10. Developing socially responsible intellectual property licensing policies: non-exclusive licensing initiatives in the pharmaceutical sector[1]

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1. INTRODUCTION

In the ten years since the adoption of the WTO Declaration on Public Health and Intellectual Property (the Doha Declaration) pharmaceutical research companies have increasingly been using non-exclusive license agreements and non-assert declarations to allow generic companies to market their products in a defined geographical area. This chapter will consider these developments from a public health perspective. The chapter begins with a definition of license agreements and an overview of the license initiatives in place. This is followed by an analysis of the agreements as well as projections for the future. Annex 1 provides an overview of all the identified agreements and includes information on licensees, the character of the agreement, and terms and conditions of the license regarding territory, royalties and technology transfer where such information was available.

Inventions as a form of knowledge are characterized by non-excludability and non-rivalry, rather than by the properties applied to physical inventions. Once made public, the originator cannot physically exclude others from using the knowledge. The use of the knowledge by others does not prevent

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the originator or others from using it, thus there is no rivalry in consumption. Intellectual property rights change these characteristics by creating legal boundaries using exclusive rights that allow the rights holders to exclude others from using the knowledge commercially, usually for a limited time. It is, however, up to the rights owner to decide whether and how he wants to exercise his exclusive rights. A patent owner thus can decide to allow others to (also) use the invention. License agreements, or simply, licenses, allow for sharing of the rights under patent protection. A license is a contract in which the patent holder allows the contracting party to use the patent, either against a payment of royalties or free of charge for a defined period of time.[2] The rights owner is thus voluntarily sharing his/her rights under the patent with third parties. In this context, the adjective voluntarily is used as opposed to compulsory licenses that under most national legislations can be issued under certain conditions to address situations where a license is needed to address issues of public interest.

Other ways for a rights holder to allow third parties to use a patented invention are through non-assert declarations or non-assertion covenants and immunity-from-suit agreements. In these arrangements the rights holder states that she/he will not assert his/her rights, i.e. not enforce his patent(s). These agreements guarantee that the rights owner will not sue the other party for infringement or alleged infringement of the rights specified in the agreement. Non-assert declarations and immunity-from-suit agreements contain an explicit set of conditions, including permitted actions and designated territories, for which the patent owner commits not to enforce his patent rights. They can take the form of agreements between two or more parties, but can also be issued as unilateral declarations describing the intention of the rights holder not to enforce his rights. The agreements or declarations can have additional conditions; for example, Boehringer-Ingelheim requires that licensed producers be prequalified by WHO to ensure good quality.[3] To avoid legal conflicts it is essential that the scope of the agreements – regarding rights that will not be enforced, activities that will not be considered infringement, as well as territorial and other possible

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[2] See Chapter 6 on international patent licensing in this book.

[3] Under the UN prequalification programme, WHO, in cooperation with national regulatory agencies and partner organizations, evaluates the quality, safety and efficacy of medicinal products, based on information submitted by the manufacturers, and inspection of the corresponding manufacturing and clinical sites with the aim of making quality priority medicines available for the benefit of those in need. The resulting list of prequalified medicinal products used for HIV/AIDS, malaria, tuberculosis and for reproductive health is used in international and national procurement decisions, available at http://apps.who.int/prequal/ (last accessed April 16, 2012).

conditions for non-enforcement – are clearly set out in the agreements or declarations.[4]

In the pharmaceutical field the exclusive rights granted by patents are particularly important, given the time and investment needed for research and development, the high risk of failure and the fact that marginal production costs, at least in the area of small molecule medicines, are relatively low in comparison to the overall investment. Traditionally, pharmaceutical companies use patent protection to keep generic products out of the market for as long as possible, thereby ensuring that price can be set above the marginal production costs which can pose challenges for health systems and patients if no cheaper alternative treatments are available. This situation has been particularly acute in the area of HIV/AIDS, where existing treatments have been developed relatively recently and thus are still under patent protection or patent applications are still pending.[5] For this reason, current voluntary licensing programmes are focusing on products for HIV/AIDS treatment. Access to antiretroviral (ARV) HIV/AIDS therapy in low- and middle-income countries has increased dramatically in the past decade from only 400,000 people receiving such therapy in 2003 to 6.65 million by the end of 2009.[6] This was made possible by steep reductions in the price of treatment, with the annual price of first-line antiretroviral drugs decreasing from over US$10,000 per person in 2000 to a weighted median price of the ten most widely used first-line regimens of US$121 per person per year in 2010.[7] These price reductions are the result of competition with and among generic producers as well as increasing market size due to the financial engagement of donors and national governments in financing procurement of HIV/AIDS treatment in developing countries.

Today the main producer of generic treatments is India, with Indian ARV treatments accounting for more than 80 per cent of the donor-funded developing country market comprising 87 per cent of ARV purchase

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[4] See Anatole Krattiger, "The Use of Non-assertion Covenants: A Tool to Facilitate Humanitarian Licensing, Manage Liability, and Foster Global Access", in *IP Handbook of Best Practices, 2007*, available at http://www.iphandbook.org/handbook/ch07/p06/ (last accessed April 16, 2012).

[5] "The Patent Status Database for Selected HIV Medicines" established by the Medicines Patent Pool Foundation in collaboration with WIPO provides an overview of the patent situation of the main HIV/AIDS treatments, available at http://www.medicinespatentpool.org/LICENSING/Patent-Status-of-ARVs (last accessed April 16, 2012).

[6] Global HIV/AIDS response: epidemic update and health sector progress towards universal access: progress report 2011, WHO, UNAIDS, UNICEF, 2011.

[7] *Ibid.*

volumes in 2008. In the paediatric market, Indian-produced generics accounted for 91 per cent of purchase volume in 2008.[8] One reason for India's dominant role in the generic ARV market is that India did not grant pharmaceutical product patents before 2005. Another factor is that under the revised Indian Patents Act, new forms of a known substance that do not enhance the efficacy of that substance are not considered inventions (Section 3d). A number of patent applications for antiretroviral treatments have been rejected in the examination process on this condition, often following pre-grant oppositions.[9] In the past, countries also have made use of compulsory licenses and government use orders to increase access to HIV/AIDS treatment. The revised WHO HIV treatment guidelines[10] now recommend starting treatment earlier to reduce HIV-related mortality and to prevent opportunistic infections such as tuberculosis; this has increased the number of people estimated to be in need of antiretroviral therapy from 10 million to 15 million.[11] Low prices are essential if governments and donor programmes are to meet the 2015 target of having 15 million people living with HIV on antiretroviral treatment as set out in the 2011 UN Political Declaration on HIV/AIDS,[12] and to keep patients on lifelong antiretroviral therapy.

Against this background and given the increasing public attention pharmaceutical research companies have expanded their corporate responsibility programmes in the past ten years, following different approaches to increase access to antiretroviral therapy in developing countries which include tiered pricing, donations, non-enforcement of patents and not filing patents in least developed countries (LDCs[13]) and in sub-Saharan Africa

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[8] Brenda Waning, Ellen Diedrichsen and Suerie Moon, "A lifeline to treatment: the role of Indian generic manufacturers in supplying antiretroviral medicines to developing countries", *Journal International AIDS Society* 2010 13: 35.

