

**Fostering R&D and Promoting Access to Medicines: Locating Common Ground:  
Operationalising Patent Pools for ARVs**

**Abbreviations and Acronyms**

ABC	Abacavir
ARV	Antiretroviral
CL	Compulsory Licence/Licensing
d4T	Stavudine
ddI	Didanosine
DOJ	Department of Justice
DVD	Digital Versatile Device
EC	European Communities
EFV	Efavirenz
EMLA	Essential Medicines Licensing Agency
EPPA	Essential Patent Pool for AIDS
EU	European Union
FDC	Fixed Dose Combination
FTC	Federal Trade Commission
GDP	Gross Domestic Product
GNI	Gross National Income
IP	Intellectual Property
LPV/r	Lopinavir/ritonavir (FDC)
MOU	Memorandum of Understanding
MPEG	Moving Picture Experts Group
NNRTI	Non-nucleoside Reverse Transcriptase Inhibitor
NRTI	Nucleoside Reverse Transcriptase Inhibitor
OECD	Organization for Economic Cooperation and Development.
PLWHA	Person living with HIV/AIDS
SARS	Sudden Acute Respiratory Syndrome
TDF	Tenofovir
WHO	World Health Organisation
WTO	World Trade Organisation
ZDV	Zidovudine
3TC	Lamivudine

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## 1. Introduction

A patent pool is an agreement between two or more patent owners to licence one or more of their patented intellectual property (IP) as a package. This agreement can take many different forms (Serafino, 2007). In one common form, the IP is cross-licensed to each of the other patent owners. In another form, probably more relevant to the present discussion, a third party administers one or more package of patent licences to third party manufacturers (e.g., makers of generic antiretrovirals (ARVs)).<sup>1</sup> Thus, this IP package would be offered to third party licencees who would be authorized to use the bundle of patented inventions to exploit the technology encompassed by the patent pool. The third parties typically would pay royalties to the patent holders or to the organization structured to administer the pool. The organization allocates royalties back to the patent owners. This form of collective IP management has been around for over 100 years in a variety of industries.<sup>2</sup> (Bekkers, Iversen and Blind, 2006) Theoretical and practical reasons to create collective management structures include the possibility of lower prices, improved economies of scale; lower transaction costs of negotiating and administering licensing programmes; increased innovation; removing blocking patents and managing or eliminating litigation risks. (Grassler and Capria, 2003)

Operationalising these collective management structures for ARVs is complicated by the fact that market- driven and public health- driven views of innovation and IP in the pharmaceutical value chain are often at odds. This factor is manifest as continued debate over IP and “access” to medicines. The OECD countries have technology buyers and sellers (Evenson, 2001). However, with some exceptions (South Africa, Brazil, India, China, Indonesia), developing countries are predominantly just buyers of technology. The poorest countries do not want to commit to strong IP rights and most do not have the infrastructure (IP, computer and related legal systems) or the investments in science and technology to affectively participate in the international technology market.

This document is a review and brief evaluation of existing proposals for ARV and other essential medicine downstream patent pools. To the extent possible in a short paper, it identifies various components of these existing proposals that ultimately might be brought together and operationalised for either or both voluntary and/or compulsory patent pools. This paper is not concerned with pools for generic engineering tools or diagnostic testing.<sup>3</sup> (See Clark, Piccolo, Stanton and Tyson (2000); Delmer, D., C. Nottenburg, G. Graff and A. Bennett (2003); Ebersole, Guthrie and Goldstein (2005); Verbeure, van Zimmeren, Mathijs and Van Overwalle (2006).

- The modern (post 1995) antitrust template developed by the US and the EU to scrutinize patent pools is useful to identify in a preliminary way those operational factors in a patent pool that would be considered “pro-competitive” by legal authorities and thus be viewed favourably.

No pharmaceutical patent pool has yet formed and has yet to receive such legal scrutiny, despite suggestions that such pools could be “pro-competitive” for the biotechnology industry at least

(Clark, Piccolo, Stanton and Tyson 2000). It remains to be seen if the way the pharmaceutical industry views IP is fundamentally different from view of the industries where patent pools have already been formed.<sup>4</sup>

- Notwithstanding different market-driven and public health-driven perspectives on access to pharmaceuticals, a public-health viewpoint still needs to be aligned with these patent pool elements that have been crafted to avoid running afoul of US and EU competition laws (OECD 2005; US DOJ 2007).<sup>5</sup>
- The justification for, and practicability of, important components of a feasible downstream ARV patent pool are summarized in the ‘bullet points’ throughout the text. I have been asked specifically to comment on the possibility of a downstream patent pool for ARVs (current and future) to facilitate the production of fixed dose combination (FDC) pills.

### *Definitions*

#### **1.1.1 Complementary (essential) patents.**

An “essential” patent is one that is necessary to implement the technology. Thus, for an FDC consisting of three patented ARVs, X+Y+Z, each patent is essential to the pool. Essential’ ARV patents, by definition, have no substitutes. That is, one needs licences to each of them in order to make a product (i.e., FDC). One operational implication endorsed by the US and EU antitrust authorities is that patents inside AND outside the pool should **not** be substitutes (Lerner and Tirole, 2007) . However, this may literally not be possible with ARVs, or with many other medicines generally (see Section 1.1.2, below).

#### **1.1.2 Substitute patents:**

A “substitute” patent is a **competitive substitute** for other patents in the pool. Indeed, at present many ARVs in the same class are technically “substitutes”. The World Health Organization (WHO) 2006 Treatment Guidelines (WHO 2006) requires 2 NRTIs + 1 NNRTI for first line standard triple therapy. To create FDCs of these triple regimens (See Table 3) requires two different NRTIs that would likely be “competitive substitutes” absent the pool.

### 1.1.3 “Downstream”

A final product or process of making or using an ARV.

## 2. Proposals for Downstream Biomedical Patent Pools

### 2.1 Essential Medical Inventions Licensing Agency (EMLA)

EMLA is a non-profit designed to assist various partners to “create and manage” one or more patent pools. The mechanisms for establishing a patent pool are such that once a pool is established, EMLA will seek voluntary licences from IP owners as a licensee via an EMLA “in licence” and the IP contained in the primary licence to EMLA will be further sublicensed for generic production and distribution. If EMLA cannot negotiate a primary in-licence, it will consider seeking compulsory licences.

