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## **Licensing Terms and Effectiveness of the Medicines Patent Pool**

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## List of abbreviations

ABC.....	abacavir
API .....	active pharmaceutical ingredients
API .....	active pharmaceutical ingredients
ARV .....	antiretroviral
CMV.....	cytomegalovirus
COBI.....	cobistat
EMA .....	European Medicines Agency
EVG.....	elvitegravir
FDA.....	US Food and Drug Administration
FTC.....	emtricitabine
GNI.....	gross national income
GSK.....	GlaxoSmithKline
ICH .....	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
INCO Terms.....	International Commercial Terms
KEI .....	Knowledge Ecology International
MPP.....	Medicines Patent Pool
MSF.....	Médecins Sans Frontières
NIH.....	US National Institute of Health
OECD .....	Organisation for Economic Co-operation and Development
SARS.....	Severe Acute Respiratory Syndrome
TDF .....	tenofovir
TRIPS Agreement .....	Agreement on Trade-Related Aspects of Intellectual Property Rights
UNDP .....	United Nations Development Programme
UNICEF .....	United Nations Children’s Fund
WHO .....	World Health Organization
WIPO.....	World Intellectual Property Organization
WTO.....	World Trade Organization

## 1. Introduction

HIV/AIDS is one of the leading causes of disease and death in developing countries.<sup>1</sup> Approximately, 34 million people, of whom 95% live in low- and middle-income countries, are infected with HIV/AIDS today. Thereof, 2.5 million are children.<sup>2</sup> HIV/AIDS can be treated with a combination of antiretrovirals (ARVs), which are drugs suppressing the virus and stopping the progression of the disease. Problematically, only 9.7 million people infected with HIV/AIDS of the 15 million people, who are in need of treatment due to an advanced stage of disease, have access to ARVs.<sup>3</sup> Even there already is a huge access gap, the World Health Organization (WHO) uttered the recommendation to initiate HIV/AIDS treatment at earlier stages. This leads to an increase of people eligible for treatment by 50%, which represents a great challenge.<sup>4</sup>

The lack of access to ARVs in low- and middle-income countries refers, among others, to the existing intellectual property regimes, which have often been criticized for inhibiting access to medicines.<sup>5</sup> Indeed, intellectual property has become an important part of international competition in the globalised world, because its temporal protection through patents stimulates innovation<sup>6</sup>, which in turn raises an economy's competitiveness and growth.<sup>7</sup> However, besides stimulating innovation, the protection of intellectual property through patents, as provided in the almost worldwide valid Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), creates at least 20 years long lasting monopolies, connected with the ability to unlimitedly set prices.<sup>8</sup> Since patents are connected with the ability of monopoly pricing, they can lead to high ARV prices, which make the needed drugs unaffordable for people in the developing world. Simultaneously, high drug prices result in an extensive burden on public health budgets.<sup>9</sup> As long as patents are valid, only the patent holders are allowed to exploit their inventions. Regarding ARVs this means that generic versions of ARVs, which are brand-free copies of the original patented drug<sup>10</sup>, cannot enter the market. This is a critical issue, since the advantage of generics is their lower sale price that makes

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<sup>1</sup> Cf. WHO (2011).

<sup>2</sup> Cf. UNITAID (2012), p. 8.

<sup>3</sup> Cf. WHO (2013a).

<sup>4</sup> Cf. UNITAID (2012), p. 8.

<sup>5</sup> Cf. 't Hoen, Ellen et al., *Journal of the International AIDS Society*, 2011, No. 15, p. 3; Westerhaus, Michael/Castro, Arachu, *PLoS Med*, 2006, No. 8.

<sup>6</sup> Cf. Ridder, Claudia (2004), p. 264.

<sup>7</sup> Cf. Shadlen, Kenneth C. et al. (2011), p. 1.

<sup>8</sup> Cf. Art. 33 of the TRIPS Agreement.

<sup>9</sup> Cf. 't Hoen, Ellen et al., *Journal of the International AIDS Society*, 2011, No. 15, p. 3.

<sup>10</sup> Cf. WTO (2006).

them affordable even in poorer settings.<sup>11</sup> In contrast to the manufacturer of the original drug, a generic producer does not spend money on research and development, so the price of generics solely depends on the costs of production. Only in case patent holders voluntarily grant licenses allowing for the manufacture of generics, mostly in turn for remuneration, low-cost copies of the original drugs may enter the market before the period of patent protection expires.

To prevent a situation, where the protection of intellectual property through patents is contradictory to health care, the patent holder's exclusive right to decide about the use of their patented products is not absolute, but rather can be limited through compulsory licenses.<sup>12</sup> A compulsory license is granted to an entity other than the patent holder by a governmental body, predominantly with the aim to protect public health.<sup>13</sup> The receiver of the license is permitted to produce the patented drug without the approval of the patent holder, but in exchange for an adequate monetary compensation.<sup>14</sup> Hence, a compulsory license can be classified as an instrument ultima ratio between patent holders' economic interest of gapless protection and the general interest to restrict this right for the society's benefit.

To tackle the problem that drugs produced under a compulsory license had predominantly to be used for supplying the domestic market<sup>15</sup>, but numerous developing countries did not possess sufficient domestic manufacturing capacities, the Doha Declaration on the TRIPS Agreement of 2001 strengthened that the agreement "can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all"<sup>16</sup>. In consequence, a waiver of Art. 31 (f) TRIPS was agreed in 2003, which permits to issue compulsory licenses in cooperation with another country in case of insufficient local manufacturing capacities.

Nevertheless, the intention to enhance access to medicines in developing countries this way has not been reached, since the waiver remains mainly unused. The reason for that is that the current process of issuing a compulsory license brings along several economic disincentives. For instance, the generic export manufacturer has to bear the costs of, if necessary, obtaining

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<sup>11</sup> Cf. Zürcher-Fausch, Nicole, *Außenwirtschaft*, 2002, No. 4, p. 501.

<sup>12</sup> Cf. Ridder, Claudia (2004), p. 57.

<sup>13</sup> Regarding pharmaceutical patents, the protection of public health is the most important reason to restrict patent holders' exclusive rights through compulsory licenses. Cf. Ridder, Claudia (2004), p. 55 and Art. 8.1 of the TRIPS Agreement.

<sup>14</sup> Cf. Art. 31 (h) of the TRIPS Agreement.

<sup>15</sup> Cf. Art. 31 (f) of the TRIPS Agreement.

<sup>16</sup> Cf. Art. 4 of the Declaration on the TRIPS Agreement and Public Health.

regulatory approval for the manufacture of generics, the production, remuneration and shipping as well as the adoption of measures to prevent re-export.<sup>17</sup> In addition to that, the process of granting a compulsory license from the issuance by the government until the transport of the needed drugs to the destination country cannot only be very time-consuming and pose bureaucratic hurdles, but also lead to a situation, where the generic manufacturer not yields any profit except the recoupment of its costs.<sup>18</sup> Therefore, besides two cases, no further compulsory licenses involving the export of needed drugs have been granted since 2003.<sup>19</sup> Hence, the issue of an appropriate balance of patent rights and access to medicines remains an unsolved problem.<sup>20</sup> Moreover, also granting compulsory licenses the traditional way, meaning to manufacture generics domestically, is a hazardous way to enhance access to medicines. This is due to the fact that issuing a compulsory license might be connected with retaliation measures of the patent holder, which are posed against the country concerned. Such measures may include a stop of registering new medicines or the threat of trade sanctions.<sup>21</sup>

A further problem, which exacerbates access to low-cost medicines by developing countries, is that the legal admissibility of India to manufacture generic ARVs to a great extent, which even led to its designation as “pharmacy of the developing world”,<sup>22</sup> expired in 2005. That year, India had to introduce patents for pharmaceuticals according to the end of its transition period under the TRIPS Agreement.<sup>23</sup> Additional reasons for non-existent access to ARVs are difficulties in local distribution due to logistical supply and storage problems.<sup>24</sup> Missing incentives for the development of ARVs, which are adapted to the specific needs of the developing world, are another issue.<sup>25</sup> Moreover, since there are hardly health insurance schemes, most people in the developing world have to pay out of pocket for drugs. Due to poverty, this restricts the ability to pay even further. Beyond that, weak healthcare systems, a lack of trained staff and brain drain represent problems, which also contribute to insufficient access to needed medicines.<sup>26</sup>

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<sup>17</sup> Cf. Tsai, George, *Virginia Journal of International Law*, 2009, No. 4, p. 1081.

<sup>18</sup> Cf. *Ibid.*

<sup>19</sup> Cf. Thapa, Rojina, *Journal of Intellectual Property Rights*, 2011, No. 6, p. 473.

<sup>20</sup> Cf. Ho, Cynthia M., *Chicago-Kent Law Review*, 2007, No. 3, p. 1471.

<sup>21</sup> Cf. *Financial Times* (2007) and Office of the US Trade Representative (2007), p. 11.

<sup>22</sup> Hein, Wolfgang/Moon, Suerie (2013), p. 1960.

<sup>23</sup> India did not need to apply the majority of the TRIPS provisions until ten years after filing the application. Cf. Art. 66.1 of the TRIPS Agreement.

<sup>24</sup> Cf. 't Hoen, Ellen (2003), p. 42.

<sup>25</sup> Cf. Zakus, David et al., *The Open AIDS Journal*, 2010, No. 4, p. 26.

<sup>26</sup> Cf. *Ibid.*

Numerous measures to enhance access to ARVs in the developing world have been initiated. These include, for instance, donations or bilateral licenses. This master thesis shall focus on the Medicines Patent Pool (MPP) founded by UNITAID, which operates as a “collaborative patent licensing model”<sup>27</sup>. The pool aims to increase access to ARVs through generic competition. In addition to that, it strives to enhance the development of new formulations and combination products.<sup>28</sup> In the following, based on an examination of the impacts of patents in the pharmaceutical industry, the special features of patent pools and their usage in the pharmaceutical sector is supposed to be investigated. Then, it will be depicted, which motives led to the foundation of the MPP. Subsequently, the Pool’s operating mechanism will be represented. Following, a detailed analysis of the licensing terms of the licenses the Patent Pool obtained from patent holders will take place. Thereby, the focus will be on the geographic scope, the field of use and on the termination provisions of the licenses. Besides, sublicenses will be examined in regard to the number of sublicensees, the source of active pharmaceutical ingredients, the ability to supply countries outside the licensed territory, grant back provisions, the ability to challenge the licensed patents and termination provisions. Moreover, it shall be investigated under which requirements the Medicines Patent Pool will be able to work effectively, meaning under which conditions patent holders and generic manufacturers are willing to license to, respectively from the Pool. Afterwards, on the basis of a study of the Pool’s advantages, its differences from previous approaches to enhance access to ARVs and a cost-benefit analysis, an evaluation of the MPP’s effectiveness will take place. The Pool’s disadvantages leading to areas with need for improvement shall be determined thereupon. In the end, the results are summarized in a conclusion and the questions, whether the Medicines Patent Pool is able to effectively enhance access to ARVs in the developing world, shall be answered.

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<sup>27</sup> t Hoen, Ellen (2012).

<sup>28</sup> Cf. Medicines Patent Pool (2013f).

## 2. Intellectual property in the field of pharmaceuticals

Patents are exclusive economic rights granted by the state for inventions, which fulfill three patentability criteria: They need to be novel, involve an inventive step and have the ability for industrial application.<sup>29</sup> Hence, the invention may neither be part of the existing state of the art, nor be obvious to a person skilled in the art and has to be usable on an industrial scale.<sup>30</sup> Patent protection is granted in accordance to the principle of territoriality. This implies that patent rights are governed exclusively by the laws of the country, where protection is claimed.<sup>31</sup> Since patents are generally offered for a period of 20 years from the date of filing the application<sup>32</sup>, the rights are finite. Patents are substitutes to secrecy and implicate the disclosure of the patented technology. Thus, they can be understood as social contracts, which imply that in exchange for exclusive rights patent holders have to provide benefits, such as innovation, to the society.<sup>33</sup> Through turning knowledge into private property, patents reward their owners for conducting costly, time-consuming and high-risk research.<sup>34</sup> Patent holders have the right to prevent third parties from making, using, offering for sale, selling or importing his invention without approval.<sup>35</sup> However, patent holders may permit third parties to apply their inventions via granting licenses to them. Such licenses are contracts, which allow the licensees –in return for a monetary compensation or free of charge– to make use of the patent for a predetermined period of time.<sup>36</sup>

Nevertheless, having exclusive rights means that patent owners have monopolistic power and may ward off competition. This enables them to appropriate the monopoly benefits from their inventions.<sup>37</sup> Therefore, patents could also be seen as legal instruments securing markets to firms.<sup>38</sup> Since the patent owners may set prices freely, the exclusive right to commercialize the patented invention leads to higher purchase prices of products, which contain the patented technology. Due to higher purchase prices and the non-existence of competitors on the market, patents may have anti-competitive effects.<sup>39</sup> Nevertheless, patents can also induce competition by follow-up inventions. By collecting revenue from sales as well as by collecting royalties from licenses, research expenditures can be refunded. This stimulates creativity and

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<sup>29</sup> Cf. Art. 27.1 S. 1 of the TRIPS Agreement.

<sup>30</sup> Cf. Falvey, Rod/Martinez,Feli/Reed, Geoff (2008), p. 407.

<sup>31</sup> Cf. Ibid., p. 408.

<sup>32</sup> Cf. Art. 33 of the TRIPS Agreement.

<sup>33</sup> Cf. 't Hoen, Ellen et al., Journal of the International AIDS Society, 2011, No. 15, p. 6.

<sup>34</sup> Cf. Shadlen, Kenneth C. (2011), p. 182.

<sup>35</sup> Cf. Article 28.1 (a) of the TRIPS Agreement.

<sup>36</sup> Cf. Beyer, Peter (2013), p. 228.

<sup>37</sup> Cf. Shadlen, Kenneth C. et al. (2011), p. 2.

<sup>38</sup> Cf. Falvey, Rod/Martinez,Feli/Reed, Geoff (2008), p. 405.

<sup>39</sup> Cf. Rodriguez, Victor, The Open AIDS Journal, 2010, No. 4, p. 63.

invention. Furthermore, the monopoly position of the patent owner solely exists temporary, meaning as long as new inventions with superior technology arrive on the market.

Through ensuring that inventors continue to conduct research and development in future, patents promote medicinal and therapeutical progress.<sup>40</sup> In knowledge-intensive industries such as the pharmaceutical industry, instead of prices and current market share competition is primary based on novelty of products and technologies as well as on future market share.<sup>41</sup> Before a drug is brought onto the market, extensive investments for the lengthy and costly research and development process and clinical testing occur. The researching drug manufacturers invest 450-950 million euro into research and development of a new active pharmaceutical ingredient.<sup>42</sup> As a consequence, sunk costs are extraordinary high. Besides, only a small number of research and development projects are successful.<sup>43</sup> Due to the time-consuming process of research and development, a patent is usually just effective for a period of ten to twelve years.<sup>44</sup>

As mentioned above, patents increase the prices of ARVs due to the monopolistic market power of patent holders. Prices might be so high that they place drugs out of reach for the vast majority of people in developing countries. ARV prices exceed most patients' average per capita income in developing countries.<sup>45</sup> The high prices can be referred to the fact that in most developing countries, it is more profitable for firms to sell their medicines just to the wealthy people at high price instead of selling medicines at cheaper price, but to the majority of people.<sup>46</sup> Price reductions, which would make drugs affordable to a higher number of people, cannot be compensated by the resultant rise in sales volume.<sup>47</sup> Hence, there is a clear trade-off between the provision of an adequate return on research and development investments for the patent holders and the provision of necessary medicines at affordable prices to people without sufficient financial resources in the developing world.<sup>48</sup> Lacking health insurance schemes and underdeveloped local health infrastructure, including deficiencies in cold-storage and supply chains additionally contribute to the inaccessibility of ARVs.<sup>49</sup>

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<sup>40</sup> Cf. Moon, Suerie/Bermudez, Jorge/'t Hoen, Ellen, *PLoS Medicine*, 2012, No. 5, p. 1.

<sup>41</sup> Cf. Rodriguez, Victor, *The Open AIDS Journal*, 2010, No. 4, p. 64.

<sup>42</sup> Cf. Fischer, Dagmar/Breitenbach, Jörg (eds.) (2013), p. 42.

<sup>43</sup> Cf. Johnson, Hilde, *Brown Journal of World Affairs* 2005, No. 1, p. 168.

<sup>44</sup> Cf. Muzaka, Valbona (2011), p. 25.

<sup>45</sup> Cf. *Ibid.*, p. 32.

<sup>46</sup> Cf. Grover, Anand et al., *Journal of Law, Medicine & Ethics*, 2012, No. 2, p. 235.

<sup>47</sup> Cf. Flynn, Sean/Hollis, Adian/Palmedo, Mike, *Journal of Law, Medicine & Ethics*, 2009, No. 1, p. 191.

<sup>48</sup> Cf. Falvey, Rod/Martinez,Feli/Reed, Geoff (2008), p. 417.

<sup>49</sup> Cf. Johnson, Hilde, *Brown Journal of World Affairs* 2005, No. 1, p. 168 and Grover, Anand et al., *Journal of Law, Medicine & Ethics* 2012, No. 2, p. 235.

Consequently, access to ARVs poses a serious problem in developing countries. Disadvantageously, patent-protected ARVs are typically the most recent and effective ones. Regarding HIV/AIDS, drugs have been developed lately, wherefore they are still protected by patents.<sup>50</sup> Only when a patent's term of protection expires, generics can enter the market. Because generic manufacturers do not have to conduct research and development, the sale price of generics amounts just 40-70% of the sale price of the original drug.<sup>51</sup> Since applying for patent protection involves high costs, medicines are rarely patented in every potential market.<sup>52</sup> To be precise, because developing countries are net importers of pharmaceuticals, patent protection is more important in the developed world<sup>53</sup>, from where resident pharmaceutical companies manufacture and sell the majority of branded new medicines, which amounts to two-thirds of global pharmaceutical sales.<sup>54</sup> Although three-quarters of the world population lives in developing countries, these states account for less than 10% of the global pharmaceutical market.<sup>55</sup> Albeit, the patenting of ARVs in the developing world has strongly risen during the last years.<sup>56</sup> In addition to that, although in case no patent exists in a developing country, the state might still miss the manufacturing capacity to produce ARVs on its own or do not dispose of the money necessary to import them. The lack of a more developed partner country exporting needed generics could be an obstacle to access to ARVs as well. A further problem is that ARVs are often not adapted to developing countries conditions or are not available for children. The reason for this is that profit-maximizing pharmaceutical companies solely conduct research if the potential market allows them to make up for their research expenditures and to gain profits.<sup>57</sup> Thus, besides high purchase prices as well as lacking manufacturing capacities and compulsory licensing partners, the missing alignment of medicines to environmental conditions also constitutes an urgent problem.

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<sup>50</sup> Cf. Beyer, Peter (2013), p. 229.

<sup>51</sup> Cf. Scherer, F. M. (2000), p. 1322.

<sup>52</sup> Cf. Falvey, Rod/Martinez,Feli/Reed, Geoff (2008), p. 405.

<sup>53</sup> Cf. Peng, Xiao, US-China Law Review, 2009, Vol. 6, p. 38.

<sup>54</sup> Cf. International Federation of Pharmaceutical Manufacturers and Associations (2011), p. 47.

<sup>55</sup> Cf. 't Hoen, Ellen (2003), p. 41.

<sup>56</sup> Cf. 't Hoen, Ellen/Passarelli, André, Current Opinion in HIV and AIDS, 2013, No. 1, p. 71.

<sup>57</sup> Cf. Muzaka, Valbona (2011), p. 29.

### 3. Patent pools and their development of application

In general, a patent pool is a cooperative mechanism between at least two or more patent owners, through which these share the rights to use knowledge by licensing one or more of their patents to each other or as a package to third parties.<sup>58</sup> A key feature of patent pools is that they involve a multiparty agreement between all patent owners participating in the pool. Licenses are subject to the terms the pool members agreed to.<sup>59</sup> In exchange for access to technologies, royalties can be demanded. Generally, a patent pool implies that part of the licensing fees collected by the pool is allocated to each member in accordance to each patent's contributory value.<sup>60</sup>

The initial purpose of patent pools was to find a remedy for legislatively widely allocated patent rights.<sup>61</sup> By pooling patents, pools should overcome blocking and hold-up resulting from single patent holders impeding others from the usage of components, which present indispensable parts of products. The situation is known as "tragedy of the anti-commons"<sup>62</sup>. Such an under-use of patented resources may take place in case a large number of patent owners hold exclusionary rights.<sup>63</sup> Then, patent pools serve as tools, which support access to technologies and enhance product development and production.<sup>64</sup> The reason for this is that pools collect all patents necessary for a certain product or technology. Since with patent pools only one license agreement has to be concluded to gain access to all indispensable components, high transaction costs arising from the negotiation of multiple licenses with different patent holders are circumvented.<sup>65</sup> In addition to that, the management of negotiations and administration of the license agreement is much easier. Because it is examined if the patents pooled contain a valid claim, infringement litigation costs can be reduced as well. Furthermore, patent pools distribute risks among the pool members.<sup>66</sup> Through the sharing of royalties among the pool members the likelihood to recover a huge part of one's own research and development investments rises. Moreover, the risk of developing new technologies decreases.

What has to be differentiated from patent pools are clearinghouses. In contrast to patent pools, clearinghouses are platforms or neutral intermediaries for licensable innovations bringing

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<sup>58</sup> Cf. OECD (2012), p. 134.

<sup>59</sup> Cf. Lerner, Josh/Tirole, Jean (2008), p. 159.

<sup>60</sup> Cf. Merges, Robert P. (1999), p. 16.

<sup>61</sup> Cf. Beldiman, Dana, *Tulane Journal of Technology and Intellectual Property*, 2012, No. 31, p. 54.

<sup>62</sup> Rodriguez, Victor, *The Open AIDS Journal*, 2010, No. 4, p. 62.

<sup>63</sup> Cf. Gold, E. Richard et al. (2007), p. 2.

<sup>64</sup> Cf. *Ibid.*, p. 23.

<sup>65</sup> Cf. Scala, Courtney C., *Connecticut Law Review*, 2009, No. 5, p. 1635.

<sup>66</sup> Cf. Clark, Jeanne/Piccolo, Joe/Stanton, Brian/Tyson, Karin (2000), p. 9.

together owners and users of technologies, goods, services and information.<sup>67,68</sup> Patent holders enter into a standardized license agreement with the clearinghouse.<sup>69</sup> The clearinghouse then matches patent owners and licensees. In addition to that, clearinghouses may also offer royalty collection and distribution, mediation or arbitration in case of disputes.<sup>70</sup> Hence, transaction costs of search and selection among available intellectual property options and negotiation costs are diminished.<sup>71</sup> Furthermore, the dissemination of inventions can be maximized.<sup>72</sup> There are several types of clearinghouses, for instance industry-established clearinghouses, which operate on a for-profit basis, non-profit or philanthropic clearinghouses, which are either established by the industry or by a foundation, open-source clearinghouses and open-access clearinghouses.<sup>73</sup>

Both patent pools and clearinghouses are collaborative patent licensing models and serve as tools to enhance access to inventions.<sup>74</sup> Moreover, since with both a clearinghouse and the majority of modern patent pools licenses are non-exclusive, they raise few antitrust and anti-competition concerns.<sup>75</sup> Nevertheless, as with clearinghouses the licensees chose, which patents to license on a case-by-case basis, there is less necessity for a vetting process than in case of a classical patent pool. The reason for this is that with a clearinghouse the infringement liability risk falls on the licensee.<sup>76</sup> Furthermore, the establishment of clearinghouses seems to be easier and is more rarely connected with high costs or an administrative burden.<sup>77</sup> However, several clearinghouses, such as the Pool for Open Innovation against Neglected Tropical Diseases, are hampered by their limited scope. Limited levels of participation in clearinghouses constitute a problem as well.<sup>78</sup>

Patent pools can take different forms. In the early 1900s, patent pools arose to overcome strategic behaviour of patent holders, who blocked the development and commercialization of new products for instance in the aircraft and automobile industry.<sup>79</sup> The reason for the USA to

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<sup>67</sup> Cf. van Zimmeren, Esther et al., Trends in Biotechnology 2011, No. 11, p. 570.

<sup>68</sup> The original term “clearing house” refers to the exchange mechanism of cheques and bills among member banks to transfer solely the net balances in cash. Cf. van Overwalle, Geertrui et al., Nature Reviews Genetics, 2006, No. 7, p. 148.

<sup>69</sup> Cf. OECD (2011), p. 25.

<sup>70</sup> Cf. van Zimmeren, Esther et al., Trends in Biotechnology, 2011, No. 11, p. 570.

<sup>71</sup> Cf. Gallini, Nancy (2011), p. 2.

<sup>72</sup> Cf. van Zimmeren, Esther et al., Trends in Biotechnology, 2011, No. 11, p. 570.

<sup>73</sup> Cf. OECD (2011), p. 25.

<sup>74</sup> Cf. van Zimmeren, Esther et al., Trends in Biotechnology, 2011, No. 11, p. 569.

<sup>75</sup> Cf. OECD (2011), p. 25 and Layne-Farrar, Anne/Lerner, Josh, International Journal of Industrial Organization 2011, No. 2, p. 295.

<sup>76</sup> Cf. van Zimmeren, Esther et al., Trends in Biotechnology 2011, No. 11, p. 570.

<sup>77</sup> Cf. OECD (2011), p. 25.

<sup>78</sup> Cf. OECD (2011), p. 32.

<sup>79</sup> Cf. Gold, E. Richard et al. (2007), p. 8.

induce the aircraft pool in 1917 was to broader develop airplane technology to enter into the First World War.<sup>80</sup> However, many of the early patent pools solely constituted of cross-licensing mechanisms, which facilitated the control of a few actors to dominate the market.<sup>81</sup> The pools served to fix prices and to keep competitors out of the market.<sup>82</sup> Consequently, due to their anti-competitive effects, numerous patent pools were dismantled in the 1950s.<sup>83</sup> Since the middle of the twentieth century, the incentive to establish a patent pool has often been the creation of a framework for an industry standard, meaning that companies wished to establish a common technological standard. Thus, such pools are comprised of complementary patents, which have to be applied together to establish the standard.<sup>84</sup> In contrast to the early patent pools, such pools are pro-competitive because they facilitate the production of new technologies. Examples of standard-setting pools can be found in the consumer electronics and television industry. These technology-intensive industries are associated with a broad distribution of patent rights. Through implementing standards, pools contributed essentially to the improvement of television and DVD.<sup>85</sup> A special feature of standard-setting patent pools is that the push for the pool emanates from the industry.<sup>86</sup>

#### **4. The Medicines Patent Pool**

##### **4.1 Patent pools in the field of medicines: The foundation of the Medicines Patent Pool**

The deployment of patent pools in the pharmaceutical area is a new development.<sup>87</sup> In contrast to patent pools emerging out of cooperative industry standard-setting efforts<sup>88</sup>, they have lately also been established due to social-entrepreneurial motives. Such patent pools aim to reduce transaction costs in order to serve the public, instead of commercial interests.<sup>89</sup> When the Severe Acute Respiratory Syndrome (SARS) epidemic broke out in the end of 2002, numerous research institutes and private companies plunged into decoding the SARS virus genome.<sup>90</sup> As a multitude of public and private patent applications incorporating various parts of the SARS genome was filed, the WHO SARS Consultation Group and the key SARS intellectual property owners created the SARS IP Working Group. Seeking for a possibility to pre-

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<sup>80</sup> Cf. Dykman, Harry T., *Journal of Patent Office Society*, 1964, p. 647.

<sup>81</sup> Cf. Gold, E. Richard et al. (2007), p. 8.

<sup>82</sup> Cf. WHO/WIPO/WTO (2012), p. 118.

<sup>83</sup> Cf. Gold, E. Richard et al. (2007), p. 8.

<sup>84</sup> Cf. Layne-Farrar, Anne/Lerner, Josh, *International Journal of Industrial Organization*, 2011, No. 2, p. 295.

<sup>85</sup> Cf. Scala, Courtney C., *Connecticut Law Review*, 2009, No. 5, p. 1636.

<sup>86</sup> Cf. Gold, E. Richard et al. (2007), p. 28.

<sup>87</sup> Cf. Sukkar, Elizabeth, *British Medical Journal*, 2009, No. 7701, p. 974.

<sup>88</sup> Cf. Layne-Farrar, Anne/Lerner, Josh, *International Journal of Industrial Organization*, 2011, No. 2, p. 295.

<sup>89</sup> Cf. Gold, E. Richard et al. (2007), p. 8.

<sup>90</sup> Cf. KEI (2007), p. 3.

vent complications in the development of medicines due to diverse ownership of patents, the group proposed to found an upstream patent pool to prevent disputes, to intensify research and to enhance the development of a vaccine. Nevertheless, since there were no further outbreaks of the disease and thus the economic drive for the formation of the pool disappeared, the SARS patent pool has never worked in practice.<sup>91</sup>

In 2006, Knowledge Ecology International (KEI)<sup>92</sup> and Médecins Sans Frontières (MSF) submitted the proposal of establishing a patent pool for medicines to UNITAID<sup>93,94</sup>. Two years later, patent pools were first considered as feasible mechanisms to widen access to generics in developing countries by the resolutions of the 61<sup>st</sup> World Health Organization's World Health Assembly.<sup>95</sup> In consequence, UNITAID decided to establish the Medicines Patent Pool as a non-profit patent pool, which shall serve the public interest, in December 2009.<sup>96</sup> In contrast to pools, which are initiated by the industry and developed in parallel with standard-setting<sup>97</sup>, there is a clear distinction between the donors of patents, the patent holders, and the users of these patents, which are generic manufacturers, with the MPP. Standard-setting pools however consist of companies, which contribute and make use of the licensed patent rights at the same time.<sup>98</sup>

The MPP is a downstream pool, which pools patents related to HIV/AIDS treatment received on a voluntary basis, and then licenses them out. Through its aim to overcome market failures in the production of ARV combinations and new HIV/AIDS medicines<sup>99</sup>, the Pool pursues a humanitarian objective.<sup>100</sup> The MPP provides access to all patents necessary to manufacture a generic to interested generic manufacturers, while solely concluding one license agreement. It involves the opportunity to bundle licenses into a one package license, which can be licensed out to a third party.<sup>101</sup> Since licenses are non-exclusive, participation in the MPP does not terminate the property rights of the patent holders. Because the Pool does not include a multi-

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<sup>91</sup> Cf. van Zimmeren, Esther et al., *Trends in Biotechnology* 2011, No. 11, p. 570.

<sup>92</sup> First, KEI proposed the establishment of an Essential Health Care Patent Pool at the International AIDS Conference in Barcelona in 2002. Cf. KEI (2002).

<sup>93</sup> UNITAID is a global health organization hosted by the WHO, which funds for greater access to treatments and diagnostics for HIV/AIDS, malaria and tuberculosis in low-income countries. It has no legal personality and operates under the aegis of the WHO. Cf. Gold, E. Richard et al. (2007), p. 34.

<sup>94</sup> Cf. KEI (2009).

<sup>95</sup> Cf. Art. 32 4.3 (a) of the Annex Global Strategy on Public Health, Innovation and Intellectual Property of the Resolutions and Decisions/Annexes of the 61<sup>st</sup> World Health Assembly.

<sup>96</sup> Cf. UNITAID (2009).

<sup>97</sup> Cf. van Zimmeren, Esther et al., *Trends in Biotechnology*, 2011, No. 11, p. 571.

<sup>98</sup> Cf. Center for Global Health R&D Policy/The Results for Development Institute (2012), p. 1.

<sup>99</sup> Cf. Gold, E. Richard et al. (2007), p. 1.

<sup>100</sup> Cf. van Zimmeren, Esther et al., *Trends in Biotechnology*, 2011, No. 11, p. 572.

<sup>101</sup> Cf. van Zimmeren, Esther et al., *Trends in Biotechnology*, 2011, No. 11, p. 570.

party agreement between the patent owners, it is even closer to the clearinghouse concept than to classical patent pools in this respect.<sup>102</sup>

The MPP was constructed as a distinct entity, which should enlarge trust of the pharmaceutical industry in the institution.<sup>103</sup> The advantage of the MPP being legally and functionally independent from UNITAID is that access to ARVs is strongly politically charged. In turn, due to its independence from the pool, UNITAID as the pool administrator is able to secure transparency and neutrality to the licensing processes.<sup>104</sup> The Pool is based on the non-profit independent Medicines Patent Pool Foundation organized under Swiss law, which was established in July 2010. UNITAID funds the Pool based on a common Memorandum of Understanding on a five year-basis.<sup>105</sup> The MPP Foundation has been provided with US-\$ 4.43 million by UNITAID during the first year of their collaboration. Operations are undertaken by the MPP's seven staff members working full-time.<sup>106</sup> In 2011, UNITAID decided to continue funding of the MPP for another four years.<sup>107</sup> Hence, the Pool has not only been initiated, but still is strongly supported by the international organization.

#### **4.2 Motives to establish the Medicines Patent Pool**

As mentioned before, in developing countries, of the 15 million people infected with HIV/AIDS, who are in need of treatment, 5.3 million people lack access to ARVs.<sup>108</sup> Hence, above all, the MPP aims to reach price reductions of ARVs in developing countries. In addition to that, pooling patents on ARVs shall enhance the development of new formulations, fixed-dose combinations, ARVs adapted to developing countries needs and pediatric formulations.<sup>109</sup> Thereby, the MPP aims to encourage access to quality, safe, efficacious, more appropriate and more affordable health products regarding HIV/AIDS.

Since the prices of ARVs available on developing countries markets are predominantly unaffordable for people infected with HIV/AIDS, the Pool aims to lower ARV prices through generic competition. Due to the lower prices of generics, an increase in drug supply is possible if generic versions enter the market. Nevertheless, since most ARVs are still patented, patent holders' exclusive rights to make use of their patented invention represent barriers to the in-

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<sup>102</sup> Cf. *Ibid.*, p. 571.

<sup>103</sup> Cf. Sukkar, Elisabeth, *British Medical Journal* 2009, No. 7701, p. 975.

<sup>104</sup> Cf. Gold, E. Richard et al. (2007), p. 36.

<sup>105</sup> Cf. Medicines Patent Pool Foundation Memorandum of Understanding, p. 4.

<sup>106</sup> Cf. Medicines Patent Pool Foundation Memorandum of Understanding, p. 23.

<sup>107</sup> Cf. UNITAID (2011).

<sup>108</sup> Cf. WHO (2013a).

<sup>109</sup> Cf. Medicines Patent Pool Foundation Memorandum of Understanding, p. 4.

roduction of low-cost generics.<sup>110</sup> Therefore, the MPP aims to induce patent holders to license their patents to the Pool. The MPP will in turn license the patents obtained to generic manufacturers. Further reason for the MPP's activity in enhancing access to ARVs are increasing drug prices, which result from a change of treatment guidelines and the impact the financial crisis had on national health budgets and donors.<sup>111</sup>

The reason to strive for the development of new formulations is that a development of resistances to first-line ARVs occurs with 20% of patients within three years from the beginning of treatment.<sup>112</sup> As a consequence, the number of people needing second-line therapy rises. Resistances especially arise in context of unplanned interruptions of treatment, which often result from poor management of matching supply to demand as well as from eventual distribution in developing countries.<sup>113</sup> Generally, second-line regimens are more than twice as expensive as first-line ARVs.<sup>114</sup> Thus, besides resistances, the prohibitively high price of existing second-line treatment for developing countries<sup>115</sup> constitutes a further reason for the MPP's commitment in this area.

Since one-third of ARVs are not available for children and only 38% of children infected with HIV/AIDS have access to ARVs<sup>116</sup>, the Pool also aims to encourage the development of pediatric formulations. On the pediatric market, there are only few safe and effective ARVs approved for use.<sup>117</sup> Nevertheless, in OECD member countries, there is almost no need of pediatric ARVs.<sup>118</sup> In addition to the very small and unprofitable market for pediatric ARVs in developed countries<sup>119</sup>, initiatives that successfully strive to reduce HIV transmission from mothers to children lead to a further decline of the demand for pediatric ARVs.<sup>120</sup> Besides the resulting drop of returns on investment for the development of pediatric ARVs, production costs are high due to the small quantities needed. This prevents the realization of economies of scale in production and distribution.<sup>121</sup> Thus, there are disincentives to engage in research and development for manufacturers and the small number of existing pediatric ARVs is very expensive. A supplementary problem is that as children grow, medicines with different strengths are needed. This fragments the pediatric ARV market even further. Additionally,

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<sup>110</sup> Cf. 't Hoen, Ellen/Passarelli, André, *Current Opinion in HIV and AIDS*, 2013, No. 1, p. 70.

<sup>111</sup> Cf. Medicines Patent Pool Foundation Memorandum of Understanding, p. 2.

<sup>112</sup> Cf. Cox, Krista L., *Hastings Science & Technology Law Journal*, 2012, No. 2, p. 295.

<sup>113</sup> Cf. Popp, Danielle/Fisher, Jeffrey, *AIDS*, 2002, No. 4, p. 676.

<sup>114</sup> Cf. UNITAID (2012), p. 13.

<sup>115</sup> Cf. WHO (2006), p. 12.

<sup>116</sup> Cf. WHO/UNAIDS/UNICEF (2009), p. 6.

<sup>117</sup> Cf. UNITAID (2012), p. 14.

<sup>118</sup> Cf. Berger, Jonathan (2008), p. 30.

<sup>119</sup> Cf. Dionisio, Daniele et al., *Current HIV Research*, 2007, No. 2, p. 157.

<sup>120</sup> Cf. Kaiser Health News (2009).

<sup>121</sup> Cf. Waning, Brenda et al., *BMC Pediatrics*, 2010, No. 74, p. 2.

varying dosage forms like liquids for infants and chewable tablets and sprinkles for older children are necessary.<sup>122</sup> Although the pediatric ARV market has grown from US-\$5 million in 2004 to approximately US-\$40 million in 2009, it is still much smaller than the adult ARV market.<sup>123</sup>

Another goal of the MPP is to enhance the development of first- and second-line fixed-dose combinations so that people infected with HIV/AIDS only need to take one pill.<sup>124</sup> Fixed-dose combinations yield the advantage of facilitating patient adherence and reducing the risk of developing resistances. Indeed, the development of fixed-dose combinations is especially difficult because one patent holder, who owns a patent for a single component of the combined drug, is able to prevent the deployment of a formula.<sup>125</sup>

### **4.3 The MPP's entities and its operating mechanism**

The MPP is both an upstream and a downstream patent pool. Its upstream organization refers to the creation of new and pediatric ARVs as well as fixed-dose combinations, which are, through heat stability or else, suitable for developing countries. The downstream part of the MPP encompasses its aim to reduce prices for existing ARVs through generic competition.<sup>126</sup> The first step in the licensing process is the determination of target drugs and missing essential ARVs, respectively relevant patents thereof, which are of interest for low- and middle-income countries by the MPP.<sup>127</sup> To identify the relevant products, the Pool collaborates with the WHO HIV and Essential Medicines Department.<sup>128</sup> The Pool then depends on the patent owners holding patents on target ARVs to voluntarily offer their patents to the MPP.<sup>129</sup> The licenses the MPP concludes with patent holders are non-exclusive, meaning that pool members may additionally grant licenses outside the Pool to other parties in the contractual territory; a provision the majority of modern patent pools allows for.<sup>130</sup> The MPP tries to pool together all the relevant patents, which are indispensable to produce generic ARVs as downstream products. Advantageously, the Pool only needs to enter into one license agreement, which could cover patents on different ARVs, with each manufacturer instead of negotiating

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<sup>122</sup> Cf. UNICEF/WHO (2010), p. 15.

<sup>123</sup> Cf. Waning, Brenda et al., *BMC Pediatrics*, 2010, No. 74, p. 8f.

<sup>124</sup> Cf. Bermudez, Jorge/'t Hoen, Ellen, *The Open AIDS Journal*, 2010, No. 4, p. 37.

<sup>125</sup> Cf. Mara, Kaitlin, *Africa Health*, 2012, No. 2, p. 21.

<sup>126</sup> Cf. WHO (2010), p. 74.

<sup>127</sup> Cf. Medicines Patent Pool Foundation Memorandum of Understanding, p. 6.

<sup>128</sup> Cf. *Supra* note 7 Appendix C – Development Plan of the MPP-NIH License Agreement.

<sup>129</sup> Cf. 't Hoen, Ellen/Passarelli, André, *Current Opinion in HIV and AIDS*, 2013, No. 1, p. 73.

<sup>130</sup> Cf. Layne-Farrar, Anne/Lerner, Josh, *International Journal of Industrial Organization*, 2011, No. 2, p. 295.

multiple licenses for every single ARV.<sup>131</sup> Afterwards, the MPP licenses the patents obtained to third parties, namely generic manufacturers. Again only one license agreement is necessary for the sublicensee<sup>132</sup> to receive the approval to manufacture, sell and develop several generic ARVs and to get market access. Hence, through pooling patent rights, the MPP acts as a one-stop-shop for pharmaceutical companies and generic producers.<sup>133</sup> Sublicensees are obliged to pay royalties based on net sales of generic ARVs manufactured to the patent holder. This way, licenses via the MPP shall result in a win-win-situation for both the patent holder and the generic manufacturer. In order to strengthen competition and to conform with anti-trust law requirements, sublicenses are granted on a non-discriminatory basis.<sup>134</sup> To guarantee the quality of the generics manufactured by the sublicensees under a license by the MPP, the MPP leverages existing mechanisms like the WHO Prequalification of Medicines Programme, US Food and Drug Administration (FDA)<sup>135</sup> or European Medicines Agency (EMA)<sup>136</sup> approval standards, as well as other stringent regulatory agencies, which are listed in the sublicense agreements.<sup>137,138</sup> However, since the MPP is based on a voluntary mechanism, its success depends on the willingness of pharmaceutical companies to participate in the MPP and to share their intellectual property with the Pool.<sup>139</sup>

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<sup>131</sup> Cf. Gold, E. Richard et al. (2007), p. 3.

<sup>132</sup> The generic manufacturers, who are granted licenses by the MPP, are hereafter named as “sublicensees”, since their sublicense was granted to them by the MPP, the original licensee. Cf. Anderson, F. Andrew/Anderegg, Maria H. (2003), p. 1.

<sup>133</sup> Cf. Lerner, Josh/Tirole, Jean (2008), p. 159.

<sup>134</sup> Cf. Supra note 2 Appendix C – Development Plan of the MPP-NIH License Agreement.

<sup>135</sup> Current Good Manufacturing Practice for Finished Pharmaceuticals according to Code of Federal Regulations Title 21.

<sup>136</sup> Good Manufacturing Practice Guidelines for medicines and investigational medicines for human use according to Directive 2003/94/EC.

<sup>137</sup> Cf. Supra note 2 Appendix C – Development Plan of the MPP-NIH License Agreement.

<sup>138</sup> Cf. for instance Art. 6.2 (a) of the MPP-Gilead-Aurobindo Sublicense Agreement.

<sup>139</sup> Cf. Dionisio, Daniele, *Transnational Biomedicine*, 2011, No. 1, p. 2.

## **5. Licenses granted to the MPP and their licensing terms**

### **5.1 Licenses in the pool<sup>140</sup>**

#### **The MPP-NIH License<sup>141</sup>**

The MPP received its first license from the US National Institute of Health (NIH), an agency of the United Nations Public Health Service, for patents on darunavir in September 2010.<sup>142</sup> The company is the world's biggest funder of biomedical research.<sup>143</sup> Darunavir is a protease inhibitor, which is of high importance for treatment of people infected with HIV/AIDS, who have developed resistances.<sup>144</sup> The drug has been first approved by the FDA in 2006. The non-exclusive and royalty-free license<sup>145</sup> encompasses the right to make, have made and use, but not to sell, the licensed products and processes.<sup>146</sup> Regarding the licensed patents' value, since darunavir is recommended by the WHO as a potential third-line treatment for patients experiencing failure with second-line medicines<sup>147</sup>, the drug is of high importance for people infected with HIV/AIDS. Resistances arise with 20% of people on treatment and most frequently take place in developing countries due to unplanned interruptions of treatment.<sup>148</sup> Previously to its license agreement with the MPP the NIH has granted non-exclusive licenses on darunavir among others to the pharmaceutical company Tibotec, which thereby was permitted to market the drug.<sup>149</sup>

#### **The MPP-Gilead License**

The second license was concluded between the MPP and the American pharmaceutical company Gilead Sciences in July 2011.<sup>150</sup> Gilead, which conducts research and development as well as commercializes medicines<sup>151</sup>, is listed in the stock exchange, where it exhibits increasing success since 2012.<sup>152</sup> The company commands a market share of 31% on the global HIV

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<sup>140</sup> The framework for the analysis of the license agreements has been developed based on Cox's study of the MPP-Gilead License Agreement. Cf. Cox, Krista L., *Hastings Science & Technology Law Journal*, 2012, No. 2, p. 305ff.

<sup>141</sup> For the sake of clarity, the analysis of the license agreements is subdivided according to the individual agreements.

<sup>142</sup> Cf. Medicines Patent Pool (2010b), p. 1.

<sup>143</sup> Cf. National Institute of Health (2013).

<sup>144</sup> Cf. Medicines Patent Pool (2010a), p. 1.

<sup>145</sup> Non-Exclusive Patent License Agreement of the National Institute of Health and the Medicines Patent Pool Foundation. Hereafter MPP-NIH License Agreement.

<sup>146</sup> Cf. Art. 3.1 of the MPP-NIH License Agreement.

<sup>147</sup> Cf. WHO (2013b), p. 153.

<sup>148</sup> Cf. Popp, Danielle/Fisher, Jeffrey, *AIDS*, 2002, No. 4, p. 676.

<sup>149</sup> Cf. Medicines Patent Pool (2010b), p. 1.

<sup>150</sup> Cf. Preamble of the MPP-Gilead License Agreement.

<sup>151</sup> Cf. Gilead (2013a).

<sup>152</sup> Cf. Nasdaq (2013).

drug market.<sup>153</sup> In 2012, Gilead gained revenues of US-\$ 9.7 billion.<sup>154</sup> In the same year, ARV sales of Atripla<sup>155</sup>, Truvada<sup>156</sup>, Viread<sup>157</sup>, Complera/Eviplera<sup>158</sup> and Stribild<sup>159</sup> rose by 15% to US-\$ 8.14 billion. Of these, Atripla was the ARV generating most profit.<sup>160</sup> Gilead describes itself as the “leader in the development of ARVs”<sup>161</sup> for more than a decade.

The non-exclusive and non-transferable license Gilead granted to the MPP<sup>162</sup> covers the right to make, use, sell, have sold, offer for sale, export from India and import TDF product in the field in the TDF territory, COBI product in the COBI territory and EVG product and the Quad in the field in the EVG-Quad territory.<sup>163</sup> The company additionally assures not to sue on sublicensees for using its patents on FTC.<sup>164</sup> Supplementary to the product licenses is the royalty-free, non-exclusive, non-transferable API license, which permits sublicensees to make, use, offer to sell and sell API in the field and in India, for internal use or for the selling process to licensed product suppliers.<sup>165</sup> According to the MPP-Gilead License Agreement, sublicensees may also produce and sell combinations of TDF and COBI with other API in case sublicensees are allowed to legally manufacture and sell the other API in the applicable country, and the manufacture and sale of the combined products is in accordance with the sublicense agreement.<sup>166</sup> Regarding EVG, sublicensees additionally need Gilead’s prior written consent to produce or sale combined products in the EVG-Quad territory.<sup>167</sup> This can be referred to the fact that Gilead has licensed the right to develop and market EVG from Japan-Tobacco in 2005. Through this license agreement Gilead has been granted the exclusive rights to develop and commercialize an integrase inhibitor, which was named EVG later, in all countries of the world, except Japan, in turn for a payment of US-\$ 100 million.<sup>168</sup>

TDF has been approved by the FDA in 2001<sup>169</sup>, whereas FTC received approval in 2003.<sup>170</sup> Regarding the importance and value of the ARVs patents are licensed on, TDF is an ARV,

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<sup>153</sup> Cf. Hirschler, Ben (2009).

<sup>154</sup> Cf. Gilead (2013d).

<sup>155</sup> Atripla is a fixed-dose combination consisting of efavirenz, emtricitabine (FTC) and tenofovir (TDF).

<sup>156</sup> Truvada consists of FTC and TDF.

<sup>157</sup> Viread consists of TDF.

<sup>158</sup> Complera/Eviplera is a fixed-dose combination consisting of rilvipirina, FTC and TDF.

<sup>159</sup> Stribild is a fixed-dose combination consisting of elvitegravir (EVG), cobicistat (COBI), FTC and TDF, which is also known as “the Quad”.

<sup>160</sup> Cf. Gilead (2013d).

<sup>161</sup> Gilead (2013e), p. 1.

<sup>162</sup> License Agreement between Gilead Science and the Medicines Patent Pool. Hereafter MPP-Gilead License.

<sup>163</sup> Cf. Art. 2.3 S. 1 of the MPP-Gilead License Agreement.

<sup>164</sup> Cf. Art. 5.3 of the MPP-Gilead License Agreement.

<sup>165</sup> Cf. Art. 2.2 of the MPP-Gilead License Agreement.

<sup>166</sup> Cf. Art. 2.4 (b) i and ii of the MPP-Gilead License Agreement.

<sup>167</sup> Cf. Art. 2.4 (b) iii of the MPP-Gilead License Agreement.

<sup>168</sup> Cf. Finanznachrichten (2005).

<sup>169</sup> Cf. FDA (2013).

which is recommended by the WHO to replace the older ARV stavudine due to TDF's fewer side effects.<sup>171</sup> As TDF and FTC are part of the WHO Model List of Essential Medicines<sup>172</sup>, the licensed drugs are very important ones from a medical point of view. When the license agreement was signed, COBI, EVG and the Quad have been pipeline products, which were still in clinical development.<sup>173</sup> Gilead solely planned on FDA approval in the later 2012. However, although sales cannot take place before Gilead has received regulatory approval, the inclusion of these drugs in the agreement allows sublicensees to start preparing to market the drugs. The inclusion of COBI, EVG and the Quad in the MPP-Gilead License presents the basis for early generic competition for these medicines. Consequently, there is greater probability that developing country patients have earlier access to new ARVs at decreased prices.<sup>174</sup> So far, the Quad has been approved by the FDA in August 2012<sup>175</sup>, whereas COBI and EVG have not, although they are components of the Quad. The reason why the Quad could, despite the missing approval of EVG and COBI, already receive admission seem to be "deficiencies in documentation and validation of certain quality testing procedures and methods"<sup>176</sup> regarding COBI and EVG, but not safety concerns.

The MPP-Gilead License Agreement has been amended four times. At first, South Sudan has been added to the TDF, COBI and EVG-Quad territory after the Republic was created in July 2011.<sup>177</sup> The reason for that is that coverage of ARV therapy is less than 20% in the developing country.<sup>178</sup> Second, the license agreement was clarified in regard to the FTC license in November 2011.<sup>179</sup> In the amendment, Gilead stated that it will not sue a sublicensee in case it manufacturers, uses or sales products containing TDF and FTC in the TDF territory.<sup>180</sup> If the TDF license is terminated, sublicensees may keep on manufacturing combination products, which contain TDF and FTC.<sup>181</sup> Moreover, the amendment straightens out that the supply of a country outside the approved territories with API or products is no breach of agreement, in case a compulsory license for import has been granted in that country and, respectively or, the Indian government has issued a compulsory license for export.<sup>182</sup> The third amendment of

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<sup>170</sup> Cf. FDA (2003).

<sup>171</sup> Cf. WHO (2013b), p. 113.

<sup>172</sup> Cf. WHO (2013e), p. 15.

<sup>173</sup> Cf. Medicines Patent Pool (2011b).

<sup>174</sup> Cf. Cox, Krista L., *Hastings Science & Technology Law Journal*, 2012, No. 2, p. 305.

<sup>175</sup> Cf. *The Wall Street Journal* (2012).

<sup>176</sup> Gilead (2013c).

<sup>177</sup> Cf. Medicines Patent Pool (2011c).

<sup>178</sup> Cf. UNAIDS (2012).

<sup>179</sup> Cf. S. 1 of the Second Amendment to MPP-Gilead License Agreement.

<sup>180</sup> Cf. Art. 3 S. 2 of the Second Amendment to MPP-Gilead License Agreement.

<sup>181</sup> Cf. Medicines Patent Pool (2011a).

<sup>182</sup> Cf. Art. 4 (b) S. 2 of the Second Amendment to MPP-Gilead License Agreement.

July 2012 removes Gilead's obligation to pay 5% of the royalties received by the sublicensees per calendar year to the MPP.<sup>183</sup> The fourth and last amendment was concluded in November 2012, when Gilead agreed to provide technology transfers regarding the production of FTC.<sup>184</sup> Before participating in the MPP in 2011, Gilead had voluntarily concluded non-exclusive bilateral license agreements for TDF (Viread) and a combined product of TDF and FTC (Truvada) with generic manufacturers. In 2005, Gilead concluded a non-exclusive license agreement with Aspen Pharmacare, a South African company, to manufacture TDF and TDF-FTC combination products for sale in 95 developing countries.<sup>185</sup> In 2006, after patent opposition was filed against Gilead's patent application on TDF in India<sup>186</sup>, eleven license agreements with Indian manufacturers were concluded.<sup>187</sup> These license agreements solely allowed the generic manufacturers to sell TDF in 95 low-income countries.<sup>188</sup> The initial royalty rate for sales of generics was 5%, albeit lowered to 3% in 2011.<sup>189</sup>

The conclusion of these voluntary prior licenses of Gilead has been criticized by MSF, which claims that Gilead had the intention to thereby circumvent weak patent prospects for TDF and to ward off opposition.<sup>190</sup> However, the generic companies signing the license agreement might have pursued a low-return low-risk strategy, meaning that in case the patents would be granted to Gilead and others accepted the license agreement, but they did not, they would be pushed out of the market.<sup>191</sup> In July 2011, Gilead extended the TDF license agreements to COBI, EVG and the Quad, but only with the four generic manufacturers Ranbaxy, Matrix, Strides and Hetero.<sup>192</sup> Moreover, regarding TDF, the field of use was widened to treatment of Hepatitis B. Besides, 16 additional countries were included, so that the total number of countries in the territory rose to 111.<sup>193</sup> Gilead announced the extension the same day the MPP-Gilead License Agreement was made public.<sup>194</sup> The extension of the territory of the bilateral licenses allows the four licensees to market EVG, COBI and the Quad even in nine countries, which are not included in the MPP-Gilead territory of EVG, COBI and the Quad.<sup>195</sup> These are Botswana, Ecuador, Indonesia, Kazakhstan, Namibia, Sri Lanka, Thailand and Turkmenistan.

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<sup>183</sup> Cf. Art. 2 (a) of the Third Amendment to MPP-Gilead License Agreement.

<sup>184</sup> Cf. Recital 1 of the Fourth Amendment to MPP-Gilead License Agreement.

<sup>185</sup> Cf. The Body (2005).

<sup>186</sup> Cf. United Nations Development Programme (UNDP) (2010), p. 27.

<sup>187</sup> Cf. Gilead (2006b) and Gilead (2006a).

<sup>188</sup> Cf. Médecins Sans Frontières (2011), p. 3.

<sup>189</sup> Cf. Médecins Sans Frontières (2013), p. 83.

<sup>190</sup> Cf. Médecins Sans Frontières (2011), p. 3.

<sup>191</sup> Cf. UNDP (2010), p. 27.

<sup>192</sup> Cf. Médecins Sans Frontières (2013), p. 79 (COBI), p. 80 (EVG), p. 83 (the Quad).

<sup>193</sup> Cf. Gilead (2011).

<sup>194</sup> Cf. Gilead (2011) and Medicines Patent Pool (2011b).

<sup>195</sup> Cf. Médecins Sans Frontières (2011), p. 4.

The nine additional countries are divided between the four licensees, so that each of the four companies has the advantage of semi-exclusivity in a particular territory.<sup>196</sup> Hence, due to the special division of rights to sell in the additional nine countries, in these countries there is no competition between manufacturers. Although licensing conditions are not public, Cox states that the four licenses encompass higher royalty rates of 15% for TDF, COBI and EVG and 10% for the Quad. This reflects the stronger business interest of Gilead.<sup>197</sup> Since royalties on pediatric formulations are waived, the licensees have to show “progress” on developing pediatric formulations.<sup>198</sup>

When Gilead joined the MPP, the pharmaceutical companies, which had already signed a license agreement on TDF with Gilead, were offered the opportunity to become a sublicensee of the MPP-Gilead License in form of an Amended and Restated License Agreement.<sup>199</sup> Generic manufacturers accepting this proposal were Emcure and Hetero<sup>200</sup> as well as Aurobindo and Shasun.<sup>201</sup> Especially noteworthy is the decision of Hetero, which before commanded semi-exclusive rights to sell generics in certain developing countries. The only reasons, which seem to be reasonable for Hetero to quit the semi-exclusive license and to license the same products, but on a smaller geographical scope and without exclusive rights to supply certain states, via the Pool again, are the lower royalty rates and the lack of duty to show progress in the development of pediatric formulations.

### **The MPP-ViiV Healthcare License**

In February 2013, the MPP announced a collaboration agreement with ViiV Healthcare, which is a joint venture of the pharmaceutical companies GlaxoSmithKline (GSK), Pfizer and Shionogi.<sup>202</sup> The company features a market share of about 19% in the global HIV/AIDS drug market.<sup>203</sup> The license agreement between the MPP and ViiV Healthcare<sup>204</sup> encompasses a non-exclusive, non-transferable license to enter into sublicenses for pediatric formulations of

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<sup>196</sup> Matrix has semi-exclusivity in Sri Lanka and Thailand, Ranbaxy and Hetero in Botswana and Namibia and Strides in El Salvador, Ecuador, Indonesia, Kazakhstan and Turkmenistan. Cf. *Médecins Sans Frontières* (2011), p. 4.

<sup>197</sup> Cf. Beyer, Peter (2013), p. 239.

<sup>198</sup> Cf. Cox, Krista L., *Hastings Science & Technology Law Journal*, 2012, No. 2, p. 308.

<sup>199</sup> Cf. Art. 2.1 S. 2 of the MPP-Gilead License Agreement.

<sup>200</sup> Cf. Gilead (2006b).

<sup>201</sup> Cf. Gilead (2006a).

<sup>202</sup> Cf. *Medicines Patent Pool* (2013e).

<sup>203</sup> Cf. Hirschler, Ben (2009).

<sup>204</sup> License Agreement between ViiV Healthcare and the Medicines Patent Pool. Hereafter MPP-ViiV Healthcare License Agreement.

abacavir (ABC), whereby sublicensees may be granted the right to formulate, manufacture and use ABC.<sup>205</sup>

The MPP-ViiV Healthcare License is the first and single one of the MPP dealing with an ARV for children infected with HIV/AIDS. At least 3.4 million children under 15 years are infected with HIV/AIDS worldwide. Only 562000 children have access to ARVs<sup>206</sup>, which implies that 72% of children, who are in need of treatment, are not provided with medicines.<sup>207</sup> In comparison, 46% of adults infected with HIV lack access to ARVs.<sup>208</sup> Thus, the license of ABC constituted an important step to stem the issue of lacking access to pediatric ARVs. As an alternative nucleoside reverse transcriptase inhibitor for first-line therapy, ABC is even recommended by the WHO Model List of Essential Medicines for children infected with HIV/AIDS.<sup>209</sup> In addition to that, ViiV Healthcare had already received market approval for adult and pediatric use of ABC in 1998<sup>210</sup>, so generic manufacturing of the ARV could immediately start. This differentiates the ViiV Healthcare License favorably from the MPP-NIH and part of the MPP-Gilead License.

Before joining the MPP, ViiV Healthcare announced that it concluded a royalty-free license on ABC with Aspen Pharmaceuticals, a generic manufacturer from South Africa, in July 2009.<sup>211</sup> This bilateral license covered 69 countries, which are sub-Saharan African, least-developed and low-income countries.<sup>212</sup> However, in September 2009, GSK, one of the founders of ViiV Healthcare, and Aspen merged their South African operations. Thereby, GSK became the largest share holder of Aspen. The South African Competition Commission only approved the merger under the condition that GSK has to grant non-exclusive licenses to at least five South African generic manufacturers mentioned by name, but also to other interested companies. The license has to including the production and, respectively or the import of ABC, on terms not less favorable than those granted to Aspen.<sup>213</sup> Hence, before the MPP-ViiV Healthcare Agreement was concluded, at least six royalty-free bilateral licenses on ABC existed.

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<sup>205</sup> Cf. Art. 2.1 of the MPP-ViiV Healthcare License Agreement.

<sup>206</sup> Cf. Intellectual Property Watch (2013).

<sup>207</sup> Cf. ViiV Healthcare (2013).

<sup>208</sup> Cf. Essential Drugs (2013).

<sup>209</sup> Cf. WHO (2013f), p. 13.

<sup>210</sup> Cf. FDA (2002).

<sup>211</sup> Cf. The Guardian (2009).

<sup>212</sup> Cf. Médecins Sans Frontières (2013), p. 78.

<sup>213</sup> Cf. The Competition Commission (2009).

### **The MPP-Roche License**

In August 2013, the MPP announced an agreement on valganciclovir for use in people living with HIV/AIDS, which was concluded with Roche.<sup>214</sup> It is the first agreement, which involves a pricing element, meaning a price cut of 90%, as well as a licensing element, which will become effective one year after the agreement<sup>215</sup> came into effect. Valganciclovir is a key easy-to-take oral medicine to treat cytomegalovirus (CMV) disease. CMV is a late-stage opportunistic infection in people infected with HIV/AIDS. Through attacking the retina of the eye, the virus is able to cause blindness in people infected with HIV/AIDS.<sup>216</sup> According to a recent study, CMV disease occurs in 17.6% of HIV/AIDS patients.<sup>217</sup>

The use of valganciclovir has been approved by the FDA in 2001.<sup>218</sup> It is the only branded ARV for the treatment of infections by the CMV. This as well as patent protection continuing in the USA until 2013 and in Europe until 2015 are the reasons for Roche's strong market presence in the ARV market regarding the treatment of CMV disease.<sup>219</sup> Because HIV/AIDS clinics rarely screen people for CMV disease, the demand for treatment is small. Besides, current treatment options for CMV disease are predominantly unaffordable for the population of the developing world. Consequently, preventable blindness currently still occurs in people infected with HIV/AIDS in developing countries.<sup>220</sup> Apparently, licenses on valganciclovir have not been concluded with generic manufacturers before ViiV Healthcare joined the Pool.

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<sup>214</sup> Cf. Medicines Patent Pool (2013d).

<sup>215</sup> License Agreement between Roche and the Medicines Patent Pool. Hereafter MPP-Roche License Agreement.

<sup>216</sup> Cf. Medicines Patent Pool (2013d).

<sup>217</sup> Research period 2009-2013. Cf. Ford, Nathan et al., *Clinical Infectious Diseases*, 2013, No. 1, p. 1.

<sup>218</sup> Cf. FDA (2004).

<sup>219</sup> Cf. *The Pharmaletter* (2013).

<sup>220</sup> Cf. Medicines Patent Pool (2013d).

## 5.2 Field of use

### The MPP-NIH License

Generally, to determine a field of use gives the licensor more freedom to deal with the patents with further parties in other fields of use. This way, licensors are able to make greater profits.<sup>221</sup> The MPP-NIH License encompasses the right to make, have made and use the licensed products and processes in the licensed field of use<sup>222</sup>, which consists of the “treatment and prevention of medical conditions affecting humans”<sup>223</sup>. Thus, the field of application is drawn very broadly and does not solely include the treatment of HIV/AIDS.

### The MPP-Gilead License

According to the license agreement, the field of use for the licensed products encompasses treatment and prophylaxis of HIV infection. In addition to that, the field of use of products, which contain TDF as a sole ingredient, also includes treatment and prophylaxis of Hepatitis B infection.<sup>224</sup> Supplementary to treatment and prophylaxis of HIV infection, EVG and COBI may be applied to treat any disease, for which their use is consistent “with the labels approved by the FDA or applicable foreign regulatory authority”<sup>225</sup> as well. Thus, sublicensees have the right to use the licensed medicines for several purposes besides the treatment of HIV/AIDS. This implies that patients in developing countries, who are afflicted by other diseases, may also benefit from the sublicenses. Moreover, since the permission to manufacture the licensed ARVs for the treatment of other diseases might lead to higher amounts of generics produced, the realization of economies of scale may be facilitated. Economies of scale result in lower sale prices of the generic ARVs, which is an additional positive impact of the large field of use.<sup>226</sup> However, read together with the definition of “patents” in the sublicense agreements, which states that patents also include patent applications<sup>227</sup>, this means that if Gilead had filed a pending application for a new use patent, sublicensees would also have to pay royalties to the company for drugs in that regard.<sup>228</sup>

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<sup>221</sup> Cf. WHO/WIPO/WTO (2012), p. 135.

<sup>222</sup> Cf. Art. 3.1 S. 1 of the MPP-NIH License Agreement.

<sup>223</sup> Appendix B II (a) of the MPP-NIH License Agreement.

<sup>224</sup> Cf. Art. 1 “Field” (a) of the MPP-Gilead-Aurobindo Sublicense Agreement.

<sup>225</sup> Art. 1 “Field” (b) of the MPP-Gilead-Aurobindo Sublicense Agreement.

<sup>226</sup> Cf. Cox, Krista L., *Hastings Science & Technology Law Journal*, 2012, No. 2, p. 306.

<sup>227</sup> Cf. Art. 1 “Patent” of the MPP-Gilead-Aurobindo Sublicense Agreement.

<sup>228</sup> Cf. ITPC/I-MAK (2011b), p. 5.

### **The MPP-ViiV Healthcare License**

According to the MPP-ViiV Healthcare License Agreement, raw materials for the use in the manufacture of ABC and ABC product may only be produced, used, sold, supplied, imported or exported in the territory for “use in antiretroviral therapy for HIV/AIDS”<sup>229</sup>. Thus, the field of use solely encompasses treatment of HIV/AIDS, which consequently not allows sublicensees to benefit from economies of scale resulting from more encompassing opportunities to apply the licensed product.

### **The MPP-Roche License**

Valganciclovir is directly supplied to HIV treatment organizations by Roche in effort to enhance “screening, diagnosis and treatment of HIV-related CMV in developing countries”<sup>230</sup>. Therefore, the field of use of valganciclovir just consists of the treatment of CMV disease in people infected with HIV/AIDS in the developing world.

In total, the fields of use the licenses allow for vary between the treatment of medical conditions in general, the treatment of certain specified diseases and the sole treatment of HIV/AIDS. Taking into account that the MPP predominantly strives to increase access to medicines for people infected with HIV/AIDS, the broad scope has to be assessed positively, since this additionally provides the opportunity for people infected with other diseases to benefit from the MPP’s license agreements.

## **5.3 Geographic coverage**

### **The MPP-NIH License**

The territory for the darunavir patents licensed to the MPP by the NIH encompasses 24 high-income countries, which are Australia, Austria, Belgium, Canada, Cyprus, Denmark, Finland, France, Germany, Great Britain, Greece, Ireland, Italy, Liechtenstein, Luxembourg, Japan, Monaco, Netherlands, Portugal, Spain, Sweden, Switzerland and the United States.<sup>231</sup> In these countries patents had partly already been granted (USA and Australia) or otherwise had been pending (the other 22 countries), when the license was agreed.<sup>232</sup> The states, which are allowed to be supplied, include all low- and middle-income countries as defined by the World

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<sup>229</sup> Art. 2 of the MPP-ViiV Healthcare-Aurobindo Sublicense Agreement.

<sup>230</sup> Fourth Recital of the MPP-Roche License Agreement.

<sup>231</sup> Cf. Appendix B I of the MPP-NIH License Agreement.

<sup>232</sup> Cf. Appendix A – Patents or Patent Applications of the MPP-NIH License Agreement; Appendix B – Licensed Products, Processes, Territory, Field of Use and Termination of the MPP-NIH License Agreement and Medicines Patent Pool (2010a), p. 1.

Bank.<sup>233</sup> Low-income countries have a 2012 gross national income (GNI) per capita of US-\$ 1035 or less, whereas middle-income countries exhibit a GNI per capita of US-\$ 1036-\$12615.<sup>234</sup> Currently, there are 36 low-income countries<sup>235</sup> and 103 middle-income countries, which are subdivided into 48 low-middle-income<sup>236</sup> and 55 upper-middle-income countries<sup>237</sup>. Hence, in total, theoretically 29.2 million people infected with HIV/AIDS are able to benefit from the MPP-NIH License. Regarding the 34 million people infected with HIV/AIDS worldwide, 85.9% of people are covered by the license.<sup>238</sup>

### **The MPP-Gilead License**

The products covered by the MPP-Gilead License exhibit different territories. The TDF license covers 112 countries<sup>239</sup>, which is the largest geographical scope of all the products the MPP obtained from Gilead. In contrast to the voluntary bilateral 2006 TDF licenses of Gilead, which covered 95 low- and middle-income countries, the MPP-Gilead License Agreement

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<sup>233</sup> Cf. Art. 3.1 of the MPP-NIH License Agreement.

<sup>234</sup> Cf. World Bank (2013b).

<sup>235</sup> These are Afghanistan, Bangladesh, Benin, Burkina Faso, Burundi, Cambodia, Central African Republic, Chad, Comoros, Democratic Republic Congo, Eritrea, Ethiopia, Gambia, Guinea, Guinea-Bissau, Haiti, Kenya, Democratic Republic Korea, Kyrgyz Republic, Liberia, Madagascar, Malawi, Mali, Mozambique, Myanmar, Nepal, Niger, Rwanda, Sierra Leone, Somalia, South Sudan, Tajikistan, Tanzania, Togo, Uganda and Zimbabwe. Cf. World Bank (2013a).

<sup>236</sup> These are 48 Countries: Armenia, Bhutan, Bolivia, Cameroon, Cape Verde, Congo Rep., Côte d'Ivoire, Djibouti, Egypt, El Salvador, Georgia, Ghana, Guatemala, Guyana, Honduras, Indonesia, India, Kiribati, Kosovo, Lao PDR, Lesotho, Mauritania, Micronesia, Moldova, Mongolia, Morocco, Nicaragua, Nigeria, Pakistan, Papua New Guinea, Paraguay, Samoa, São Tomé and Príncipe, Senegal, Solomon Islands, Sri Lanka, Sudan, Swaziland, Syrian Arab Republic, Timor-Leste, Ukraine, Uzbekistan, Vanuatu, Vietnam, West Bank and Gaza as well as Yemen. Cf. World Bank (2013a).

<sup>237</sup> These are Angola, Albania, Algeria, American Samoa, Argentina, Azerbaijan, Belarus, Belize, Bosnia and Herzegovina, Botswana, Brazil, Bulgaria, China, Colombia, Costa Rica, Cuba, Dominica, Dominican Republic, Ecuador, Fiji, Gabon, Grenada, Hungary, Iran, Iraq, Jamaica, Jordan, Kazakhstan, Lebanon, Libya, Macedonia, Malaysia, Maldives, Marshall Islands, Mauritius, Mexico, Montenegro, Namibia, Palau, Panama, Peru, Romania, Serbia, Seychelles, South Africa, St. Lucia, St. Vincent and the Grenadines, Suriname, Thailand, Tonga, Tunisia, Turkey, Turkmenistan, Tuvalu and Venezuela. Cf. World Bank (2013a).

<sup>238</sup> Own calculations based on WHO (2013c).

<sup>239</sup> These are 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, Republic Congo, Democratic Republic Congo, 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, People's Democratic Republic Lao, Lesotho, Liberia, Madagascar, Malawi, Maldives, Mali, Mauritania, Mauritius, Republic of Moldova, Mongolia, Montserrat, Mozambique, Myanmar, Namibia, Nauru, Nepal, Nicaragua, Niger, Nigeria, Pakistan, Palau, Papua New Guinea, Rwanda, Saint Kitts and Nevis, Saint Lucia, Saint Vincent & the Grenadines, Samoa, São Tomé and Príncipe, Senegal, Seychelles, Sierra Leone, Solomon Islands, Somalia, South Africa, South Sudan, Sri Lanka, Sudan, Surinam, Swaziland, Syrian Arab Republic, Tajikistan, United Republic of Tanzania, Thailand, Timor-Leste, