing agreement on reasonable terms with the patent holder and that she can work the invention sufficiently to remedy the problem which is giving rise to the issuing of the license. (s. 5 of Schedule 1, PDA)</p> <p><u>Restrictions</u> Compulsory licenses do not give the holder the right to import the patented item. (s. 6(a) of Schedule 1, PDA) However, this is subject to s. 13 PDA(see below). There is no sub-licensing (s8, Schedule 1, PDA)</p>	<p>published in the <i>Gazette</i>.</p> <p><u>Liability for Government Use</u></p> <ul style="list-style-type: none"> - Any party involved with the use of a patent under ss. 15 & 16 is exempt from liability for its infringement or from the liability to make payment to the patent holder for its use. (s. 17 of Schedule 1, PDA)
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		<p><u>Cancellation</u> A compulsory license can be cancelled by the court, on application by the patent holder, if the circumstances that gave rise to it have ceased to exist or the licensee has violated a condition of the license. (s. 9 Schedule 1 PDA)</p> <p><u>Government Declaration</u> Ministers can declare certain drugs exempt from some of the compulsory licensing rules for reasons of public health or for the defense and economy of Nigeria. In this case, the 3-4 year period of waiting does not apply and the compulsory licensee <i>is</i> permitted to import the patented invention. (s. 13 Schedule 1 PDA)</p>	
<p>SOUTH AFRICA</p>	<ul style="list-style-type: none"> • The sale of a patented article by or on behalf of a patentee or his licensee shall, subject to other patent rights, give the purchaser the right to use and dispose of that article (s45(2) PA) • s.15 C of the 1997 Amendments Act of the Medicines and Related Controlled Substances Act 	<p><i>Compulsory licences in respect of dependent patent (s.55 PA)</i> Where the working of a patent is dependent upon the obtaining of a licence to use another patent and an agreement cannot be reached as to such licence with the proprietor of that patent, that inventor may apply to the commissioner for a licence under the prior patent,</p> <p>The commissioner may grant such a licence on</p>	<ul style="list-style-type: none"> • The Minister may, on behalf of the State, acquire, on such terms and conditions as may be agreed upon, any invention or patent (s.78 PA)

	<p>vested the power in the Minister of Health to determine conditions under which parallel imports of medicines</p>	<p>such conditions as he may impose</p> <p>The licence can only be used only to allow the dependent patented invention to be used.</p> <p><i>Compulsory licence in case of abuse of patent rights (s.56 PA)</i></p> <p>Any interested person who can show that the rights in a patent are being abused may apply to the registrar for a compulsory licence</p> <p>The rights in a patent are abused if-</p> <ul style="list-style-type: none"> - the patented invention is not being worked in the Republic on a commercial scale or to an adequate extent, after four years subsequent to the date of the application for the patent or three years subsequent to the date on which that patent was sealed, and there is in the opinion of the commissioner no satisfactory reason for such non-working; In this case, the licence will be non-exclusive and will not be transferable except to a person to whom the business or the part of the business in connection with which the rights under the licence were exercised has been transferred. 	
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- the working of the invention in the Republic on a commercial scale or to an adequate extent is being prevented or hindered by the importation of the patented article;
- the demand for the patented article in the Republic is not being met to an adequate extent and on reasonable terms;
- the patentee's refusal to grant a licence or licences upon reasonable terms, prevents the trade or industry or agriculture of the Republic or the trade of any person or class of persons trading in the Republic from developing, or prevents the establishment of any new trade or industry in the Republic, and so, it is in the public interest that a licence or licences should be granted; or
- **the demand in the Republic for the patented article is being met by importation and the price charged by the patentee, his licensee or agent for the patented article is excessive in relation to the price charged in countries where the patented article is manufactured by or under licence from the patentee or his predecessor or successor in**

		<p><u>title.</u></p> <p>The commissioner will determine the terms of the compulsory license and <u>may preclude the licensee from importing into the Republic the patented articles.</u></p> <p><i>Conditions of the Licences</i></p> <p>In determining the conditions on which any licence is granted the commissioner will consider the risks to be undertaken by the licensee, the research and development undertaken by the patentee and the terms and conditions usually stipulated in licence agreements in respect of the subject-matter of the invention, between persons who voluntarily enter into such agreements.</p> <p>A compulsory licensee will have the same rights and obligations as any other licensee under a patent.</p> <p>A compulsory license may be granted over any composition of matter, product of a patented process or method or product produced by a patented machine.</p>	
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Opposition

The grant of the licence may be opposed and costs may be awarded for this opposition.

Medicines and Related Controlled Substances Act

- *15C. The Minister may prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public, and in particular may—*

(a) notwithstanding anything to the contrary contained in the Patents Act, 1978 (Act No. 57 of 1978), determine that the rights with regard to any medicine under a patent granted in the Republic shall not extend to acts in respect of such medicine which has been put onto the market by the owner of the medicine, or with his or her consent;

(b) prescribe the conditions on which any medicine which is identical in composition, meets the same quality standard and is intended to have the same proprietary name as that of another medicine already registered in the Republic, but which is imported by a person other

		<p><i>than the person who is the holder of the registration certificate of the medicine already registered and which originates from any site of manufacture of the original manufacturer as approved by the council in the prescribed manner, may be imported;</i></p> <p><i>(c) prescribe the registration procedure for, as well as the use of, the medicine referred to in paragraph (b).'</i></p>	
CAMEROUN	See Mali	See Mali	See Mali
MALI	<p>It is unclear whether the <i>RBA</i> establishes a national or a regional approach to exhaustion. Article 3 establishes that the rights are independent national rights, while article 8(1)(a) <i>RBA</i> states that patent rights do not extend to patented subject matter brought into a state by the patent holder or with his consent. While the latter provision is not clear about whether or not “territory of a member state” includes all member states or just the one in question, the provisions</p>	<p><u>For Non-Working</u></p> <ul style="list-style-type: none"> - According to art. 46(1) of the <i>RBA</i>, four years following filing, or three years following the grant of a patent (whichever period expires last) a non-voluntary license can be granted: <ul style="list-style-type: none"> a. “the patented invention is not being worked on the territory of a member State at the time the request is made;” b. “the working of the patented invention on such territory does not meet the demand for the protected product on 	<p>Licensing Terms</p> <p>Article 37 of the <i>RBA</i> sets out the following limits on terms in contractual licenses of patents:</p> <ul style="list-style-type: none"> - “(1) Clauses in license contracts or relating to such contracts shall be invalid in so far as they impose on the licensee, in the industrial or commercial sphere, restrictions not deriving from the rights conferred by the patent or not necessary for the upholding of such rights.

	<p>do not allow parallel importation of generics manufactured in India or Brazil (for example).</p>	<p>reasonable terms;”</p> <p>c. “on account of the refusal of the owner of the patent to grant licenses on reasonable commercial terms and procedures, the establishment or development of industrial or commercial activities on such territory is unfairly and substantially prejudiced.”</p> <p>- 46(2) RBA states that a non-voluntary license cannot be issued if the patent holder gives good reasons for the non-working.</p> <p><u>Dependent Patent</u> Where a later patent is dependent on an earlier one to be worked, the holder of the later patent may apply for a non-voluntary license of the first. The new patent must be a substantial technical progress of considerable economic interest in relation to the first patent. The owner of the earlier patent will have the right to a reciprocal license. (Article 47 of the <i>RBA</i>)</p> <p><u>Request for a Non-Voluntary License</u></p>	<p>- (2) The following shall not be considered restrictions within the meaning of paragraph (1) above:</p> <ul style="list-style-type: none"> o (i) limitations relating to the extent, the scope or the duration of exploitation of the patented invention; (ii) the obligation on the licensee to abstain from any act liable to harm the validity of the patent.”
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		<ul style="list-style-type: none"> - When made to the court it must be accompanied by both proof that the applicant has attempted to obtain a license from the owner but has not received one on reasonable commercial terms as well as proof that the applicant is capable of working the invention. (Article 48(3) of the <i>RBA</i>) - The civil court will solicit submissions from the patent holders and any licensees, and if it decides to issue the non-voluntary license it will set the terms. However, neither a patent for non-working nor that for a dependent patent can apply to the act of importation. (Article 49(4) of the <i>RBA</i>) <p><u>Limitation of the Non-Voluntary License</u></p> <ul style="list-style-type: none"> - Article 51(1) RBA states: “The beneficiary of the non-voluntary license may not, without the consent of the owner of the patent, grant any third party permission to perform any of the acts that he is authorized to perform under the non-voluntary license.” - However, article 51(2) RBA allows such a license to be transferred along with the 	
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establishment that it was granted to, as long as the authorization of the civil court that originally granted the non-voluntary license has been obtained.

Amendment and Withdrawal

- The court can amend the license on request from either the license holder or the patent holder. (Article 52(1) of the *RBA*)
- Court can withdraw the license if the owner of the patent requests and if the grounds for it to exist have ceased, the beneficiary violates the license, or the beneficiary does not pay. (Article 52(2) *RBA*)

Ex-Officio Licenses

- A Minister may, through administrative enactment, subject a patent to the non-voluntary license regime described above. The enactment will specify who will benefit from the license, as well as the conditions, terms and scope, and can be issued for the following reasons: **vital interest to the economy; public health; national defense; or where non- or insufficient working seriously compromises the country's needs.**

		<p>(Article 56(1) of the <i>RBA</i>)</p> <ul style="list-style-type: none"> - If no agreement on the conditions, they will be set by the court. (Article 56(2) of the <i>RBA</i>) 	
SWITZERLAND	<p>Switzerland does not permit parallel imports although the law is currently under review.</p>	<p>Dependent Invention As per article 36 FLPI the holder of a patent of a dependent invention that is an important technical improvement of economic importance, has a right to a license on the first invention. Owner of first invention can require, as a condition on licensing, a license over the second invention.</p> <p>Non-Exploitation Article 37 FLPI – non-voluntary license for non-exploitation. Contains the usual time requirements, and that a license can be demanded where the patent has not been “sufficiently exploited” in Switzerland and the patent holder cannot justify this. Importation is considered to be exploitation. Furthermore, if in two years time from the issuance of such a patent the use of the invention is still not meeting the requirements of the Swiss market, a interested party can apply to the court for the forfeit of the patent (Article 38 FLPI).</p>	<p>Article 32 FLPI allows the Swiss government to expropriate a patent when the public interest demands it. This is subject to the requirement of full compensation, to be determined (where agreement fails) by the federal tribunal in accordance with the Swiss federal law on the subject. This action is not subject to the limits on non-voluntary licenses outlined below.</p>

		<p>Public Interest License Article 40 FLPI also allows licenses to be granted for the public interest when the holder of the patent has refused to license it to a particular party. “Lorsque l’intérêt public l’exige, celui auquel le titulaire du brevet a refusé, sans raisons suffisantes, d’accorder la licence requise peut demander au juge l’octroi d’une licence pour utiliser l’invention.”</p> <p>Limits on Non-Voluntary Licenses Article 40<i>b</i> FLPI puts the following limits on the issue of the non-voluntary licenses described in articles 36-40 FLPI:</p> <ul style="list-style-type: none"> - Para 1: They are only issued in the party making the request has spent a reasonable amount of time trying to obtain a voluntary license on reasonable commercial terms. However, this requirement is waived in situations of national emergency or other situations of extreme urgency. - Para 4: The license is principally awarded for supplying the domestic market. - Para 5: Once the circumstances that led to the issuance of the non-voluntary license have ceased, and are unlikely to reoccur, the non-voluntary license will be withdrawn. 	
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		<p>- Para 6: The patent holder has a right to remuneration. The amount is determined based on the circumstances and the economic value of the license.</p> <p>- Para 7: The extent of the license, amount of remuneration, and the beginning and end of the license are all determined by a judge.</p>	
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	COMPETITION LAW	DRUG REGULATION/PRODUCT LIABILITY	LICENSING/CONTRACT RULES
BRAZIL	<ul style="list-style-type: none"> Article 20 of Brazil's Competition Act (CA) provides that "any act in any way intended or otherwise able to produce the effects listed below, even if any such effects are not achieved, shall be deemed a violation of the economic order". These effects include to limit, restrain or in any way injure open competition or free enterprise; to control a relevant 	<ul style="list-style-type: none"> Pharmaceuticals are regulated by the National Health Surveillance Agency (ANVISA). The civil code and consumer protection statutes impose strict liability for products liability. Any damages awarded to consumers for injuries caused by drugs will be limited to an objective measurement of the harm suffered. Criminal penalties for producing a defective drug range from 2 000 to 	<p>Registration of Licences (s.61-s.63, IPL)</p> <ul style="list-style-type: none"> License contracts must be registered with the INPI in order to have effect The Agreement will take effect upon publication Any improvement to a licensed patent will belong to the party that makes the improvement, and the other party is entitled to a preferential right to the licensing

	<p>market of a certain product or service; to increase profits on a discretionary basis; and to abuse one's market control.</p> <ul style="list-style-type: none"> • Further, Article 21 CA contains a lengthy but non-exclusive list of acts, including various kinds of horizontal and vertical agreements and unilateral abuses of market power, that are considered unlawful if they produce the effects enumerated in Article 20. • In 1999, CADE (the Administrative Council for Economic Defense) issued enforcement guidelines for actions under Articles 20 and 21 specifying that for either horizontal or vertical restrictions to be found illegal, there must be evidence of the existence of market power as well as an anti-competitive effect on a substantial share of the relevant market. 	<p>200 000 Real, depending on the severity of the offence. Brazil Law 9.695.</p>	<ul style="list-style-type: none"> • The freedom of parties to contract is to be exercised according to and within the limits of the social function of contracts. Brazil Civil Code, 2002.
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	<ul style="list-style-type: none"> Article 54 CA provides that “any acts that may limit or otherwise restrain open competition, or that result in the control of relevant markets for certain products or services” must be submitted to CADE for review. 		
INDIA	<ul style="list-style-type: none"> The proposed patent pool may qualify as an anti-competitive trade practice. The Monopolies and Restrictive Trade Practices Act, 1969. Criminal penalties including fines and imprisonment apply to a person or group of persons “able directly or indirectly to control the policy” of an organization engaging in anti-competitive practices. There is no requirement that those in control of policy have a controlling financial stake in the venture. The Monopolies 	<ul style="list-style-type: none"> A person or any other person acting on his behalf who, “manufactures for sale or for distribution, or sells, or stocks or exhibits or offers for sale or distributes” a drug causing death or grievous hurt “on account of such drug being adulterated or spurious or not of standard quality,” is subject to five years to life in prison and a minimum fine of 10 000 rupees, The Drugs and Cosmetics Act, 1940, Section 27. Grievous hurt is defined as permanent disability or “hurt which endangers life or which causes the sufferer to be during the space of twenty days in 	<ul style="list-style-type: none"> Any licence agreement must be in writing and embody all the terms and conditions governing their rights and obligations Patents (Amendment) Act, 2005, s. 68.

	<p>and Restrictive Trade Practices Act, 1969, Sections 2 & 53.</p> <ul style="list-style-type: none"> • In order to avoid penalties, patent pool participants may seek Central Government authorization to engage in patent pooling or register as a co-operative society. The Monopolies and Restrictive Trade Practices Act, 1969, Section 3, The Multi-State Co-operative Societies Act, 2002. 	<p>severe bodily pain, or unable to follow his ordinary pursuits.” The Indian Penal Code, 1860, Section 320.</p> <ul style="list-style-type: none"> • The government may also implead any manufacturer of a pharmaceutical when, “the Court is satisfied, on the evidence adduced before it, that such manufacturer or agent is also concerned in that offence.” The Drugs and Cosmetics Act, 1940, Section 32A. • Any civil liability resulting from harmful medication will be determined by India’s Consumer Courts and damages will be limited to the actual harm suffered. 	
<p>THAILAND</p>	<ul style="list-style-type: none"> • The Trade Competition Act (TCA), that came into force April 30, 1999 regulates competition in Thailand • Section 25 TCA prohibits business with dominant position and their ability to abuse their market power by :1) setting unfair prices for goods and services ; 2) 	<ul style="list-style-type: none"> • There is currently no explicit product liability for pharmaceuticals in Thailand. • Under the Consumer Protection Act, consumers must first bring their complaint to the Consumer Protection Committee who, after an investigation, may then bring an action against a manufacturer. 	<ul style="list-style-type: none"> • A patentee may license or assign his patent to any other person. Licenses may not include unjustifiably anti-competitive conditions, restrictions or royalty terms. • Joint owners of patents may exercise the exclusive patents rights individually, without the consent of

	<p>setting unfair trading conditions, directly or indirectly, to customers in order to restrict customers normal business practices; 3) limiting supply of goods and services to create a shortage of supply; and 4) intervening in other business without proper reasons.</p> <ul style="list-style-type: none"> • A business operator with market domination is defined under the Competition Act as one or more business operators in the market of any goods or services who have the market share and sales volume above the level that is prescribed by the Commission. • Section 27 TCA prohibits a business operator from conspiring, colluding or collaborating with another business operator in order to create monopolistic power, or reduce competition. In the case where it is reasonably necessary in the business and has no serious 	<ul style="list-style-type: none"> • Committee action may result in penalties to the manufacturer but does not compensate the injured party. If enough complaints are brought, the committee may bring an action on behalf of the injured seeking compensation (similar to a class action). This action must be based in either tort or contract. • In order to recover under Thai tort law, the plaintiff must prove intentionality or gross negligence leading to injury; strict liability does not apply to pharmaceuticals. • Damages are limited to compensation for harm suffered. 	<p>other owners. However, a jointly held patent may not be licensed or assigned without the consent of all holders.</p>
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	<p>harm to the economy, the business operators shall submit an application for permission to the Commission. The Commission has already approved forms, rules and procedures to apply for permission of any kinds of anti-competitive agreements.</p> <ul style="list-style-type: none"> • Section 28 of the Act deals with agreements between domestic and oversea business operators performing an activity which will restrict the freedom or opportunity of a person residing in the Kingdom from purchasing goods or services for his/her own use directly from business operators outside the Kingdom. • Section 29 of the Act also prohibit a business operator from performing any act which is not free and fair competition and which results in destroying, impairing, obstructing or impeding or restricting business operation of other business 		
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	<p>operators or preventing other persons from carrying out business or causing the cessation of business.</p> <ul style="list-style-type: none"> • Civil penalties are based on the damage suffered by the plaintiff. • Criminal penalties include fines of two million to six million Baht and imprisonment of one to three years. • Managers of groups that engage in anti-competitive acts subject to criminal penalties “unless the offence at stake was committed without his/her knowledge or consent and/or reasonable measures were taken to prevent such offence.” • Liability can be completely avoided by applying to the Competition Commission for approval to establish the medicine patent pool. The application must include the 		
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	<p>reason and necessity for allowing the practice.</p> <p>Permission is granted where there is “reasonable necessity” and “no serious harm to the economy.”</p>		
KENYA	<ul style="list-style-type: none"> - 6(1)(b) of Kenya’s <i>Restrictive Trade Practices Act</i>, which states that “an agreement or arrangement between manufacturers, wholesalers or retailer to sell goods at prices or on terms agreed upon between themselves” is a restrictive trade practice. - Under Kenya’s competition law if a person is found to be engaged in restrictive trade practices and does not, after such a finding, cease to act in this restrictive way, they are guilty of an offense and could face a maximum of 2 years in prison and a fine of 100,000 Kenyan shillings. (s. 21 of <i>RTPA</i>) - The indicia of “unwarranted concentrations of economic 	<ul style="list-style-type: none"> o Kenya has adopted the common law of England relating to contracts. (<i>Law of Contract Act</i>) Negligence is a recognized tort action in Kenyan law but product liability is not specifically enumerated. (<i>Limitation of Actions Act</i>) Damages in a tort action, must “state the precise amount claimed.” (<i>The Civil Procedure Rules Order VII, Section 2</i>) o The criminal penalty for producing a defective drug is 500 000 Shillings and / or two years imprisonment. (<i>Food, Drugs and Chemical Substances Act</i>) 	<ul style="list-style-type: none"> - All license agreements must be registered with the Kenya Industrial Property Institute (s.68(1) <i>PA</i>) - Any party to the contract may make a request for registration - the agreement will be registered so long as it meets the requirements set out below: <p>“The Managing Director may refuse to register a licence contract if</p> <p>A) he is of the opinion that any clause in a licence contract imposes unjustified restrictions on the licensee with the consequence that the contract, taken as a whole, is harmful to the economic interests of Kenya, AND that B) a term in the contract has one of the effects listed in the article.</p>

	<p>power” focus on concentrations of distributional power and vertical integration of business. (s. 23 of <i>RTPA</i>)</p> <ul style="list-style-type: none"> - Neither does a patent pool that issues non-exclusive licenses seem to come under the meaning of a “restrictive trade practices” as it does not reduce or eliminate opportunities to participate in a specific market, nor does it prevent people willing to pay fair market prices for goods from acquiring those goods. (s. 4 <i>Restrictive Trade Practices Act</i>) - Section 71 of the <i>Act</i> establishes the personal responsibility of every director, manager or officer of a corporation that is charged with offenses under the <i>Act</i>. Where the corporation is found guilty, the people in these positions must prove that 		<ul style="list-style-type: none"> - If it does not meet the requirements, the Managing Director must notify the parties and allow them to submit any comments, correct defects or amend any of the terms -If registration is refused, the contract is void. <p>Refusal to Register a Licensing Contract</p> <p>If the Managing Director refuses to register a licensing contract, any party to the contract has two months to appeal the decision on one of the following grounds:</p> <ul style="list-style-type: none"> • “(a) that the decision of refusal contains no statement of the reasons for refusal; • (b) that none of the reasons specified in the decision is a valid reason under this Act or that such reason was wrongly applied to the petitioner or to the licence contract; or • (c) that the procedure applied by the Managing Director was
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	<p>they had no knowledge of the offense or that they used due diligence in carrying out their role in order to exonerate themselves.</p>		<p>irregular and prejudicial to the rights of the petitioner.” (s. 71 IPA)</p>
<p>NIGERIA</p>	<ul style="list-style-type: none"> • Anti-competitive practices are regulated by the Consumer Protection Council of Nigeria. It exists to “provide speedy redress to consumer complaints through negotiations, mediation and conciliation.” A representative from the Federal Health Ministry sits on the council. Consumer Protection Council Act. • The Council also has the function of causing, “an offending company, firm, trade association or individual to protect, compensate, provide relief and safeguards to injured consumers or communities from adverse effects of technologies that are inherently harmful, violent or highly hazardous.” <i>Consumer</i> 	<p>. The decree that established the National Agency for Food and Drug Administration and Control (NAFDAC) requires that all drugs imported and sold in the country be approved and registered with the agency. According to the Drugs and Related Products (Registration, Etc.) Decree, in order to register a Power of Attorney or an Agency Agreement has to be given by the manufacturer of the drug to NAFDAC – manufacturers are unlikely to do so as this may inadvertently allow cheaper versions to be imported into Nigeria.</p> <ul style="list-style-type: none"> • The Consumer Protection Council has the authority to apply to the courts to get an injunction against the distribution of dangerous products. It may also request quality testing, labelling, etc. Successful action of the Consumer Protection Council Act may give rise to civil liability 	<ul style="list-style-type: none"> • All licensing of foreign technology has to be registered with NOTAP. The Director of NOTAP may refuse to register any agreement where the price is not commensurate with the technology acquired, where the contract gives the licensor undue influence on the licensee, or where the licensee has to agree to a choice of forum/law clause that requires disputes about the contract’s interpretation and enforcement in Nigeria to be decided elsewhere. (NIPC article) • No funds can leave the country pursuant to a licensing agreement unless a certificate of registration by NOTAP can be produced. Thus, NOTAP has

	<p><i>Protection Council Act.</i></p> <ul style="list-style-type: none"> • The Council also deals with anti-competitive behaviour by ensuring “that consumers' interests receive due consideration at appropriate forum and to provide redress to obnoxious practices or the unscrupulous exploitation of consumers by companies, firms, trade association or individual.” Consumer Protection Council Act. 	<p>for the manufacturer. Consumer Protection Council Act.</p> <ul style="list-style-type: none"> • The Council also has the function of causing, “an offending company, firm, trade association or individual to protect, compensate, provide relief and safeguards to injured consumers or communities from adverse effects of technologies that are inherently harmful, violent or highly hazardous.” Consumer Protection Council Act. • Penalties for violation of the Consumer Protection Council Act are fines up to 50 000 Naira and imprisonment up to five years. Consumer Protection Council Act. 	<p>certain requirements for the contracts to ensure that Nigerian licensees aren't agreeing to an unbalanced contract. For example, if the contract relates to the licensing of a process, the licensor is required to provide performance guarantees.</p> <p>License Agreements (s.23 and following, PDA)</p> <ul style="list-style-type: none"> • A patentee owner may by a written agreement grant a licence to any person to exploit the relevant invention; (2) Where a licence is granted under subsection (1) of this section • The licence shall be registered, and shall be of no effect against third parties until registration is effected and the prescribed fee paid; and • Registration may be cancelled at the request of the licensor if the Registrar is satisfied that the licence has been terminated. • A licence contract may not include
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			<p>clauses that impose on the licensee in the industrial or commercial field restrictions which do not derive from the rights conferred by the relevant patent or are unnecessary for the safeguarding of those rights so long as limitations concerning the scope, extent, territory or duration of the exploitation of the patent or the quality or quantity of the products in connection with which the patent or design may be exploited; obligations imposed on the licensee to abstain from all acts capable of prejudicing the validity of the patent; and limitations justified by the interest of the licensor in the technically efficient exploitation of the subject of the patent, are not restrictions of the kind mentioned in this subsection.</p> <p>Unless the contract says otherwise. The licensor will still be allowed to grant further licenses and exploit the patent. Furthermore, the licensee cannot assign</p>
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			<p>the licence or sub-licence.</p> <p>If a contract involves payment of royalties outside Nigeria, the Minister may also hold the agreement invalid if he is satisfied that it is in the interest of Nigeria and its economic development to do so.</p>
<p>SOUTH AFRICA</p>	<ul style="list-style-type: none"> • The <i>Competition Act</i> prohibits restrictive horizontal practices, vertical practices and abuse of dominant position that lessens competition and whose effects do not outweigh the negative lessening of competition • In 2003, the Competition Tribunal held that GSK and BI violated a dominant position in respect of the ARV market for 1) denying a competitor access to an essential facility, 2) excessive pricing and 3) engaging in an exclusionary act • Under the Competition Act of 1998, the patent pool may qualify as an anti-competitive practice. 	<p>Drug Regulation</p> <ul style="list-style-type: none"> • all clinical trials are subject to review and approval • The Department of health has established guidelines on the minimum standards that are acceptable for conducting clinical trials in South Africa. • Ethical approval for clinical trials is also required from the National Health Research Ethics Council • According to the <i>Medicine and Controlled Substances Act</i>, all manufacturers and distributors must apply for a license to distribute, import or export medicines. • The Medicines Control Council is responsible for ensuring that applicants comply with the legislation, quality assurance and manufacturing 	<ul style="list-style-type: none"> • License contracts or contracts for the sale of patented articles will be null or void if they contain any of the following conditions (sec 90 PA): <ul style="list-style-type: none"> - to prohibit or restrict the purchaser or licensee from purchasing or using any article or class of articles, whether patented or not, supplied or owned by any person other than the seller or licensor or his nominee; - to prohibit or restrict the licensee from using any article or process not protected by the patent; - to require the purchaser or licensee to acquire from the seller, licensor or his nominee any article or class of

	<ul style="list-style-type: none"> • Failure to comply with an order from the Competition Tribunal or the Competition Appeal Court can result in fines up to R500 000 and imprisonment of up to ten years. (<i>Competition Act, 1998, Section 74</i>) • According to the Anti-competitive Practices (Art. 2), Act (Consolidation), 21/06/1979 (1991), No.96 (No. 51) the Competition Board may on its own initiative, and shall at the request of the Minister, investigate A) any restrictive practice which the board or the Minister, has reason to believe exists or may come into existence; in order to determine whether 1) any acquisition has been, is being or is proposed to be made; 2) the nature and extent of the controlling interest held and acquired, being acquired or proposed to be acquired or B) any particular type of business 	<p>processes.</p> <ul style="list-style-type: none"> • Only drugs that are registered may be imported, produced, stored, exported and sold. These licensees will be granted as they meet the “Good Manufacturing Practice” requirements. • South Africa also maintains a list of essential drugs (reflecting the WHO’s list of essential medicines) and registration for these medicines will be fast-tracked and there will also be prioritization of registration based on need. • . The fast track process generally allows the drug to be assessed within nine months after application for registration. However, several drugs, for example, Tenofovir, have seen lengthy delays in registration. This delay is ascribed to the number of drugs requiring registration (1 130 applications for registration were received by the MCC in 2006) and the lack of resources. • Drugs may only be sold in places that are licensed to sell drugs and that provide a pharmaceutical service 	<p>articles not protected by the patent;</p> <ul style="list-style-type: none"> - to require or induce the purchaser to observe a specified minimum resale price in respect of any article or class of articles protected by the patent; or - to prohibit or restrict the making, using, exercising or disposing of the invention concerned in any country in which the invention is not patented, <p>The following clauses remain valid:</p> <ul style="list-style-type: none"> - clauses that affect any condition in a contract whereby a person is prohibited from selling any goods other than those of a particular person; or - affect any condition in a contract for the lease of or a licence to use a patented article, whereby the lessor or licensor reserves to himself or his nominee the right to supply such new parts of the patented article,
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	<p>agreement, arrangement, understanding, business practice or method of trading in general or in relation to any particular commodity or any class or kind of commodity or any particular business or undertaking or any class or type of business or undertaking or any particular area which in the opinion of the board or the Minister, is commonly adopted for the purpose of or in connection with the creation or maintenance of restrictive practices; C) into any monopoly situation which the board or the Minister, as the case may be, has reason to believe exists or may come into existence.</p> <p>(2) An investigation referred to in subsection (1) (a), (b), (c) or (d) must be in the public interest.</p> <ul style="list-style-type: none"> • In order to avoid these penalties, the patent pool may apply to exempt itself from the application of the Competition Act. (<i>Competition Act, 1998, Section 10 (4)</i>) • Applies to all economic 	<p>Product Liability</p> <ul style="list-style-type: none"> • Under contract law, there is “strict liability for consequential damages arising out of defective merchandise to a merchant seller who professes expert knowledge in relation to such goods.” (<i>Kroonstad Westelike Boere Ko-operatiewe Vereniging, Bpk v Botha, 1964 (3) SA 561 (AD)</i>) • Strict liability applies to the seller only when there is a direct contractual relationship with the buyer. Liability can therefore be limited through contractual provisions between parties. • Manufacturers may be liable for product defects but this is not a strict product liability. Each element of a claim including fault, must be shown. Fault may be established by evidence or through res ipsa loquitur. (<i>Wagener v Pharmacare Ltd; Cuttings v Pharmacare Ltd, 2003 SACLR LEXIS 20</i>) • More recently, the proposed 	<p>other than ordinary articles of commerce, as may be required to put or keep it in repair.</p> <ul style="list-style-type: none"> • Any contract, in so far as it relates to a licence under a patent to make, use, exercise or dispose of a patented invention, shall terminate on the date on which the patent, under which the licence was granted, expires, is revoked or otherwise ceases to protect such invention: Provided that where the contract relates to licences under more than one patent, such part of the contract as relates to any particular licence shall terminate when the patent under which it was granted expires, is revoked or otherwise ceases to protect the invention concerned, and that the contract as a whole shall terminate when all the patents under which all such licences were granted and which were in
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	activity within or having an effect on the Republic	Consumer Protection Bill of 2005 would consolidate and amend legislation relevant to patent pool participant liability. The proposed act would consolidate unfair business practices, trade practices, price controls and other relevant law. The act would impose strict product defect liability accompanied by fines and imprisonment up to ten years. The act would also allow manufacturers to be held vicariously liable for the acts of their employees. (<i>South African Proposed Consumer Protection Bill, 2005, Sections 139, 140</i>)	force at the time when the contract became operative, expire, are revoked or otherwise cease to protect the relevant inventions.
CAMEROON	<p>The Competition Act, established on 14 July 1998, has not yet been implemented, because the National Competition Commission—a central body vital to enforcement of competition policy—has not yet been established.</p> <p>Cameroon is a member of OHADA, the Organisation pour</p>	The tort of negligence is the only avenue for recourse in the case of injury from defective products.	SEE MALI

	<p>l'Harmonisation du Droit des Affaires en Afrique, which was created in 1993 and which, as the name suggests, establishes common business law for its 16 members. Article 10 of the <i>Treaty on the Harmonisation of Business Law in Africa</i> states that the Uniform Acts of OHADA are directly applicable and overriding in the member states, notwithstanding any conflict with municipal law. (<i>Treaty on the Harmonisation of Business Law in Africa</i>)</p> <p>At a meeting in March 2001 the Council of Ministers decided that the organizations goal of harmonizing business law would include competition law and IP law.</p>		
<p>MALI</p>	<p>Mali does not appear to have any competition law.</p> <p>Mali is a member of OHADA, the Organisation pour l'Harmonisation du Droit des Affaires en Afrique, which was</p>	<p>Drug Regulation</p> <ul style="list-style-type: none"> The National Drug Administration regulates drug quality and importation of generic drugs <p>Possible Product Liability in Criminal</p>	<p>Article 37 of the <i>RBA</i> sets out the following limits on terms in contractual licenses of patents:</p> <ul style="list-style-type: none"> “(1) Clauses in license contracts or relating to such contracts shall be invalid in so far as they impose on the licensee, in the

	<p>created in 1993 and which, as the name suggests, establishes common business law for its 16 members. Article 10 of the <i>Treaty on the Harmonisation of Business Law in Africa</i> states that the Uniform Acts of OHADA are directly applicable and overriding in the member states, notwithstanding any conflict with municipal law. (<i>Treaty on the Harmonisation of Business Law in Africa</i>)</p> <p>Mali ratified the treaty in 1995 and has adopted each of the organization's Uniform Acts.</p> <p>At a meeting in March 2001 the Council of Ministers decided that the organizations goal of harmonizing business law would include competition law and IP law.</p>	<p>Law:</p> <ul style="list-style-type: none"> - Article 210 of the Malian Criminal Code reads as follows: “Celui qui, par maladresse, imprudence, négligence ou inobservation des règlements, aura involontairement porté des coups, fait des blessures, ou occasionné des maladies à autrui, sera puni d’un emprisonnement de trois mois à deux ans et d’une amende de 20 000 à 300 000 francs ou de l’une de ces peines seulement.” - Article 213 may also be applicable: “Quiconque, sans intention coupable, aura administré volontairement à une personne des substances ou se sera livré sur elle, même avec son consentement, à des pratiques ou manoeuvres qui auront déterminé ou auraient pu déterminer une maladie ou une incapacité de travail, sera puni de six mois à trois ans d’emprisonnement et facultativement de 20 000 à 200 000 francs d’amende et de un à dix ans d’interdiction de séjour.” - (2) “S’il résulte une maladie ou une incapacité permanente, la peine sera 	<p>industrial or commercial sphere, restrictions not deriving from the rights conferred by the patent or not necessary for the upholding of such rights.</p> <ul style="list-style-type: none"> - (2) The following shall not be considered restrictions within the meaning of paragraph (1) above: <ul style="list-style-type: none"> o (i) limitations relating to the extent, the scope or the duration of exploitation of the patented invention; (ii) the obligation on the licensee to abstain from any act liable to harm the validity of the patent.”
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		<p>de cinq à dix ans de reclusion. L'interdiction de séjour de cinq à dix ans pourra être prononcée.”</p> <ul style="list-style-type: none"> - (3) “Si la mort s’en est suivie, la peine sera de cinq à vingt ans de reclusion et facultativement, de un à vingt ans d’interdiction de séjour.” - Malian criminal law also contains provisions that address directly infractions against intellectual property. Article 248 states: “Toute atteinte aux droits d’un brevet ... soit par fabrication de produit soit par l’emploi de moyens faisant l’objet du brevet ... constitue le délit de contrefaçon et est punie d’un emprisonnement de un à cinq ans et d’une amende de 50 000 à 15 000 000 de francs.” - 249 continues: “Les receleurs et ceux qui vendent ou introduisent sur le territoire national un ou plusieurs objets contrefaits sont punis des mêmes peines que les contrefacteurs.” <p>(2) “En cas de récidive, outre l’amende visée à l’article précédent, une peine d’emprisonnement d’un</p>	
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		mois à six mois pourra être prononcée.”	
SWITZERLAND	<p><u>Basic Approach</u> As per the Swiss <i>Federal Act on Cartels and Other Restraints of Competition</i>, an agreement is unlawful that notably restricts competition unless it can be justified by the increased economic efficiency that results. Economic efficiency justifications (as defined by the law) include: lower production or marketing costs, improved products or processes of manufacture, “to promote R&D or the diffusion of technical or professional skills and knowledge and to exploit resources more rationally.” (<i>Intro to Swiss Law</i>)</p> <p><u>Exception for IP</u> Article 3 para 2 establishes a basic exception for the exercise of IP-based rights, stating: “The present Act does not apply to effects on competition that result exclusively from laws governing intellectual property.</p>	<p>Product Liability</p> <ul style="list-style-type: none"> - Federal Law on Product Liability (FLPL) of 18 June 1993 implements the European Directive on the same subject. - Article 4 FLPL– Products are defective if they are not as safe as one could expect in the circumstances and the nature of the defect is immaterial. - Law defines manufacture liability – manufacturer defined “as the person who produces the product, the one who presents himself as such, the one who imports the product within his commercial activity, or, if no such person can be found, the one who furnished the product” (article 2). - The manufacturer can avoid liability by showing that he did not put the product on the market or that he did not produce or sell the product within his commercial activity. (article 5) - Damages are measured by “the difference between the two states of 	<p>Licence contracts may be registered if the patentee so declares (<i>FLPI</i>)</p> <p><i>Sec. 90.-(1) FLPI</i> lists conditions:</p> <p><i>Any condition in a contract relating to the sale of a patented article or to a licence under a patent of which the effect will be-</i></p> <p style="padding-left: 40px;"><i>(a) to prohibit or restrict the purchaser or licensee from purchasing or using any article or class of articles, whether patented or not, supplied or owned by any person other than the seller or licensor or his nominee;</i></p> <p style="padding-left: 40px;"><i>(b) to prohibit or restrict the licensee from using any article or process not</i></p>

	<p>However, import restrictions based on intellectual property rights fall to be assessed under this Act.” Furthermore, article 6 para 1(d) states that agreements granting the exclusive use of IP rights, even where they affect competition, will generally be deemed justified on the grounds of economic efficiency.</p> <p>Some authors have noted that the second sentence of article 3 para 2 above opens the door for IP agreements to be scrutinized under the Act. This provision permits the Competition Commission to review parallel import restrictions – it can review otherwise legitimate territorial restrictions established by patent law and licensing agreements. A broad interpretation of this provision would seem to imply that Switzerland has moved towards a regime of international exhaustion of patent rights (<i>Swiss Cartel Law 2004 Reform</i>). Indeed, the authors of <i>Swiss Cartel Law 2004 Reform</i> go on to</p>	<p>the patrimony which would have existed had the injury not occurred and that which actually exists.”</p> <ul style="list-style-type: none"> - If the sued party has caused a death they have only to pay for the costs that are a direct result of the death, such as the funeral expenses. However, third parties can sue for loss of support as a result. - Can claim for moral damages for the pain suffered as a result of an injury to bodily integrity (as per article 47 of the Code des Obligations). In cases of death, spouses, parents, children, and possibly others can make a claim for moral damages under this provision. These damages are not extremely high – in case of death the indemnity has varied between CHF 10,000-40,000, and in case of injury the highest awarded damages thus far was 120,000. - Swiss law does not allow for punitive or exemplary damages. <p>Drug Regulation</p>	<p><i>protected by the patent;</i></p> <p><i>(c) to require the purchaser or licensee to acquire from the seller, licensor or his nominee any article or class of articles not protected by the patent;</i></p> <p><i>(d) to require or induce the purchaser to observe a specified minimum resale price in respect of any article or class of articles protected by the patent; or</i></p> <p><i>(e) to prohibit or restrict the making, using, exercising or disposing of the invention concerned in any country in which the invention is not patented,</i></p>
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	<p>state that: “The Competition Commission certainly takes the view that a transfer of intellectual property rights to a distributor, thus enabling him to prevent parallel imports into Switzerland, is unlawful under the revised Cartel Act by virtue of the combined effect of the newly introduced Article 3 paragraph 2 and Article 5 para 4.” (p. 14)</p> <p>[Article 5 para 4 reads as follows: “The elimination of effective competition is also presumed in the case of agreements between enterprises at different levels in the market regarding fixed or minimum prices as well as in the case of agreements in distribution contracts regarding the allocation of territories in so far as sales by other distributors into these territories are not permitted.” This provision was added in the revision of 2003.]</p> <p><u>Authorization of Agreements in the Public Interest</u></p>	<p>Pharmaceutical products are regulated in Switzerland by the public agency Swissmedic. Swissmedic was created in 2002 by the <i>Loi fédérale sur les produits thérapeutiques</i> with the purpose of overseeing the licensing, manufacturing, distribution, and quality of medicines. It controls all aspects of pharmaceutical regulation except for price, which is determined by the Federal Office for Public Health.</p> <p>All pharmaceutical products distributed in Switzerland must first be authorized by Swissmedic. An application for authorization must be filed by a company in Switzerland or through a subsidiary similarly located. Swissmedic will carry out a clinical assessment of a drug to ensure its suitability for distribution, using data provided by the pharmaceutical industry. Under the basic application stream, a drug should take 200 days to be approved, however Swissmedic’s most recent business report acknowledges that this time limit is not always achieved. There also exists a simplified authorization procedure for products containing known ingredients, complementary medicines, the in-</p>	
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	<p>The law on competition also includes a mechanism under which the parties to an agreement can exempt themselves from sanction. Article 8 states that: “Agreements affecting competition ... may be authorized by the Federal Council at the request of the enterprises concerned if, in exceptional cases, they are necessary in order to safeguard compelling public interests.”</p> <p><u>Authorization of Agreements for Economic Efficiency</u></p> <ul style="list-style-type: none"> - Can get exemption for an agreement that would otherwise restrict competition if it is justified by economic efficiency. <p><u>Technology Transfer Agreements (as outlined in <i>Swiss Cartel Law 2004 Reform</i>)</u></p> <ul style="list-style-type: none"> - To be exempt from scrutiny under competition law, these agreements must first avoid two things: 1. They cannot prohibit imports, and; 2. 	<p>house preparations of hospitals or pharmacies for their own patients, drugs for the army or those drugs that are important for rare diseases. Applications under this stream take 130 days for approval. Finally, in cases where the non-authorized drug is important for “the treatment of fatal diseases, when no equivalent is available, when there is a great expectation about the effectiveness of the treatment and if the use of the drug is compatible with health protection” there is a temporary license available that can allow its distribution prior to the 130 or 200 day period.</p> <p>Prices for pharmaceutical products listed as part of the universal health care coverage provided to Swiss citizens are determined by negotiation between the manufacturer and the Federal Office of Public Health. Drug companies are welcome to forego adding their product to the list of compounds covered by the public system and charge whatever price they wish, however in practice this is fairly rare. To be added to the list of covered drugs a product must be approved by Swissmedic, be “effective and appropriate” and be value-</p>	
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	<p>They cannot fix prices.</p> <ul style="list-style-type: none"> - Such agreements will also be subject to the requirements as set by the EU Directives on the subject. The EU does have the <i>2004 Technology Transfer Block Exemption</i> that shields agreements from scrutiny where, if the parties are competitors they make up less than 20% of the market or if non-competitors less than 30% of the market. Both technology and product markets are used to determine market share. - However, even if the actors involved in the agreement do not pass the market share thresholds, their agreement may not take advantage of the exemption if it contains the following clauses/has the following effects: <ul style="list-style-type: none"> o Clauses that prevent one party from determining the price it will charge or output it will produce; o Clauses that allocate markets or consumers <i>unless</i> they take the 	<p>for-money. For those drugs not listed, the price charged by the manufacturer is subject to scrutiny by the Price Council, a government body mandated to protect customers from excessive prices charged by companies in a dominant position.</p>	
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	<p>following form –</p> <ul style="list-style-type: none"> ▪ Where licensee in non-reciprocal agreement has obligation not to produce with the licensed technology in jurisdictions reserved for the other party; ▪ Where licensor agrees to not license the tech to another actor in a particular jurisdiction; ▪ “requirements that the licensee under a non-reciprocal agreement produce the contract products only for a particular customer where the license was granted in order to create an alternative source of supply for that customer.” (p. 40) <p>- The block exemption also does not apply to “agreements between members of a patent or know-how pool that relate to the pooled</p>		
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	<p>technology, unless all parties are free to manufacture, use or market the licensed products throughout the EU.” (p. 43)</p> <ul style="list-style-type: none"> - Also, to be valid under the exemption, the agreement must allow for a licensee to “retain the ownership” of any improvements he or she makes to the licensed technology. An obligation that the licensee assign the improvement to the licensor will not be permitted – “at most he can be required to give the licensor a non-exclusive license of his improvements in return for a non-exclusive license of the licensor’s improvements.” (p. 44) - Also must get permission to use exemption when agreement contains a provision which prevents licensee from challenging the validity of a patent within the EU. <p><u>Quality Specifications</u></p> <ul style="list-style-type: none"> - Following on above, minimum 		
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	<p>quality specifications included in an agreement must be necessary for proper technical use or for meeting minimum quality requirements binding on the parties. However, an agreement can include quality specifications greater than those above and still gain the benefit of the exemption if the EC Commission is notified and does not oppose the condition.</p>		
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