### 2.2 UNITAID Patent Pool

UNITAID proposes the formation of a pool of licenced ARVs to create FDCs. If companies refused to enter the pool, UNITAID would seek compulsory licences in a variety of ways. A comprehensive legal analysis of a proposed UNITAID pool has been completed (Charles Clift, Personal communication August 2007). It should be consulted for further details. The present paper was written without benefit of this UNITAID review.

### 2.3 Essential Patent Pool for AIDS (EPPA)

The EPPA patent pool would be a stand alone, non-profit entity that would identify essential patents for the treatment of AIDS in developing countries. Patent owners would be asked to voluntarily licence patents to the EPPA, for use in countries “not designed as high income by the World Bank”. In cases where the EPPA failed to obtain voluntary licences, it would seek compulsory licences. Licensing by the EPPA, under voluntary or non-voluntary arrangements, would be consistent with national patent laws and trade agreements on patents. Non-exclusive licences would be given to all comers (EPPA used the term “open” licence). Licensors would get “adequate remuneration using transparent and predictable royalty guidelines...”.

## 3. Feasibility/Implementation of an ARV Patent Pool

This document is concerned with patent pools but they are not the only system that may make sense. In this regard, it is useful not to think about regulating particular collective IP **structures** but instead think about regulating certain **functions**. That is, perhaps we should understand that many of the same functional things that can be accomplished through pools can be accomplished by other means including standard setting organizations, mutual covenants not to sue and so forth.

Recent patent pools in the electronics industry were established in order to promote a standard or a technology and, as these have led to a substantially larger market, they have succeeded. The higher penetration (larger market) may offset the typically lower income per licence of pools compared to bilateral licensing. This will certainly be the case with the type of royalty allocation that has been proposed in the EMLA and EPPA patent pools. When such a promotion of a technology is the key objective of the parties involved, this trade-off may be acceptable, although many other operational considerations need to be taken into account:

- Information asymmetries between the private sector and the public health community abound in terms of the perceived value of individual patents, the costs of ‘designing around’ pool IP, future research strategies and so on;
- Patent pools whose main driver is price control, not promotion and larger market size, are not very likely to be successful. There will be too many IPR owners who will conclude that joining a pool will not satisfy their expectation for licensing income. In addition, pools will loosen control over their IPR, limiting patent owners’ ability to use it as “bargaining chips”<sup>6</sup>;
- What is the main driver of an ARV/FDC patent pool? Market promotion/penetration or price control? Or both?;
- Moreover, if industry patent owners protecting a valuable market advantage are to offer non-exclusive licences to all-comers, they need some economic incentives.
- If the cost of joining the pool is small relative to the cost of the product then it is likely that a firm will join the pool regardless of other incentives. If a firm looks at their own profit and determines that the cost of the pool is high ( i.e., lowered royalties on individual products, high transaction costs, placing their IP at risk from challenge by others in the pool) then they may start to contemplate other alternatives.

### ***3.1 Forcing the creation of a pool***

The overwhelming majority of modern patent pools have been voluntary.<sup>7</sup> However, compulsory licensing is a real option (WTO/TRIPS Article 31; Abbott and Reichman (2007)) and if non-cooperative patent holders are causing serious health risks by refusing to enter a pool, the threat of a compulsory licence should be used to force uncooperative patent holders into reasonable negotiations.

However, compulsory licensing has, so far, been ineffective or unpopular in practice from the biomedical industries’ viewpoint.<sup>8</sup> Companies are primarily self-interested and revenue-driven and will try to maximize economic benefits. Further, the biomedical industry and early stage R&D entities (public and private) continue to use IP as leverage to secure initial funding

- In practice, a compulsory licence-generated patent pool might be workable for sub-Saharan Africa as it appears the pharmaceutical industry is not enforcing their IP in this region. This apparent “hands off Africa” attitude is likely NOT the case for Southeast Asia or China or India. The uproar over the recent compulsory licence issues with regard to Brazil and Thailand, plus the pressures placed on TRIPs in bilateral trade agreements by the US, suggest that a fully functional compulsory licence-generated ARV pool will be difficult (but clearly not impossible) to create and maintain. One can trot out the tired phrase “political will” but a lot of money and skilled legal advice are also needed (Abbott and Reichman, 2007));
- Abbott and Reichman (2007) provide a detailed analysis of the policy options available to the EU with regard to compulsory licensing<sup>9</sup>. It is worth quoting them: “In principle, there is no compelling reason why originator companies, as well as the generic sector,

could not prosper in a voluntary ‘low margin, high volume’ environment. Yet to date, this marketing approach has not appealed to the originator sector. This is one reason that government use and compulsory licensing remains a vital alternative for the supply of public goods in the form of medicines.”;

- Sales in the African pharmaceutical market are about 1 percent of the global HIV/AIDS market by value (Global Business Insights, 2007). The majority of innovator companies who would be members of an ARV pool (See Tables 1-3) recover most of their HIV/AIDS related R&D expenses in the OECD. Compulsory licence use by an ARV pool for sub-Saharan Africa countries may not have much of an impact on innovation and R&D levels by these companies. Indeed, as discussed below in Section 4.3, voluntary or compulsory licensors to the EMLA pool would receive almost no royalty income from sub-Saharan countries in any case.

### **3. 2 ARV Patent Pool: WHO OWNS WHAT?**

- A first order question before creating any collective scheme for IP is knowledge of the patent landscape. What licences are need and from whom? A worldwide, easily accessible, IP database as a global public good is a creature that does not now exist.

Table 1 (Annex 1) summarizes information gleaned from several sources on ARVs, their patent expiry dates and the patent owners. There are surely many other patents covering these ARVs that are not shown in these Tables (specific dosages, formulations, methods of use and so on). All these will have to be identified as a first step.

Table 1 reveals that most ARVs are the result of joint inventorship (>1 patentee) but joint inventorship is not the same as joint ownership.<sup>10</sup>

- The concept of joint ownership of a US patent introduces some uncertainty into understanding of who needs to be in the pool, who needs to be remunerated, and the financial advantages, if any, to join a pool. Obviously, much “due diligence” will need to be done and industry will have to find good reasons to enter into an ARV patent pool voluntarily;<sup>11</sup>
- Absent some agreement to the contrary (such as an exclusive license from the other co-owners to one co-owner in exchange for royalties), joint ownership of a US patent allows for each joint owner to licence independently without accounting to the other owners. In Europe, each country has their own rules about this (European Commission, 2007). It is not clear what the situation would be in other countries around the world.

Tables 2 and 3 (Annex 2) summarize the triple therapies (none of which are in triple FDC form at present) recommended by the WHO 2006 Treatment Guidelines for first line and second line treatments, respectively. The likely number of potential licensors into a pool designed to facilitate production of generic versions of these ARV (whether in blister pack or FDC) is small but not trivial.

#### **4. Essential Operation Elements of Successful Patents Pools: Are These the Correct Ones for an ARV/FDV Pool?**

##### **4.1 A protocol to objectively define those patents that may be in the pool**

From the viewpoint of antitrust authorities, one way to ensure that a proposed downstream ARV pool will integrate only complementary patent rights is to limit the pool to patents that are 'essential' to comply with some standard (OECD 2005; US DOJ/FTC, 1995; USDOJ/FTC, 2007). Most modern patent pools have emerged from, or have been closely associated with, industries where the value of a product to a particular consumer is a function of how many other consumers use the same (or a compatible) product. The best example is the telephone network, in which the value of the product is entirely driven by the number of other people on the same network. These industries require a standard setting organization that is required to create consistent interoperability (Lemley, 2002; Shapiro 2000). Vaccines as well as ARVs appear to have this type of 'network' property.

- At present, there is no “standard setting” organization with regard to ARVs and/or FDC although a “standard” is not absolutely required by antitrust authorities. However, the WHO Standard Treatment Guidelines seem as good a starting place as any for an FDC patent pool. Further, there are other biomedical standard setting bodies such as governments (e.g., NIH), industry trade groups; and non-profits (Goldstein, 2005);
- A valid operational choice for an ARV pool would be to compete within a standard rather than for a standard. That is, the members of the pool will collaborate on a standard, and then compete on price, quality, or whatever else that is within the implementation of the standard;
- Antitrust authorities could insist that an ARV pool not combine patents that would otherwise be competing with each other, as placing them in one pool would in principle eliminate competition between them. Specifically, the concern is that, if **substitute ARV** patents are combined in a pool, the risk is the pool can act as a price-fixing cartel.<sup>12</sup>
- This may be avoided by creating a “standard” set of FDCs and the patents would be commensurate with the standard. Operationally, “substitutes” should be permitted in an FDC pool when: a) at least one of the substitutes is necessary to produce the downstream product or follow the standard specified in the licence and b) the substitute IP is not sufficient by itself to produce the downstream product or follow the standard but other intellectual property is required and is offered by the licence;
- Where no standard exists, it is possible to operationalise this by clearly defining a limited field of use for a pool’s license in order to determine whether the included patents are “complements” or “substitutes”.
- Most pools have an independent expert(s) look at “essentiality”. It is likely that this expert is being compensated by the pool organization to make these determinations. EMLA would appoint an advisory board for this purpose. Political/industry pressure to list or “delist” one or another patents essential (or not), will be intense. In a perfect

- operational system, a foundation would exist whose sole purpose will be to determine “essentiality” of patents to a standard;
- Operationally, it may be important to have a ‘menu’ of ARV patents that licensees can choose from, rather than a “take them all’ approach. This might ease the problem of “substitute” patents in the pool. Further, licensees should not have to pay for IP that is “not necessarily needed” (Morse, 2002);
  - A partial menu of licences may be important as well since what may be “essential” today may not be tomorrow. That is, over time, some patents may no longer be essential to all the pool’s licensees. Further, some licensees may desire partial licences if they already have access to some of the necessary technology through pre-existing licences;
  - Partial licensing for certain IP will be important to operationalise correctly. If a pool administrator could be required to offer many different permutations of licences, perhaps at differing royalties, in addition to the broader pool licence, this may not create the efficiencies that flow from reducing transaction costs in a pool. Possibly, the right of division would defeat the purpose for which the licence is created;
  - **Possibly, a more preferable mechanism would be a continuous review of the licensed patent portfolio that is designed to exclude patents from the pool that have become nonessential over time;**
  - **The more bureaucratic complexity that is built into the pool operations, the costlier it will be to operate and maintain and, arguably, the less desirable it is.**

#### **4.2 Preservation of opportunity for patent owners to licence its patents outside the pool**

In virtually all patent pools, whether voluntary or not, the patent owners grant a nonexclusive licence to the pool and retain the right to licence its patent outside the pool. This is an advantage as members of the pool can take their technology in directions unrelated to the pool and market the outcome. Thus, preventing patent owners to licence outside the pool could be a strategy for stifling new collaborations and this is not looked upon favourably by administrators and the courts.

If a licensee independently negotiates a bi-lateral licence directly with a patent owner, that should be a matter to be worked out directly between them. Licensees should not begrudge patent holders their right to collect royalties for their patents outside the pool as long as that revenue stream is separate from the royalties that pool licensees pay so that its fairness is apparent.

- Maintaining some freedom to operate outside the pool may be a ‘selling point’ for industry as licensors and licensees be free to combine technology either to improve or compete with the pooled technology, particularly critical if IP rights are arranged relative to a standard or a product (e.g., FDC).

- Maintaining some freedom to operate outside the pool, in effect, facilitates price discrimination because one can charge different prices for the same piece of IP, but price discrimination by itself may offer benefits to pool members;
- Operationally, if the pool is large and there are many IP owners, independent licensing outside the pool may seem less attractive to existing patent owners in the pool because of the high transaction costs.