[9] See the list of Pharmaceutical Patent Decisions on I-Mak – Initiative For Medicines, Access & Knowledge, available at http://www.i-mak.org/indian-pharmaceutical-patent-d/ (last accessed April 16, 2012).

[10] WHO, "Antiretroviral therapy for HIV infection in adults and adolescents – Recommendations for a public health approach, 2010 revision", 2010, available at http://whqlibdoc.who.int/publications/2010/9789241599764_eng.pdf (last accessed April 16, 2012).

[11] WHO, "New progress and guidance on HIV treatment: fact sheet, July 2010", WHO 2010, available at http://www.who.int/hiv/pub/arv/ARTfactsheet/en/index.html (last accessed April 16, 2012).

[12] UN General Assembly, A/65/L.77, June 8, 2011, paragraph 66.

[13] Currently, 48 countries are classified as LDCs under the UN system of which 33 are in Africa, see http://www.unohrlls.org/en/ldc/25/ (last accessed April 16, 2012).

(SSA[14]).[15] In the past decade, companies have increasingly been using non-exclusive license agreements, non-assert declarations and immunity-from-suit agreements, allowing generic companies to produce and market antiretroviral treatments in a defined geographical area. While Annex 1 provides a systematic overview of the current license agreements in place, the following section describes a number of these programmes in more detail and assesses and highlights observed trends.

2. CURRENT NON-EXCLUSIVE LICENSING INITIATIVES IN THE PHARMACEUTICAL SECTOR: BACKGROUND

Looking back at the roots of these licensing programmes reveals that often these programmes developed out of specific legal cases or disputes in history. The immunity-from-suit agreements policy of Bristol-Myers-Squibb (BMS) originally goes back to a request by Médecins sans Frontières (MSF). When MSF began antiretroviral treatment in South Africa, stavudine (d4t), a key product at the time, was much more expensive in South Africa than generic versions available in other developing countries.[16] In December 2000, MSF approached BMS who marketed stavudine in South Africa for permission to import generic stavudine. BMS however referred MSF to Yale University, which owned the patent rights to stavudine. Stavudine had been synthesized in 1966 and discovered to have reverse transcriptase inhibitor properties by researchers at Yale in the early 1990s; both projects had been supported by federal grants. Yale had exclusively licensed stavudine's production, marketing and distribution to BMS, which sponsored a Phase 3 clinical trial of the drug. Yale's response to MSF was to refer to the terms of their licensing agreement with BMS, which gave BMS the exclusive rights on stavudine in South Africa. Under pressure from the Yale student body and researchers, including the inventor of stavudine, Yale and BMS revised their licensing agreement and in March

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[14] Sub-Saharan Africa includes all African countries, except northern Africa, with the Sudan and South Sudan included (52 countries overall). Northern African countries are Algeria, Egypt, Libya, Morocco, South Sudan and Sudan, Tunisia and Western Sahara, see UN Statistics Division, available at http://unstats.un.org/unsd/methods/m49/m49regin.htm (last accessed April 16, 2012).

[15] See for an overview of company programmes the IFPMA Developing World Health Partnerships Directory, available at http://www.ifpma.org/resources/partnerships-directory.html (last accessed April 16, 2012).

[16] Médecins sans Frontières, *Untangling the Web of Antiretroviral Price Reductions* (14th ed., MSF Campaign for Access to Essential Medicines 2011), p. 50.

2001 BMS reached an immunity-from-suit agreement with Aspen Pharmacare, a generic company in South Africa, which allowed Aspen to market stavudine in South Africa and other African countries.[17] This case triggered an intense debate on licensing practices in general and of universities in particular, where research is often funded by public grants, and led to the development of the concept of socially responsible licensing, which endorses social goals and incorporates them in the licensing policies of public research bodies and university technology transfer offices.

Boehringer-Ingelheim was one of the first companies to grant license agreements, in the first instance for its product nevirapine to generic producers in Egypt, Kenya and South Africa in early 2003. These agreements were part of a settlement following a decision of the South African Competition Commission. Following complaints filed by generic manufacturers, AIDS treatment activists and patients, the Commission found that GlaxoSmithKline (GSK) and Boehringer-Ingelheim contravened the Competition Act of 1998 by abusing their dominant positions in their respective antiretroviral markets. The Commission found that the companies engaged in restrictive practices, including excessive pricing, and referred the case to the Competition Tribunal. The companies reached a settlement before the case was heard by the Tribunal.[18] Under the terms of the settlement Boehringer-Ingelheim and GSK agreed to enter into several license agreements for their ARVs covering both the public and private sectors in all sub-Saharan countries. Royalties were not to exceed 5 per cent of the net sales.[19]

Outside the field of HIV/AIDS, Roche entered into a number of license agreements covering oseltamivir, an oral antiviral treatment for influenza. These agreements date back to the avian flu/H5N1 crisis in 2005 when countries started to stockpile oseltamivir in order to be prepared for a possible avian flu pandemic. The demand for oseltamivir skyrocketed and Roche faced difficulties meeting the exploding demand; some countries

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[17] *Ibid*; Consumer Project on Technology, Stavudine (d4T), available at http://www.cptech.org/ip/health/d4T.html (last accessed April 16, 2012); Ellen 't Hoen, *The global politics of pharmaceutical monopoly power* (AMB Publishers 2009), pp. 49–53.

[18] See the Media Release of the Competition Commission No. 33 of 2003, 16 December, 2003 quoted in William W. Fisher III and Cyrill P. Rigamonti, *The South Africa AIDS Controversy – A Case Study in Patent Law and Policy* (Harvard Law School, 2005), available at http://cyber.law.harvard.edu/people/tfisher/South%20Africa.pdf (last accessed April 16, 2012).

[19] See the text of the settlement agreements: http://www.wcl.american.edu/pijip_static/competitionpolicyproject.cfm (last accessed April 16, 2012).

started considering using compulsory licenses to produce the drug themselves. Roche invited manufacturers worldwide to apply for sub-licenses in order to respond to the shortage and eventually granted manufacturing sub-licenses to four generic companies in China, India and South Africa.[20] These royalty-bearing licenses were limited to the production to control influenza in emergencies and thus only allowed production for pandemic planning purposes, which mainly refer to governmental stockpiling of oseltamivir. Ultimately, only Taiwan issued a compulsory license for oseltamivir in 2005, but it never produced under this license, as Roche finally met the local demands for stockpiling.

One major development with regard to non-exclusive licensing programmes in the past years was the creation of the Medicines Patent Pool Foundation. The Pool, created by UNITAID in 2010, has started to negotiate license agreements with companies regarding HIV/AIDS products, with the aim of sub-licensing these products to generic companies to increase access to treatment in low- and middle-income countries. The Pool also endeavors to assemble the necessary intellectual property rights regarding key HIV/AIDS products in order to develop new fixed-dose combination products that unite different products in one pill or formulation. These combination products facilitate treatment, especially in developing country settings. Another objective of the Pool is to develop missing paediatric formulations of existing treatments. The economic incentive for the pharmaceutical industry to develop such paediatric treatments is often insufficient because there is no market for paediatric HIV/AIDS treatments in developed countries where very few children are infected.[21]

The Pool has approached all companies holding patents relevant to the target products and publishes on its website a regularly updated list of companies that have and have not entered into negotiations. In 2010, the Pool signed the first license agreement with the U.S. National Institutes of Health (NIH) regarding patents filed in a number of developed countries

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[20] Roche, "Preparing for and responding to influenza pandemics: roles and responsibilities of Roche", revised August 2009, available at http://www.roche.com/access_to_healthcare.htm (last accessed April 16, 2012).

[21] See for further background on the Medicines Patent Pool: Jorge Bermudez, Ellen 't Hoen, "The UNITAID Patent Pool Initiative: Bringing Patents Together for the Common Good", *Open AIDS Journal* 2010 4: 37–40; Michelle Childs, "Towards a Patent Pool for HIV Medicines: The Background", *Open AIDS Journal* 2010 4: 33–36; Jorge Bermudez and Ellen 't Hoen, "The UNITAID Patent Pool Initiative: Bringing Patents Together for the Common Good", *Open AIDS Journal* 2010 4: 37–40.

relating to protease inhibitors used to treat HIV, including darunavir.[22] However, as Tibotec holds additional patents on darunavir, the NIH license alone does not allow for the production of darunavir. In 2011, the Pool has reached an agreement on non-exclusive licenses with Gilead on tenofovir (TDF), the co-formulation with emtricitabine as well as on elvitegravir, cobicistat and their combination with tenofovir and emtricitabine. In the context of these negotiations, Gilead expanded the territory of its license agreements to include 112 countries (see Annex 3). The negotiations also led to the inclusion of the use of TDF for treatment of hepatitis B.

Subsequently, the Pool has signed three license agreements with Aurobindo Pharma, MedChem Limited as well as Emcure Pharmaceuticals for the manufacturing of these products. Aurobindo made use of a specific clause negotiated by the Pool that allowed it to "unbundle" the licenses for the four products, thereby opting out of the TDF license and only signing an agreement regarding elvitegravir and cobicistat. This has to be seen in the context that in 2009 the main patent application for TDF in India was rejected.[23]

The creation of the Medicines Patent Pool, and especially its license agreement with Gilead, has led to a vigorous debate among public health groups about the added value of voluntary licenses in general and of the Patent Pool in particular. Criticism was raised regarding the limited territory, the relation of royalties and actual patent coverage, the expected cost savings linked to the Pool, as well as the transparency of the process, the involvement of patient groups and the mandate of the Pool.[24] This debate has led to some changes in the license agreement with Gilead.[25]

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[22] See the text of the agreement: http://www.medicinespatentpool.org/LICENSING/Current-Licences (last accessed April 16, 2012).

[23] Brook K. Baker, "Corporate Self-Interest And Strategic Choices: Gilead Licenses To Medicines Patent Pool", ip-watch, July 21, 2011, http://www.ip-watch.org/2011/07/21/corporate-self-interest-and-strategic-choices-gilead-licenses-to-medicines-patent-pool/ (last accessed April 16, 2012).

[24] See the related documents on the homepage of the Medicines Patent Pool, http://www.medicinespatentpool.org/LICENSING/Current-Licences as well as the analysis by I-MAK: http://www.i-mak.org/storage/ITPC%20I-MAK%20-%20The%20Broader%20Implications%20of%20the%20MPP%20and%20Gilead%20Licenses%20on%20Access%20-%20FINAL%2025–7-2011.pdf and MSF http://www.msfaccess.org/content/msf-review-july-2011-gilead-licences-medicines-patent-pool (last accessed April 16, 2012).

[25] See the text on the homepage of the Medicines Patent Pool, http://www.medicinespatentpool.org/LICENSING/Current-Licences (last accessed April 16, 2012).

3. CURRENT TRENDS IN THE DEVELOPMENT OF VOLUNTARY LICENSING PROGRAMMES IN THE PHARMACEUTICAL INDUSTRY

While the examples above show that not all of the initial license agreements were totally "voluntarily" at the beginning, companies now are adopting a more proactive approach reflected in an expansion of the programmes with regard to territory, products, and number of licensees. There are also some trends to be observed regarding royalties and technology transfer.

3.1 Products and Disease Areas

Overall, the licensing programmes in place differ widely with regard to their background, motivation and scope. This has to be seen in the context of the variable sizes and structures of the respective companies. Relatively smaller companies such as Tibotec and Gilead are using licensing schemes with generic producers in developing countries as distribution networks, where agreements can develop into partnerships in which the generic companies provide local expertise on the registration process, procurement and supply chain development and logistics.[26] Other programmes, such as the non-assert declarations by Boehringer-Ingelheim, simply allow generic companies the distribution in a defined territory. While Boehringer initially required a signed letter for its non-assert declarations, generic companies now can operate under these declarations without any legal formalities. The declarations therefore do not create any kind of partnership between the companies involved. Those companies who want to manufacture nevirapine can request a royalty-free license.

At the other end of the spectrum is the cooperation between GSK and Aspen Pharmacare. The recent licensing agreement covering abacavir is just one of several collaborations between the two companies. GSK and Aspen formed a collaboration to market and sell pharmaceuticals in SSA called Shelys Pharmaceuticals Ltd.[27] In 2009, GSK acquired a significant

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[26] Janssen, Global Access & Partnerships Program, August 2011, available at http://www.janssenrnd.com/sites/default/files/pdf/Global%202011%20GAPP%20Brochure%208.25.11.pdf#zoom=125 (last accessed April 16, 2012). Gilead, "Achieving Sustainable Access to HIV/AIDS Medicines in the Developing World", November 2011, available at http://www.gilead.com/pdf/access_fact_sheet.pdf (last accessed April 16, 2012).

[27] Aspen Pharmacare Holdings Limited Annual Report 2011, available at http://www.aspenpharma.com/SiteResources/documents/Aspen%202011%20Annual%20Report%20Low%20res.pdf (last accessed April 16, 2012).

number of shares in Aspen. In exchange, Aspen received the right to distribute GSK's products in South Africa, as well as the marketing rights for eight specialist branded GSK products for worldwide distribution and a GSK manufacturing facility in Germany. In this context, the South African Competition Commission required GSK to expand the license for abacavir to a number of other generic companies on terms and conditions no less favorable than those granted to Aspen.[28]

With regard to products included in voluntary licensing programmes, companies have been expanding their programmes to cover more products over the years. For example, Boehringer expanded its non-assert declarations policy to include tipranavir.[29] Merck signed two agreements for raltegravir in 2011 which was an important step as previously no generic versions were available.[30] Also, while the earliest licensing programmes covered older products that had already been on the market for some time, some companies now include new and pipeline products in their programmes. Gilead in 2011 signed agreements for three new HIV/AIDS products that are still in clinical development (elvitegravir, cobicistat and their combination with tenofovir and emtricitabine) and has amended existing TDF licenses to include the use of TDF for the treatment of hepatitis B. In 2011, Tibotec Pharmaceuticals, which belongs to Janssen Pharmaceutical Companies of Johnson & Johnson, granted non-exclusive licenses to generic manufacturers in India and South Africa to manufacture, market and distribute a new HIV/AIDS treatment, the non-nucleoside reverse transcriptase inhibitor rilpivirine hydrochloride.[31] While with previous agreements for its protease inhibitors PREZISTA® (darunavir), generic darunavir and INTELENCE® it is not clear if beyond distribution rights manufacturing rights were granted in all cases, the agreements on rilpivirine include manufacturing as well as transfer of technology. ViiV expanded its

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[28] South African Competition Commission, Press Release, September 2, 2009, available at http://www.compcom.co.za/assets/Uploads/AttachedFiles/My Documents/02-Sept-09-Competition-Commission-approves-pharma-merger-on-condition-that-Abacavir-is.pdf (last accessed April 16, 2012).