### 4.3 Royalties should be “fair, non-discriminatory and reasonable”

#### 4.3.1 Collection of royalties from sub-licensees

##### 4.3.1.1 What is a ‘fair and reasonable’ royalty?

Antitrust authorities require royalty rates be ‘fair, non-discriminatory and reasonable’ (OECD 2005; US DOJ/FTC 1995; US DOJ/FTC 2007). Market-driven and public health-driven views will likely diverge. A primary motive for a patent pool from a public health viewpoint is to accelerate adoption of certain ARVs and lower their prices, e.g., accelerate adoption of a “standard” regimen of generic FDCs. A licensor (Tables 3 and 4), who pursues patents only for ‘defensive’ means to protect its IP but wants to maximize sales of its products, would also want to accelerate market penetration, but probably **not** at the expense of lower price in royalties. For some pool members, such as non-profits or early stage research organizations (National Institutes of Health, Universities), their business agenda may mostly to maximize licensing revenue of the pool.<sup>13</sup>

- Some patents may be technically essential to implement a standard (i.e., create a specific ARV FDC regimen) but may not be practically essential if a potential licensee (e.g., Cipla, Ltd.) already has a licence to a patent in the pool. Thus, to insist that all prospective generic manufacturer licensees “take all patents or leave it”, may not be a realistic economic choice. This conditions a licence to patents on a licence to others and firms will pay twice for the right to use the technology. See Section 4.2.

In the EPPA and EMLA patent pool proposals, royalties due patent owners are based on ability to pay. In the EPPA pool, for sales in **high income countries** of a pool-related ARV, there is a base royalty of 4% of the median annual price of a yearly dose of a given product, the median estimated from Canada, Germany, Italy, France, Spain, the United Kingdom and the United States.<sup>14</sup>

- Changing market conditions may render these licence terms reasonable at the outset of the pools, unreasonable years later.

For countries with severe HIV epidemics, EPPA scales the base royalty down by the ratio: Gross domestic Product (GDP) (now called Gross National Income (GNI)) per person living with HIV (PLWHA) in that country / the average GNI per PLWHA for all “high income” countries. For countries in sub-Saharan Africa, this likely means zero royalties on ARV sales.<sup>15</sup>

- From a public health viewpoint, royalty-free licences can reduce production costs, which may allow licensees to offer lower prices to consumers because they do not have to account for per-unit royalties in the final price of the product;

- Licensors (i.e. particularly biomedical patent holders), however, tend to let their investors think that their IP is extremely valuable and this cuts against the idea of zero, or low priced royalties.

#### 4.3.1.2 Royalty non-discrimination. What does that mean in practice?

Market-driven and public health-driven motives may, or may not, diverge on this point. Tiered royalties (see above) results in royalty discrimination between countries such that a generic producer/licensee in India will pay the pool a different royalty for the same product than a generic producer/licensee in Sweden. From a public health viewpoint, this discrimination is consistent with royalties being based, in part, on the ability to pay. From a market viewpoint, this inter-country discrimination may even be acceptable as well since there is no royalty discrimination among those selling the same products in the same place in the distribution chain. As the EMLA and EPPA pools are set up, this would be true within individual countries.

Note that the Most Favoured Nation clause used in the TRIPS Agreement (Article 4), asserts that if a country grants favourable terms and conditions for one country, all other countries have the right for that same terms and conditions. MFN provisions are found in patent pools and are currently used to promise licensees that no other licensee will receive better terms.<sup>16</sup>

- Lack of an MFN clause in an ARV/FDC patent pool may actually be useful to include royalty distinctions to different applications. For instance, licensees can pay different royalties for making, using, or selling FDCs, vs. blister packs vs. loose pills. Again, note that the more complexity is built into a pool, the costlier and less desirable it might be. Many standard-setting organizations require members to license in this manner where royalty rates vary from licensee to licensee, but they must in general be set at reasonable rates that roughly correspond to the value of the underlying technology. (Lemley (2002));
- The EMLA and EPPA royalty formulas treat large, emerging markets (China, India, Brazil) in the aggregate. These particular countries, however, have wealthy middle and upper classes that, in principle, could generate important royalty income to patent owners if royalties were differentiated **intra-country**. It will likely be important to some industry members to take this intra-country ability to pay into account. To what extent this can be operationalised in an ARV pool remains to be seen.

#### 4.3.2 Allocation of royalties to licensors.

Patent pools in the US allocate royalties to licensors in several ways. Just 1 of 9 US pools since 1990 have been royalty free (Layne-Farrar and Lerner, 2006) so allocation “rules” are moot in this case. Allocation “rules” do, however, create operational issues. Numeric proportional rules are common where total royalties collected by the pool administrator are calculated as the number of patents contributed by a firm to the pool in a given country divided by total number of essential patents contributed by all firms.

- How does royalty “rent” change when new patents are added? New IP dilutes the share that other parties get. There is a perverse incentive to reduce patenting efforts if royalty

allocation shares are thus diluted. One solution is for licensing royalties for existing patents to remain unchanged when new IP is added to the pool;

- For FDCs, one could divide the total royalty collected for that FDC from a given country by the number of patent owners contributing to that FDC. Equal shares for each. If components X+Y+Z (three different patentees) are in an FDC and 3 patents are needed to make X, 1 for Y and 2 for Z, then X gets 50% of the royalties per unit, Y gets 16.6% and Z gets 33.3%;
- Note that in the previous numeric allocation rule, every additional patent into the patent pool is more or less money to the other patent owners and this may operate as an incentive for pool members to question the “essentiality” of a patent or to add as many patents as possible to the pool.

Patent counts do not reflect the value of the underlying IP. Thus, value proportional allocations are also common where pool members with more “valuable” IP contributions get more allocation. These rules can be complex with division of earnings based on certain value indicators of the patents such as age of patent and how often they are infringed. For FDC pools with few patents, this is not the best way to approach allocation.

The EMLA royalty allocation provisions are vague. EMLA pools royalties and allocates this royalty based “on the relative contribution of Licensor’s Licensed Patents to the Product”. This is to be determined by the EMLA advisory board and, if no agreement is reached, by negotiations, then some type of alternate dispute resolution.

In the EPPA proposal, when a product consists entirely of multiple patented inventions (e.g., FDCs), allocated royalties are determined upon agreement among the patent owners, or arbitration or by an outside expert.

- Operationally, organizing documents should insist that the pool operate at all times with due regard to the interests of all of the users of the technology being licensed, present and future licensees alike, members and non-members alike, and with particular regard to the public interest in a maximally open competitive market;
- Significant pool operations need to be open to public view. This could, for example, take the form of a publicly available website where minutes of the meetings of the pool’s governing board are posted

#### **4.4 Procedures and auditing features that do not disseminate competitively sensitive proprietary information among owners of pooled patents**

In practice, this is going to be very difficult to manage. Although EMLA contemplates transfer of data for drug registration in both the EPPA and EMLA pools, licence terms for entering the pool and for producing generic versions of ARVs appear to be strictly patent licences and there is no associated licence for non-patentable information owned by the patentee firms (i.e., ‘trade secrets’ or ‘know how’)<sup>17</sup>.

- There needs to be some auditing mechanism for managing royalties. Independent auditors must secure confidentiality of licensor’s competitively sensitive information. Parties can design “firewalls” to limit access to each others’ sensitive information;

- A separate know-how licence may need to be negotiated with the patent owners. Dispute resolution mechanisms will be required for these confidentiality issues but this may not be practical with a small pool;
- Notwithstanding, the auditing systems could get costly. To be fair, large and successful pools have been operating for many years with similar issues so solving questions of confidentiality and transfer of non-patentable information are not insurmountable.

#### **4.5 Avoiding licensing conditions that discourage future innovation**

Grantback provisions allow patentee members of the pool to turn to the pool for future patents that are ‘essential’ to working of the pool. The scope of the grantback should be commensurate with the scope of the pool, i.e., covering only essential patents. Grantbacks can promote competition within patent pools by enabling licensors to practice improvements that licensees make to the licensed technology. From a public health viewpoint increased innovation is to be encouraged. Specifically, royalty free grant backs can discourage situations where some new improvement is developed and then used to hold up the pool for high royalties. Some resistance to operationalising this is inevitable.

- Assume that as a 3<sup>rd</sup> party licensee in an ARV pool, Aurobindo develops an improved form of ddI. Royalty free grant backs thrown into an ARV pool would, from patentee Abbott’s viewpoint, be sub-optimal as this tends to encourage ‘free riding’ by other licensees and, particularly, other patent owners in the pool- e.g., GlaxoSmithKline, Merck etc.;<sup>18</sup>
- Overall, grantbacks limited to innovations within the scope of the existing patents in the pool and further limited to include only essential patents are more likely to be pro-competitive. In addition, favoured grantbacks are nonexclusive, so licensees may freely use their own inventions and licence them to others;
- Future inventions made by the original patent owners should also be rolled into an existing pool but the package royalty rent may have to be adjusted accordingly. For example, perhaps royalties on Merck’s new patents in an existing pool should be weighed more than royalties on Merck’s “old” IP as everyone would benefit from new essential patents into the pool.

#### **4.6 Some mechanism to determine validity of patent or decide what to do if patents are invalid**

A licensing scheme premised on invalid patents will not stand antitrust scrutiny. Definitive conclusions as to validity take years.

- Licensees need to have a mechanism to bring relevant information regarding the validity and ‘essentiality’ of patents in the pool to the attention of the independent experts;

- A pool administrator should rely on good faith, reasonable determinations by independent experts that it is more likely than not that a patent is valid and thus, infringed absent a licence.

EMLA includes any issued, pending and future patents and patent applications as part of the pool to be licensed to generic manufacturers. EMLA licensees pay a royalty for products provided that there is a “Patent” in-country covering the product. However, “Patent” is defined to include patent applications. EPPA appears to restrict licences to issued patents.

- If patent applications are part of pool, this creates uncertainty as to whether the cost of setting up pool is worth the [unknown] royalty income from a patent of unknown scope/value derived from a patent application. Royalties should be paid only on issued patents that encompass the particular ARV or process for making it;
- Patent applications should not be part of a pool. Royalties can, of course, be paid on patents issuing from applications. It is easy enough to redefine what a “Licenced Patent” can be;
- Operationally, it is important to include a procedure for deleting patents from the pool when this patent expires, is found invalid by a court, when its holder leaves the pool, or when this patent loses its “essentiality”.

Generic Name (1)	Brand Name (2)	Patentee (3)	U.S. Patent Expiration Dates (4)	U.S. FDA Applicant for Market Approval (5)
Tenofovir	Viread®	Ceskoslovenska cademic ved; Gilead ; Rega Stichting, v.z.w. (BE)	300mg: 2017	Gilead
		Inst. Of Organic Chemistry and Biochemistry of the Academy of (CZ);		
Emtricitabine	Emtriva® (FTC)	Emory University	Liquid: 2010- 2021 200mg: 2010- 2021	Gilead
Indinavir	Crixivan®	Merck	All solids: 2012- 2021	Merck
Nelfinavir	Viracept®	Agouron Pharmaceuticals	All solids: 2013- 2014	Agouron
Ritonavir	Norvir®	Abbott	Liquid: 2012- 2016 100mg: 2012- 2020	Abbott
Saquinavir	Invirase®	Hoffman La-Roche	200mg: 2010	Hoffman La-Roche
Lopinavir/ Ritonavir	Kaletra®	Abbott	Liquid: 2012- 2022 Tablet: 2012- 2020	Abbott
Atazanavir	Reyataz®	Novartis; Bristol- Myers Squibb	All solids: 2017- 2018	Bristol-Myers Squibb
Didanosine	Videx®	Wellcome Foundation, U.S. Gov't	All solids: 2006- 2012  Liquid: 2006- 2007	Bristol-Myers Squibb
Emtricitabine/ Tenofovir	Truvada®	Gilead	200/300mg: 2010-2021	Gilead

5. ANNEX 1

*Table 1: ARVs and Their Patent Status*

Generic Name (1)	Brand Name (2)	Patentee (3)	U.S. Patent Expiration Dates (4)	U.S. FDA Applicant for Market Approval (5)
-			Source: U.S. FDA. “Orange Book”	
Zidovudine	Retrovir (AZT)	Burroughs Wellcome/Duke	not listed	GlaxoSmithKline
Lamivudine	Epivir (3TC)	IAF BioChem International, Inc.; Glaxo; BioChem Pharma	Liquids: 2009-2018  Solid: 150mg: 2009-2016 300mg: 2009-2016	GlaxoSmithKline
Stavudine	Zerit (d4T)	Yale University	Liquid: 2008 Solid: 15/20/30/40 mg: 2008	Bristol Myers Squibb
Efavirenz	Sustiva®	Merck; DuPont; Bristol- Myers Squibb	600mg: 2012-2018	Bristol Myers Squibb
Nevirapine	Viramune®	Boehringer-Ingelheim	200mg: 2011-2012	Boehringer Ingelheim
Lamivudine/ Zidovudine	Combivir®	GlaxoSmithKline	150/300mg: 2009-2016	GlaxoSmithKline
Lamivudine/ Zidovudine/ Abacavir	Trizivir®	GlaxoSmithKline	300/150/300 mg: 2009- 2018	GlaxoSmithKline
Abacavir	Ziagen®	Burroughs Wellcome; Glaxo	Liquid: 2009-2020 300mg: 2009-2018	GlaxoSmithKline

Source for Table 1: <http://www.cptech.org/ip/health/aids/un aids.html>;  
<http://www.essentialinventions.org/docs/eppa/>

6. ANNEX 2

**Table 2: Potential Licensors of a First Line ARV Pool (WHO 2006 Guidelines)**

WHO 2006 Treatment Guidelines: FIRST LINE REGIMENS	
Regimen	Potential Licensors(?) to Pool
<b>ZDV/3TC/NVP</b>	Burroughs Wellcome/Duke; IAF BioChem International, Inc.; GlaxoSmithKline; BioChem Pharma; Boehringer-Ingelheim
<b>ZDV/3TC/EFV</b>	Burroughs Wellcome/Duke; IAF BioChem International, Inc.; GlaxoSmithKline; BioChem Pharma; Merck; DuPont; Bristol-Myers Squibb
<b>TDF/3TC/EFV</b>	Gilead; IAF BioChem International, Inc.; Glaxo; BioChem Pharma; Merck; DuPont; Bristol-Myers Squibb
<b>ZDV/3TC/TDF</b>	Gilead; GlaxoSmithKline; Burroughs Wellcome/Duke; IAF BioChem International, Inc.; BioChem Pharma
<b>TDF/3TC/NVP</b>	Gilead; IAF BioChem International, Inc.; Glaxo; BioChem Pharma; Boehringer-Ingelheim
<b>ABC/3TC/NVP</b>	Burroughs Wellcome; Glaxo; IAF BioChem International, Inc.; BioChem Pharma; Boehringer-Ingelheim
<b>ABC/3TC/EFV</b>	Burroughs Wellcome; Glaxo; IAF BioChem International, Inc.; BioChem Pharma; Merck; DuPont; Bristol-Myers Squibb

**Table 3: Potential Licensors of a Second Line ARV Pool (WHO 2006 Guidelines)**

WHO 2006 Treatment Guidelines: SECOND LINE REGIMENS	
Regimen	Potential Licensors(?) to Pool
<b>TDF/3TC/LPV/r</b>	Abbott; Gilead; IAF BioChem International, Inc.; Glaxo; BioChem Pharma
<b>ddI/3TC/LPV/r</b>	Abbott; IAF BioChem International, Inc.; Glaxo; BioChem Pharma; Wellcome Foundation, U.S. Gov't
<b>TDF/3TC/LPV/r</b>	Abbott; Gilead; IAF BioChem International, Inc.; Glaxo; BioChem Pharma
<b>TDF/3TC/LPV/r/ZDV</b>	Abbott; Gilead; IAF BioChem International, Inc.; Glaxo; BioChem Pharma; Burroughs Wellcome/Duke
<b>NVP/LPV/r/ddI</b>	Abbott; Wellcome Foundation, U.S. Gov't; Boehringer-Ingelheim
<b>EFV/LPV/r/ddI</b>	Abbott; Wellcome Foundation, U.S. Gov't; Boehringer-Ingelheim
<b>ddI/3TC/LPV/r/ZDV</b>	Abbott; IAF BioChem International, Inc.; Glaxo; BioChem Pharma; Wellcome Foundation, U.S. Gov't; Burroughs Wellcome/Duke

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## 8. Endnotes

<sup>1</sup> US courts often have applied the term "patent pools" to arrangements that would now be described as portfolio cross licences because these "pools" did not licence to third parties.

<sup>2</sup> In the early part of the 20<sup>th</sup> century, most important manufacturing industries had patent pooling arrangements. The first licensing pool was among members of the sewing machine industry in 1856 and subsequently in areas as diverse as aircrafts, shoe manufacturing, automobiles and the telecommunications industry (notably arrangements around MPEG-2, MPEG-4; IEEE 1394, DVD technologies). See Lerner and Tirole, 2004; Merges, 1996; Serafino, 2007; Shapiro 2001. Note that the MPEG-2 Patent Portfolio Licence has grown from the original 8 patent owners and 100 essential patents (25 patent families) to include more than 425 essential patents (100 patent families) in 39 countries owned by 20 companies and a leading university. Bekkers, Iversen & Blind (2006) characterize patent pools into three models:

<b>Pool model 1: Joint licensing schemes.</b>	These are initiated by a group of (usually larger) licensors of a particular technology (or standard). One of them may act as an agent for the joint licensing contract. Most of these pools are eventually open to any holder of essential IPR.
<b>Pool model 2: Patent pools with a licensing administrator.</b>	Typically, there is an open call for essential patents for a certain standard by an independent body. Subsequently, the body has a patent evaluation carried out (usually by an independent, third party) to determine essentiality to the standard in question. For an ARV pool of this type, it is likely that the licensors that decide to join such a pool already know who the other licensors will be that will become a member of the pool. The licensing administrator determines whether the patents are in fact essential, sets the royalty rate for the bundles (in dialogue with the licensors), and collects the royalties and redistributes them given a pre-agreed scheme.
<b>Pool model 3: Patent platforms.</b>	In this model, a flexible approach is adopted that deals with multiple technologies (standards) and multiple product groups (employing one or more patents that are essential to a certain standard). There is one overall umbrella organisation, as well as multiple entities which each develop licensing programmes for specific standards (e.g., for specific treatment regimens?). The aim is to have a standard offer (bundle) available. However, within the context of the patent platform, licensors and licencees may also agree upon other arrangements, possible licensing of non-essential patents, and so on.

<sup>3</sup> The biotechnology industry has come into the process only recently. Patent pools have been created to exploit IP relating to a fluorescent protein useful in drug discovery (GE Pool, 2007); to animal cloning technologies; to recombinantly derived rice and potentially to the genomic sequence of the SARS virus See Goldstein (2005) and Simon, Claassen, Correa and Osterhaus, (2005). The numerous and seemingly broad scope of some biotechnology patents suggest the benefits of patent pooling and other cooperative licensing arrangements for biotechnology research and development ("R&D"). See OECD (2005); Sung, (2002).

<sup>4</sup> For example, in the fields of electronics and software, rapidly moving technology, unimpeded by regulatory barriers, means that new inventions are rapidly commercialized and patents often are most valuable at the beginning of their terms. An electronics product may be protected by hundreds of patents, but their commercially effective life may be only a few years, after which they are displaced by next-

generation technology. In contrast, it takes many years to bring a pharmaceutical/biotechnology invention to market, since it requires FDA approval. Moreover, biotech and pharmaceutical products are typically protected by a small number of patents so patent pools for pharmaceuticals are likely to contain few IP. In pharmaceuticals, a patent is valuable initially to gain the investor support required to navigate the regulatory review process, but maximum commercial value often is not realized until the end of a patent's term, when the patent owner finally is able to commercialize its product.

<sup>5</sup> From the private sectors' view, overly enthusiastic enforcement of competition laws against IP owners can damage incentives to innovate. Overly broad patents, patents on marginal improvements or "junk" patents can, on the other hand, lead to market power and detrimental effects on consumers and on firms. Agencies and courts tend to compensate by using competition laws to limit the negative effects of over-patenting. But competition law is a relatively blunt instrument.

<sup>6</sup> For instance, with regard to FDCs, many in the present suite of patent holders (See Tables 2 and 3) may decide to not compete with FDCs made by Indian/South African/Chinese generics. Further, some patent-holding pool members in an FDC pool might calculate that a higher royalty obtained by selling their individual ARVs outside the pool would offset the resulting lower market penetration it would have if it stayed outside the pool.

<sup>7</sup> The earliest, and most famous, compulsory patent pool was the 1917 "US Airplane Pool". By the time of America's entry into World War I in April 1917, the Wright brothers' basic patent, licenced to the Wright-Martin Aircraft Corp., still blocked would-be manufacturers. So too, did patents in the hands of the Curtiss Aeroplane & Motor Corp. These two firms were demanding royalties from other aircraft manufacturers. The US Government could not get enough planes built as the cost of licensing constrained industry capacity. A patent pool was in place by the end of July 1917. The aircraft pool, which encompassed most airplane manufacturers, resolved all pending infringement claims and bound the members to give each other nonexclusive licences to "all airplane patents of the United States" (with unimportant exceptions) "... now or hereafter owned or controlled by them." (Serafino, 2007)

<sup>8</sup> From a public health viewpoint, compulsory licensing forces competition into a market, and this is exactly what is needed for ARVs. But it has disadvantages and burdens that affect innovation, competition agencies and courts in all countries. Industry will argue that forcing an IP owner to grant licences eliminates some of the control over the invention that served as an enticement to create it in the first place. Improvements that would otherwise have occurred may therefore be lost if innovation is left up to generic manufacturers who would be the recipients of licences to patents for ARV pool. Finally, a major drawback to compulsory licensing is that it requires competition authorities or courts (or both) to have at least some involvement in setting the terms of the licence, and perhaps in monitoring its execution in practice, as well. Agencies and courts may find it cumbersome to have initial and ongoing involvement in licensing practices. Thailand recently joined the ranks of nations that have taken advantage of the flexibilities in the TRIPS Agreement authorizing compulsory licences for pharmaceutical patents to increase access to medicines in its health system. Between November 2006 and January 2007, the Ministry of Health granted licences for patents on two antiretroviral drugs; Efavirenz®, sold by Merck, and Lopinavir+Ritonavir (Kaletra®), sold by Abbott. A compulsory licence was also issued for clopidogrel, a heart medication sold by Bristol Myers Squibb as Plavix®. The licences were issued for government use, and included a 0.5% royalty rate. Other countries that have issued compulsory licences include Rwanda, Indonesia, Malaysia, Ghana, Eritrea, Mozambique, Zambia, and South Africa (Flynn, 2007).

<sup>9</sup> The authors were asked by the European Communities to analyse if the EC should ratify and accept the Amendment to the TRIPS Agreement adopted by WTO Members on December 6, 2005 that would formally amend the TRIPS Agreement to add a new Article 31. This proposed Article 31 reflects the terms of the WTO Decision of August 30, 2003 which established a waiver of certain TRIPS obligations, that would otherwise bar exports of medicines under government use and compulsory licences.

<sup>10</sup> The inventors of a given ARV, for instance, are the individual bench scientists in the pharmaceutical company. Absent any employment contract where they are obligated to turn over IP rights to their employer, the scientists would also own the patent but invariably they do not. For US drug firms, there is almost always an employment contract where IP rights revert to the company and are owned by the company.

<sup>11</sup> With the exception of zidovudine (ZDV), stavudine (d4T), emtricitabine (FTC) and didanosine (ddI) in the US market, one of the original patentees has applied for market authorization (Table 1). For instance, GlaxoSmithKline was one of several patentees but only Glaxo filed to market lamivudine (3TC) in the US. (See columns 3 and 5 in Table 1). It is reasonable to infer that GlaxoSmithKline has licenced in all patent rights to 3TC from the other co-owners in order to exclusively exploit 3TC in the US and **possibly** world-wide. It is more likely than not that GlaxoSmithKline, if it makes and/or sells 3TC in the US has to provide royalties on sales to the other patent owners. If so, this will surely enter into their calculus as to whether they should enter into a voluntary patent pool. GlaxoSmithKline's margins on a pooled royalty for 3TC (alone or as a FDC) in the US and possibly in many other countries may or may not be less than their total financial/royalty obligations to the other co-owners of the 3TC patents. Indeed, there may be restrictions placed on Glaxo's ability to further non-exclusively sublicense its rights in 3TC from the other owners. Note that EMLA requires the licensor to warrant that it has sufficient right and title to place patents into the pool. If a licensor cannot do this, what then? Go back and renegotiate the original agreement among the original patentees?

<sup>12</sup> With any ARV patent pool for FDCs, this issue may become important but at present it is a technical nuance. Note that the WHO Treatment Guidelines recommend 2NRTIs + 1 NNRTI as the standard triple therapy. Lamivudine, emtricitabine, zidovudine, tenofovir, abacavir and stavudine are all NRTIs. If all IP were put into an FDC pool, a strict antitrust view would view them as substitutes and this may be subject to challenge in US and EU (Gaule, 2006) Note that from a pharmacological viewpoint, they may not be substitutes.

<sup>13</sup> Typical royalty provisions in patent licences are X % of total net sales of licenced product in-country (e.g., gross revenues received by the licensee, e.g., Cipla from the sale of ZDV but minus sales and/or use taxes actually paid, import and/or export duties actually paid, outbound transportation prepaid or allowed, and amounts allowed or credited due to returns).

<sup>14</sup> For example, Gilead's tenofovir® (taken once a day) has a median price in these high income countries, excluding Spain, of 6,705 USD a year (18.37 USD per tablet taken once a day) (Patented medicines review board, 2004). The royalty is about 268 USD a year (0.04\* 6705) for every 365 tablets sold (about 0.73 USD per tablet). In order to make 1M USD a year in royalty income, Gilead would have to treat about 4000 total patients for one year in high income countries.

<sup>15</sup> I estimated the **EPPA scaling factor** as follows: Using data from the World Bank (2007) and UNAIDS (2006), the denominator of the scaling factor (average GNI per PLWHA in high income countries) was estimated with data on PLWHA (adults and children), exclusive of Brunei, Channel Islands, Bermuda, Bahamas, Barbados (no World Bank GNI Information), and Qatar, Saudi Arabia and United Arab Emirates (PLWHA taken as essentially zero). The numerator (country GNI per PLWHA) was also estimated. The resulting scaling ratio is vanishingly small for many countries (e.g., Democratic Republic of Congo = 9.4E-06; Malawi = 0.000015; South Africa = 0.00008; Thailand = 0.0004; Russian Federation = 0.0005; Brazil = 0.0006). To multiply the base royalty of 0.04 by this factor effectively reduces the EPPA royalty rate to zero in many key developing countries.

The **EMLA scaling factor** would scale an annual 4% royalty on yearly sales for any country X (except "epidemic countries") by the per capita GNI in country X / average per capita GNI in high income countries. For high income countries (exclusive of the same countries as listed in the prior paragraph), the denominator is 34491 USD (the World Bank's estimate for all "high income" countries is 34510 USD). The numerator for various "non-epidemic" countries was also estimated. Using tenofovir as an example (annual price about 6705 USD- see endnote 12), the annual base royalty (USD per 365 tablets- see endnote 12) is as follows:

"Non-epidemic" Country	USD per year
Luxembourg	604.9995
Norway	529.3348
Switzerland	455.3409
Denmark	411.3424

Iceland	402.4313
Ireland	364.7978
United States of America	357.7963
Sweden	346.7370
Netherlands	339.4967
Finland	323.4249
United Kingdom	319.6854
Belgium	307.1144
Japan	305.6027
Germany	291.3609
France	290.8039
Canada	287.7805
Australia	286.3484
Austria	283.1659
Bermuda	280.5721
Italy	254.7618
Kuwait	243.7025
Singapore	233.2797
Hong Kong, China	226.4372
New Zealand	216.8101
Spain	179.5744
Greece	172.5728
Slovenia	150.2951
Israel	147.8287
Cyprus	146.6352
Portugal	144.0096
Republic of Korea	140.7475
Bahrain	114.3325
Malta	108.2857
Czech Republic	100.8863
Estonia	90.7817

For “epidemic” conditions, EMLA scales royalties by a factor of the average HIV” rate” in high income countries / HIV “rate” in country X. Clearly, this factor will be less than 1 for most developing countries. I estimated the numerator using UNAIDS 2006 data for the average percent HIV (adults 15-49) in “high income” countries (except for Bahrain, Cyprus, Israel, Kuwait, Qatar, Saudi Arabia, United Arab Emirates where HIV prevalence is essentially zero). The denominator was also estimated from UNAIDS data (exclusive of these same countries). The resulting scaling ratio is small, but not zero (e.g., Democratic Republic of Congo- 0.12; Malawi- 0.02; South Africa- 0.02; Thailand- 0.3; Russian Federation- 0.4; Brazil- 0.8). Nonetheless, to multiply the base royalty of 0.04 by this EMLA factor also effectively reduces the EMLA royalty rate to near zero in most “epidemic” countries.

<sup>16</sup> An example is the MFN provision found in section 6.1 of the DVD Patent License Agreement. The relevant language reads: “[I]n the event that Licensor grants a DVD patent license to another party with royalty rates more favorable” than those specified in the Agreement, “Licensor shall send written notice to Licensee” and “Licensee shall be entitled to an amendment to this Agreement to the extent of providing for royalty rates as favorable as those available to such other party.”

<sup>17</sup> In many licence agreements, “know how” is defined as any and all technical information, discoveries, improvements, processes, formulae, data, engineering, technical and shop drawings, inventions, biological materials, and trade secrets which are useful or necessary to make, have made, use or sell the products

licenced into the pool. Such information is developed by the patent owner prior to, and after, the pool formation or acquired by the patent owner.

<sup>18</sup> To use a second Abbott/ddI example, EMLA requires that improvements are placed in the pool as “Licenced Patents” and provides two choices: an “option” (to be exercised by Abbott within a certain time period) for a non-exclusive, royalty-free grant back for use by Abbott for improved ddI in high income countries or an option to an **exclusive, royalty-bearing** licence to improved ddI in high income countries. If this improved ddI is really a separate invention by Aurobindo, not encompassed by the original ddI patent, then an exclusive licence grant back may damage incentives for follow-on innovation because those improvements are not otherwise legally controlled by Abbott. They may serve as a means of prolonging Abbott’s market power by nullifying or reducing the threat of what would otherwise become Aurobindo’s rival ddI product. Therefore, these types of exclusive grant-backs may be subject to increased scrutiny.