[29] Tipranivir is however of limited importance as it is not included in the current WHO treatment guidelines (*supra* note 10) or the 17th WHO Model List for Essential Medicines, see http://www.who.int/medicines/publications/essential medicines/en/ (last accessed April 16, 2012).

[30] For the latter: Médecins sans Frontières, *Untangling the Web of Antiretroviral Price Reductions* (14th ed., MSF Campaign for Access to Essential Medicines 2011).

[31] See Press Release from Tibotec: http://www.tibotec.com/content/news/www.tibotec.com/TMC278_Generic_Agreements_FINAL.pdf (last accessed April 16, 2012).

voluntary licensing programme to include all regulatory-approved anti-retrovirals and made a commitment to include their pipeline assets upon regulatory approval.

3.2 The Number of Licensees

Voluntary license agreements can increase competition, which has proven to be one of the most efficient means to lower prices. This is only the case, however, if several companies have the right to distribute the product in a given market. Granting a license to one generic company is therefore not likely to have a great impact on price if there are not other competitors. This was the situation, for example, in South Africa before the ruling of the South African Competition Commission when GSK had licensed its products exclusively to one company. It is therefore important to have voluntary licensing programmes including a number of licensees. This is currently the case for most of the licensing programmes in place, but not all of them, as one can see from the overview in Annex 1. It is also difficult to identify a clear trend. Many companies who started with limited programmes later expanded them to include more licensees, but some of the more recent agreements still may only include one generic company with a limited territory.

3.3 Geographical Scope of Marketing Rights: Territory

One of the core components in increasing access to medicines is the territory covered by the license agreements. From a public health perspective, the maximum number of qualified countries, and especially those with a high disease burden, should be included in the licensed territory. An analysis of the agreements with regard to the territories covered shows that most of the license agreements include SSA and LDCs for a total of 67 countries, including South Sudan. In this regard, it needs to be highlighted that LDCs under the WTO transition periods are still exempt from granting and enforcing pharmaceutical patents, although a number of LDCs are currently granting such patents. Many companies also have a policy of not filing patents in LDCs or not enforcing existing patents in these jurisdictions. Some of the license agreements fall below this standard and only include a very limited number of countries, making for a much smaller territory, such as the agreements on oseltamivir, which are limited to pandemic influenza preparedness in China, India and Africa respectively. The agreements signed by BMS also appear to be limited to SSA and India. However, a limited territorial scope can also be an indicator for limited patent coverage. The license of Merck regarding efavirenz is limited to

manufacturing in South Africa, but since South Africa is the only country in SSA where efavirenz is under patent, licensees can distribute in the whole region. In general, most of the upper-middle-income countries and emerging economies are not included in voluntary licensing schemes, which is one of the main criticisms of these programmes.[32] From an industry perspective, the reason for this is obvious: the upper-middle-income countries are generally profitable markets for the companies. With the U.S. and European markets not exhibiting much growth or even declining, companies focus even more on these emerging economies.

Overall, the trend aims towards an expansion of the geographical scope of agreements beyond SSA and LDCs. Boehringer in its non-assertion declarations includes the relatively advanced economies of Northern Africa as well as low-income countries (LICs[33]). ViiV recently announced that it would expand the scope of its licenses to all SSA, LDCs and other LICs. As mentioned above, Gilead, following its negotiations with the Medicines Patent Pool, has extended the territory to include 112 countries. Gilead also entered into semi-exclusive license agreements covering Sri Lanka, Thailand, Botswana, Namibia, Ecuador, El Salvador, Indonesia, Kazakhstan, and Turkmenistan (five of which are upper-middle-income countries). Following Gilead's decision, Janssen/Tibotec announced that they would also expand the geographical scope of their current license agreements on rilpivirine from 66 to 112 countries (see Annex 2) and allow the licensees to manufacture the active pharmaceutical ingredient (API) as well as another fixed dose combination product.[34] These agreements now include a greater number of lower-middle-income countries (the Gilead license includes 46 lower-middle-income countries) as well as some of the

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[32] See for example KEI comments on Tibotec voluntary licenses of a new HIV-AIDS product, http://keionline.org/node/1068 as well as Tahir Amin, Voluntary licensing practices in the pharmaceutical sector: An acceptable solution to improving access to affordable medicines?, February 8, 2007, available at http://www.i-mak.org/storage/Oxfam%20-%20Voluntary%20Licensing%20Research%20IMAK%20Website.pdf (last accessed April 16, 2012).

[33] The World Bank currently classifies 35 countries as low-income economies, http://data.worldbank.org/about/country-classifications (last accessed April 16, 2012).

[34] Ed Silvermann, "Just Say No: J&J Rebuffs Medicines Patent Pool", *Pharmalot*, December 20, 2011, available at http://www.pharmalot.com/2011/12/johnson-johnson-rebuffs-medicines-patent-pool/ (last accessed April 16, 2012).

upper-middle-income countries (the Gilead license includes 21 upper-middle-income countries).[35]

Overall, the territorial scope of the license agreements shows that the majority of pharmaceutical companies are ready to give up the high-volume low-profit markets, meaning mostly poor countries with a relatively high disease burden of HIV/AIDS. However, the creation of the Medicines Patent Pool and the related debate have resulted in the trend to expand territories covered by licensing agreements with some smaller companies acting as frontrunners. This is likely to increase the pressure on other companies to follow this example and further expand the territory of their agreements.

3.4 Royalties

Currently, the majority of the agreements are not royalty-bearing. When the licenses are royalty-bearing, the range is typically 2–5 per cent. The overall picture was different some years ago. GSK started its licensing programme with royalty-bearing licenses, but now the ViiV licenses that include earlier GSK licenses are royalty-free. While the initial license agreements signed by Boehringer foresaw 5 per cent royalties, Boehringer later started using non-assert covenants available to all developing country manufacturers for marketing in LICs, LDCs, and all African countries not falling in these two groups. It needs to be mentioned however that the main patent for nevirapine has since expired. Under the non-assert covenants, generic companies do not have to pay any royalties. One of the common denominators for license agreements is that they are not profit-driven. Some companies such as Gilead are pursuing a no-cost no-benefit policy, such that royalties are expected to cover only the costs of the agreements. The more recent Gilead and Janssen/Tibotec licenses for the new products rilpivirine and combinations, elvitegravir and cobicistat are, however, royalty-bearing (2–5 per cent), indicating that agreements covering more recent products, broader territory and technology transfer might lead to higher royalties. This is confirmed by the additional semi-exclusive Gilead licenses for Sri Lanka, Thailand, Botswana, Namibia, Ecuador, El Salvador, Indonesia, Kazakhstan, and Turkmenistan. These agreements foresee higher royalty rates of 10–15 per cent which reflects the greater business interest in these countries and the potentially greater ability to pay.

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[35] See Annex 3 and the overview of the Medicines Patent Pool/Gilead Licences: Questions and Answers: http://www.medicinespatentpool.org/licensing/current-licences/the-medicines-patent-poolgilead-licences-questions-and-answers/ (last accessed April 16, 2012).

3.5 Technology Transfer

Many of the agreements include transfer of technology to different extents. In practice, this also depends on the level of know-how at the receiving end. These agreements should therefore be considered on a case-by-case basis. Roche has accomplished a very comprehensive technology transfer when it transferred the necessary technology and know-how for production of its protease inhibitor saquinavir to a total of 13 generic companies (see Annex 1). While this can be considered an exemplary approach, the public health impact remains limited, as saquinavir is currently not included in the WHO treatment guidelines and none of the generic companies actually have begun regular production. Transfer of technology does not guarantee successful outcomes. Other programmes, such as the non-assert-declarations by Boehringer, do not include transfer of technology. As the condition for benefiting from Boehringer's declarations, producers need to be prequalified by WHO such that the generic companies already manage the technology and do not have to rely on technology transfer. Generic partners can bring a certain expertise to the partnerships, for example, on local processes for registration of the products and on supply chain management in the respective countries. This expertise is valued by the smaller originator companies that do not themselves have a worldwide presence and distribution scheme. Another key aspect in license agreements relating to transfer of technology are "grant back clauses" that address the question of which rights the licensor has on any improvements made by the licensee to the licensed product. For the licensor it is important to be able to also market improved products and thus to have access to any improvements made on the product. Otherwise, innovative licensees may drive him out of business by marketing an improved version. On the other hand, incentives to invest in further improvements of the product are lost if the licensee has to grant back all the rights on such innovations. The most common way of dealing with this question are clauses that foresee a non-exclusive grant back of all improvements, which retains the incentives for the licensee to further develop the product (for example, to adapt it to the specific environment in his market) while the licensor also benefits from any improvements made. The amended Gilead licenses contain such a clause requiring a "non-exclusive, royalty-free, worldwide, sub-licensable license to all improvements, methods, modifications and other know-how developed by or on behalf of Licensee and relating to API or a Product" (Article 2.3). A royalty-bearing grant back can provide greater incentives for the licensees to invest in improvements of the product.

3.6 Other Aspects

A number of issues have been raised in the past with regard to certain details of the voluntary licensing programmes. These issues include the question of how to deal with countries where the relevant patents were not filed or granted or countries within the territory where patents are revoked as well as limitations regarding filing patent oppositions. Both pre-grant and post-grant patent oppositions can help ensure a high quality of patents. Allowing competitors and other interested groups, including public health groups, to file oppositions can prevent patents from being granted that do not fulfill the patentability criteria laid down in the respective national patent laws. Generic companies are one of the main users of these opposition procedures; by doing so they provide an additional filter to the patent system that is of particular importance in many developing countries, where patent offices may lack necessary human and financial resources to undertake in depth substantial patent examinations. Another issue with these agreements is the right to produce the needed API as well as limitations of the sourcing of API. From a public health point of view it is desirable to have a larger number of API producers to increase competition and lower prices. Many other aspects of the license agreements are important for the evaluation of the public health benefit of the agreements, such as the access to data necessary to obtain regulatory approval, the right to supply outside the territory in case of compulsory licenses, as well as the freedom to combine the licensed products with other products for the production of fixed dose combinations.[36]

4. CONCLUSION: PROSPECTIVE ANALYSIS

To assess the existing agreements is only possible to a very limited extent. Some companies on request shared (draft) agreements, but usually the terms and conditions are not disclosed, with the notable exception of agreements signed by the Medicines Patent Pool. The picture of the non-exclusive license agreements in this contribution is also incomplete as companies tend to publicize the license agreements that are signed under their corporate responsibility or access programmes, but not those with generic manufacturers that are part of normal business strategies. This

[36] See for best practice guidelines for voluntary license agreements: Tahir Amin, "Voluntary licensing practices in the pharmaceutical sector: An acceptable solution to improving access to affordable medicines?", February 8, 2007, available at http://www.i-mak.org/storage/Oxfam%20-%20Voluntary%20Licensing%20Research%20IMAK%20Website.pdf (last accessed April 23, 2012).

analysis also does not include the many license, transfer of technology and cooperation agreements between pharmaceutical companies and other partners, including public development partnerships, international organizations and generic industry, that involve production technology, know-how or pipeline products rather than registered products. From the assembled information however some observations can be made:

- Most of the companies active in the area of HIV/AIDS now have voluntary licensing programmes in place and companies are expanding these programmes regarding products and territorial coverage.
- Initially, these programmes covered older products already on the market for some time. More recent agreements also cover new and pipeline products and many cover a broader number of licensees increasing market competition.
- The average territory covered in the license agreements has been expanding over the years. While SSA and LDCs were the starting point for such agreements, companies are now going beyond this scope and include more middle-income countries. Upper-middle-income countries and emerging economies are still mostly excluded from the covered territory.
- While initially many of the agreements foresaw a 5 per cent royalty rate, the trend has been towards lower royalties or royalty-free agreements. This is not the case for agreements covering new products and more extensive territory; in these cases royalties are the norm. Gilead has in addition semi-exclusive licenses for middle-income countries with higher royalty rates.

From a public health perspective, the added value of these license agreements lies in the potential for reduced prices through increased competition in developing countries. Voluntary licenses are certainly not the universal solution to the access problem, but if they allow for robust competition, such agreements can make tangible contributions to increasing the availability of and access to antiretroviral treatment. Licensing agreements can also contribute to industrial development in developing countries as they allow for local manufacturing. In this regard, transfer of technology and support for meeting regulatory requirements and related quality standards are of key importance, especially to obtain WHO prequalification. The current voluntary licensing programmes are still limited in two ways: Most upper-middle income countries are excluded from the territory and these agreements therefore do not provide a solution to the access and affordability issues in these countries, although many of the companies complement their voluntary license policies with a tiered pricing approach for markets

not included in the agreements;[37] and, programmes are mainly limited to HIV/AIDS products and thus do not provide a solution for other disease areas.

These limitations may change in the future. The importance of the generic industry in India as a source of affordable products has already been discussed above. Even generic versions of new medical treatments could be produced in India before 2005, since no pharmaceutical product patents were granted before then. For new inventions since 2005, uninhibited generic production is not currently possible. The pressure on companies to share their intellectual property is therefore likely to grow. To counter this pressure, companies may consider expanding voluntary licensing programmes in terms of products and territory covered. The trend seems to point in this direction and has been reinforced by the creation of the Medicines Patent Pool that encourages companies to (re)consider voluntary licenses as an option to manage intellectual property in the area of HIV/AIDS. Companies have to decide whether to enter into negotiations with the Pool, which has led companies to revise their policies in this regard. The Pool also provides for increased transparency regarding the details of such licensing agreements.

Increasing pressure to expand licensing programmes could also stem from requests of generic companies for licenses under Indian patent law. Section 84 of the Indian Patents Act allows interested persons to apply for the grant of a compulsory license *inter alia* on the grounds that "the patented invention is not available to the public at a reasonably affordable price … " (Section 84, paragraph 1 b). The applicant, however, has to make efforts during a reasonable period of time, not ordinarily exceeding six months, to obtain a voluntary license from the patentee on reasonable terms and conditions (Section 84, paragraph 6 iv). Recently, based on this provision, NATCO, an Indian pharmaceutical company, requested a voluntary license to produce ViiV Healthcare-owned maraviroc.[38] Cipla, based on the same provision, requested a voluntary license from Merck to produce

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[37] According to MSF, companies however seem to be moving away from applying standardized price discounts to middle-income countries, instead entering into case-by-case negotiations that take into account income level and disease burden, see for an overview of differential pricing schemes: Médecins sans Frontières, *Untangling the Web of Antiretroviral Price Reductions* (14th ed., MSF Campaign for Access to Essential Medicines 2011).

[38] See http://spicyipindia.blogspot.com/2011/01/natco-seeks-license-from-pfizer-to.html (last accessed April 16, 2012).

raltegravir.[39] In early 2012, following an earlier request NATCO has obtained a compulsory license for sorafenib, a treatment for liver and kidney cancer.[40] The latter is an example of the increasing attention on disease areas outside HIV/AIDS. With the growing awareness of the importance of non-communicable diseases in developing countries, companies will have to redefine related market access strategies for emerging economies, and non-exclusive licenses may be one interesting option.

Brazil also seems to engage more proactively in negotiating the in-licensing of pharmaceutical products. Recently, Farmanguinhos, a technical-scientific unit of Fundação Oswaldo Cruz (Fiocruz) which itself belongs to the Brazilian Ministry of Health, has entered into a license agreement with BMS that allows for the manufacturing and distribution of atazanavir in Brazil. A local manufacturer will provide the API.[41] The Brazilian Ministry of Health also seems to be in negotiations with Merck & Co. on a voluntary license agreement to manufacture raltegravir[42] which is a remarkable development, as in 2007 Brazil issued a compulsory license for the product efavirenz, also owned by Merck.

The pharmaceutical industry is also paying increasing attention to the ratings of their social performance by the Access to Medicines Index, which ranks pharmaceutical companies according to their efforts to increase access to medicine in developing countries. The Index hopes to encourage companies to further improve their performance in this regard. Voluntary licensing policies are an essential part of this assessment.

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[39] Suchita Saigal, "CIPLA files for a compulsory license against Merck's Isentress", April 6, 2011, http://spicyipindia.blogspot.com/2011/04/cipla-files-for-compulsory-license.html?dhiti=1&p= (last accessed April 16, 2012).

[40] See http://ipindia.nic.in/ipoNew/compulsory_License_12032012.pdf (last accessed April 16, 2012).

[41] BMS Press Release November 11, 2011, available at http://www.bms.com/news/press_releases/pages/default.aspx?RSSLink=http://www.businesswire.com/news/bms/20111111005380/en&t=634600733951874311 (last accessed April 16, 2012).

[42] See http://www.agenciaaids.com.br/busca/ (last accessed April 16, 2012).

ANNEX 1

Table 10A.1 List of voluntary license agreements and non-assert declarations

Licensor	Generic name	Indication	Licensees	Year (since)	Description, terms and conditions
Boehringer-Ingelheim GmbH (BI)	nevirapine (NVP) (including extended release version once launched)	HIV/AIDS	License agreements: – Cosmos Universal – Universal Pharmacy – Aspen Pharmacare – Gemini Pharmaceuticals – Memphis – Cipla Medpro – Kimia Farma – Adcock Ingram/Ranbaxy Non-assert declarations: – Cosmos Universal – Aspen Pharmacare – Biotech Laboratories – Memphis – Aurobindo Pharma – Cipla – Emcure Pharmaceuticals – Strides Arcolab	2004	Initially, BI signed royalty bearing license agreements allowing for manufacturing. **Territory**: Cosmos, Universal Pharmacy: East African countries (Kenya, Burundi, Uganda, Rwanda, Tanzania) Aspen, Cipla, Adcock Ingram/ Ranbaxy: SSA Gemini: Nigeria Memphis: Egypt Kimia Farma: Indonesia **Royalties:** 5% (waived in 2007) In 2007, BI changed its policy to non-assert declarations allowing distribution at no additional costs. The only condition is that companies must be prequalified by WHO for producing nevirapine to ensure high quality standards. Companies may request a royalty free license for manufacturing in WHO prequalified plants.

Table 10A.1 Continued

Licensor	Generic name	Indication	Licensees	Year (since)	Description, terms and conditions
					Territory: LICs (incl. India), LDCs and all African countries not falling in these two groups **Technology transfer:** No technology transfer as WHO prequalification is condition
	tipranavir (TPV)	HIV/AIDS	–	–	Boehringer-Ingelheim offers non-assert declarations to the same conditions as for nevirapine
Bristol-Myers Squibb (BMS)	atazanavir (ATV)	HIV/AIDS	– Aspen Pharmacare – Emcure Pharmaceuticals – Farmanguinhos (Fiocruz) – Matrix Laboratories and three other companies	2006	Royalty-free non-exclusive licenses/ immunity from suit agreements for manufacturing and distribution, including for paediatric formulations **Territory:** Aspen: SSA Emcure/Matrix: SSA and India Farmanguinhos: Brazil (a not yet known local manufacturer will provide the API) **Technology transfer:** technical know-how related to manufacturing, testing, packaging, and storage

	stavudine (d4t) didanosine (ddI)	HIV/AIDS	– Aurobindo Pharma – Aspen Pharmacare – Matrix Laboratories and others	2001	11 immunity-from-suit agreements allowing generic companies to produce d4t and ddI. The agreements are royalty-free, include paediatric formulations, but do not include transfer of technology **Territory:** Matrix: SSA and India Aurobindo: SA and 49 other countries Aspen: SA and 49 other countries (d4t)
Gilead Sciences	tenofovir (TDF) alone or in combinations (i.e. with FTC)	HIV/AIDS (expanded in July 2011 to hepatitis B)	Aspen Pharmacare and twelve Indian generic companies: – Alkem Laboratories, – Cadila Healthcare (2009), – Hetero Drugs, – Laurus Labs Private Ltd. (2009), – McNeil and Argus Pharmaceuticals (2010), – Medchem International (2011 joined Medicines Patent Pool), – Micro Labs (2010), – Mylan Labs, – Ranbaxy Laboratories, – SeQuent Scientific (2009), – Shasun Pharmaceuticals, – Strides Arcolab	2006 or otherwise noted	Non-exclusive royalty-bearing licenses **Territory:** originally 95 countries expanded in July 2011 to 112 countries (see Annex 3) Aspen: 53 African countries **Royalties:** Royalty of 5% lowered to 3% in July 2011; no royalties on paediatric versions developed by licensees **Technology transfer:** Agreements include technology transfer for manufacturing

Table 10A.1 Continued

Licensor	Generic name	Indication	Licensees	Year (since)	Description, terms and conditions
	elvitegravir (EVG) cobicistat (COBI) Combination (Quad) : TDF/FTC/ EVG/COB	HIV/AIDS	– Hetero Drugs, – Mylan Labs, – Ranbaxy Laboratories, – Strides Arcolab. – Medicines Patent Pool Pipeline Licensees: – Aurobindo Pharma (2011), – Emcure Pharmaceuticals (2012), – Medchem International (2011)	2011	Non-exclusive royalty-bearing licenses **Territory:** Elvitegravir: 100 countries Cobicistat: 103 countries Quad: 100 countries (see Annex 3) In addition semi-exclusive licenses for the following territories: Mylan: Sri Lanka, Thailand Hetero/Ranbaxy: Botswana, Namibia Strides Arcolab: Ecuador, El Salvador, Indonesia, Kazakhstan, Turkmenistan **Royalties:** Royalty of 5%; no royalties on paediatric versions developed by licensees Semi-exclusive licenses: 10–15% **Technology transfer:** Agreements include technology transfer for manufacturing

ViiV Healthcare	lamivudine (3TC) zidovudine (AZT) Combination: 3TC/AZT	HIV/AIDS	– Aspen Pharmacare – Cipla-Medpro – Feza – Biotech Laboratories – Cosmos Universal – Adcock Ingram – Ranbaxy Laboratories – Universal Pharmacy – Specpharma – Aurobindo Pharma – Strides Arcolab	2001	Royalty-free non-exclusive licenses **Territory:** originally more limited territory, now LDCs, LICs and SSA **Royalties:** initially some licenses included a royalty of 5% on net sales now royalty free **Technology transfer:** –
	abacavir (ABC)	HIV/AIDS	Same as above	2009	Royalty-free non-exclusive license **Territory:** LDCs, LICs and SSA
Tibotec Pharma-ceuticals (part of Janssen Pharmaceutical Companies of Johnson & Johnson)	darunavir (DRV)	HIV/AIDS	– Aspen Pharmacare	2007 (amended 2011)	Royalty-free non-exclusive license Aspen will register, package and distribute PREZISTA® 300mg tablets at a special access price. Agreement foresees manufacturing of PREZISTA® by Aspen for SSA at a later stage. Other formulations, including paediatrics were included in 2011. **Territory:** SSA; LDCs **Technology transfer: –**

Table 10A.1 Continued

Licensor	Generic name	Indication	Licensees	Year (since)	Description, terms and conditions
		HIV/AIDS	– Emcure Pharmaceuticals	2008 (amended 2010)	Royalty-free non-exclusive license Emcure will distribute DRV under its own trade name. In 2010 the license was expanded to include manufacturing of other formulations. **Territory:** India **Technology transfer: –**
	etravirine (ETR)	HIV/AIDS	– Aspen Pharmacare	2009	Royalty-free non-exclusive license Aspen will register and distribute INTELENCE® formulations at a special price **Territory:** SSA, LDCs **Technology transfer: –**
	rilpivirine (TMC 278)	HIV/AIDS	–Aspen Pharmacare	2011	Royalty-free non-exclusive license Aspen will register and distribute EDURANT® formulations at a special access price **Territory**: SSA, LDCs **Technology transfer:** –

	rilpivirine (TMC 278) Combination : TMC 278/ TDF/3TC Combination : TMC 287/ TDF/ emtricitabine	HIV/AIDS	– Emcure Pharmaceuticals – Hetero Drugs – Matrix Laboratories – Strides Acrolab – Aspen Pharmacare	2011	Royalty-bearing non-exclusive license Licensees will manufacture, register, market and distribute rilpivirine as a generic single agent and fixed dose combination; subsequently expanded to allow API manufacture. **Territory**: SSA, LDCs and India initially and subsequently expanded from 66 to 112 countries (see annex 2) **Royalties**: 2–5% **Technology Transfer**: Tibotec to provide technical information and knowledge to allow for manufacture of API and finished products in the territory
Merck & Co.	efavirenz (EFV)	HIV/AIDS	– Emcure Pharmaceuticals S. Africa and Arrow Pharma S. Africa – Sonke Pharmaceuticals – Aspen Pharmacare – Aurobindo Pharma – Cipla- Medpro, – Adcock Ingram Healthcare	2007	Royalty-free non-exclusive licenses **Territory:** South Africa (no patents in rest of SSA) **Technology transfer: –**

Table 10A.1 Continued

Licensor	Generic name	Indication	Licensees	Year (since)	Description, terms and conditions
	raltegravir		– Emcure Pharmaceuticals – Matrix Laboratories	2011	Non-exclusive licenses **Territory:** all SSA and all low-income countries (60 in total) **Technology transfer: –**
F. Hoffmann-La Roche Ltd.	oseltamivir	Influenza	– Hetero Drugs – Shanghai Pharmaceuticals – HEC Pharm Group – Aspen Pharmacare	2006	Royalty-bearing non-exclusive licenses The licenses are limited to control of influenza in emergencies. They allow production for pandemic planning purposes (local pandemic governmental stockpiling of oseltamivir) **Territory**: Hetero: India HEC/Shanghai: China Aspen: all African countries **Technology transfer:** Roche provided technology and know-how to those licensees who needed support in this regard

	saquinavir (SQV)	HIV/AIDS	– Adcock Ingram – Addis Pharmaceutical Factory – Aspen Pharmacare – Beximco Pharmaceuticals – CAPS Pharmaceuticals – Cosmos – Muhimbili University of Health and Allied Sciences – Radiant Pharmaceuticals – Regal Pharmaceuticals – Shelys Pharmaceuticals – Universal Corporation – Varichem Pharmaceuticals – Zenufa Laboratories	2006	Technology transfer agreements **Territory:** SSA, LDCs **Technology transfer:** manufacturing and other technology

Notes:

[1] Matrix Laboratories Ltd. changed their name to Mylan Laboratories Ltd. in 2011.
[2] Gilead has also entered into an agreement on similar terms with the Medicines Patent Pool Foundation, see in the text.
[3] Initially these products were licensed by GSK, following the creation of ViiV Healthcare, which is a joint venture between GSK and Pfizer that regroups all HIV/AIDS products of both companies, all licenses were transferred to ViiV who signed additional agreements.

Sources: The information contained in this table has been gathered from a variety of sources, including company websites, direct information received from companies as well as the following publications. The information available from these sources may differ regarding details for some of the agreements. The table attempts to provide the most accurate information possible.

[1] Access to Medicine Index 2010, Company profiles, http://www.accesstomedicineindex. org/content/originator-pharmaceuticals (last accessed April 16, 2012).
[2] S. Moon, "Pharmaceutical production and related technology transfer: landscape report", WHO, Geneva 2011.
[3] Boehringer Ingelheim policy paper on HIV/AIDS, 2011 , http://corporateresponsibility. boehringer-ingelheim.com/content/dam/internet/opu/com_EN/document/01_news/05_Media_Material/policy_paper_on_hiv_aids.pdf (last accessed April 24, 2012).

[4] Gilead Sciences, Inc. Evolution of the Gilead Access Program, 2003–2010, 2011, http://www.gilead.com/pdf/GAPHistory.pdf (last accessed April 16, 2012).
[5] Merck responsibility website, 2011, http://www.merckresponsibility.com/priorities-and- performance/access-to-health/hiv/manufacturing-and-licensing/home.html (last accessed April 16, 2012).
[6] Tibotec, Press Release, "Tibotec Signs Multiple Agreements with Generic Manufacturers to Provide Access to New HIV Treatment", January 2011.
[7] Janssen, Global Access & Partnerships Program, August 2011, http://www.janssenrnd. com/sites/default/files/pdf/Global%202011%20GAPP%20Brochure%208.25.11.pdf# zoom=125 (last accessed April 16, 2012).
[8] J&J statement on refusal to license to Medicines Patent Pool, ip-health, http://lists.keionline.org/pipermail/ip-health_lists.keionline.org/2011-December/001633.html (last accessed April 16, 2012).
[9] F. Hoffmann-La Roche Ltd., "Corporate Responsibility, The AIDS Technology Transfer Initiative, 2011", www.roche.com/sus_acc_tti.pdf (last accessed April 16, 2012).
[10] Tahir Amin, "Voluntary licensing practices in the pharmaceutical sector: An acceptable solution to improving access to affordable medicines?", 2007, available at http://www. i-mak.org/storage/Oxfam%20-%20Voluntary%20Licensing%20Research%20IMAK%20Website.pdf (last accessed April 16, 2012).
[11] BMS Homepage: http://www.bms.com/responsibility/access-to-medicines/Pages/patents-licensing-technology.aspx (last accessed April 16, 2012).
[12] GSK Homepage: http://www.gsk.com/media/pressreleases/2009/2009_pressrelease_10073.htm (last accessed April 16, 2012).
[13] Treatment Action Campaign, 2009: http://www.tac.org.za/community/node/2744 (last accessed April 16, 2012).
[14] ViiV Healthcare homepage: http://www.viivhealthcare.com/access/voluntary-licensing. aspx?sc_lang=en (last accessed April 16, 2012).
[15] Médecins sans Frontières, *Untangling the Web of Antiretroviral Price Reductions* (14th ed., MSF Campaign for Access to Essential Medicines 2011).

ANNEX 2: LIST OF TIBOTEC PHARMACEUTICAL LICENSED TERRITORY FOR RILPIVIRINE AND COMBINATION PRODUCTS (112 COUNTRIES)

Afghanistan
Angola
Anguilla
Antigua and Barbuda
Armenia
Aruba
Bahamas
Bangladesh
Barbados
Belize
Benin
Bhutan
Bolivia
Botswana
British Virgin Islands
Burkina Faso
Burundi
Cambodia
Cameroon
Cape Verde
Central African Republic
Chad
Comoros
Congo
Congo, Dem. Rep.
Côte d'Ivoire
Cuba
Djibouti
Dominica
Dominican Republic
Ecuador
El Salvador
Equatorial Guinea
Eritrea
Ethiopia
Fiji Islands
Gabon
Gambia
Georgia
Ghana
Grenada
Guatemala
Guinea
Guinea-Bissau
Guyana
Haiti
Honduras
India
Indonesia
Jamaica
Kazakhstan
Kenya
Kiribati
Kyrgyzstan
Laos
Lesotho
Liberia
Madagascar
Malawi
Maldives
Mali
Mauritania
Mauritius
Moldova, Rep. of
Mongolia
Montserrat
Mozambique
Myanmar
Namibia
Nauru
Nepal
Nicaragua
Niger
Nigeria
Pakistan
Palau
Papua New Guinea
Rwanda
Saint Kitts and Nevis
Saint Lucia
Saint Vincent and the Grenadines
Samoa
Sao Tome/ Principe
Senegal
Seychelles
Sierra Leone
Solomon Islands
Somalia
South Africa
South Sudan
Sri Lanka
Sudan
Suriname
Swaziland
Syria
Tajikistan
Tanzania, U. Rep. of
Thailand
Timor-Leste
Togo
Tonga
Trinidad and Tobago
Turkmenistan
Turks and Caicos
Tuvalu
Uganda
Uzbekistan
Vanuatu
Vietnam
Yemen
Zambia
Zimbabwe

ANNEX 3: LIST OF GILEAD LICENSED TERRITORY FOR TDF, ELVITEGRAVIR AND COBICISTAT AND QUAD (112 COUNTRIES)

Afghanistan
Angola
Anguilla
Antigua and Barbuda
Armenia
*Aruba**
Bahamas
Bangladesh
Barbados
Belize
Benin
Bhutan
Bolivia
Botswana*^
British Virgin Islands
Burkina Faso
Burundi
Cambodia
Cameroon
Cape Verde
Central African Republic
Chad
Comoros
Congo
Congo, Dem. Rep. of
Côte d'Ivoire
Cuba
Djibouti
Dominica
Dominican Republic*
*Ecuador**^
*El Salvador**^
Equatorial Guinea
Eritrea
Ethiopia
Fiji Islands, Rep. of
Gabon
Gambia
Georgia
Ghana
Grenada
Guatemala
Guinea
Guinea-Bissau
Guyana
Haiti
Honduras
India
Indonesia*^
Jamaica
*Kazakhstan**^
Kenya
Kiribati
Kyrgyzstan
Lao, People's Dem. Rep.
Lesotho
Liberia
Madagascar
Malawi
Maldives
Mali
Mauritania
Mauritius
Moldova, Rep. of
Mongolia
*Montserrat**
Mozambique
Myanmar
Namibia*^
Nauru
Nepal
Nicaragua
Niger
Nigeria
Pakistan
Palau
Papua New Guinea
Rwanda
Saint Kitts and Nevis
Saint Lucia
Saint Vincent and the Grenadines
Samoa
São Tomé and Príncipe
Senegal
Seychelles
Sierra Leone
Solomon Islands
Somalia
South Africa
South Sudan
*Sri Lanka**^
Sudan
Suriname
Swaziland
Syria
Tajikistan
Tanzania, U. Rep. of
Thailand*^
Timor-Leste
Togo
Tonga
Trinidad and Tobago
*Turkmenistan**^
Turks and Caicos
Tuvalu
Uganda
Uzbekistan
Vanuatu
Vietnam
Yemen
Zambia
Zimbabwe

Notes: Countries in *italics* added as of July 2011.
Countries marked with (*) not included in elvitegravir common territory.
Countries marked with (^) not included in cobicistat common territory.

Source: Gilead Sciences, Licensing Partnerships to Accelerate HIV Treatment Access, December 2011.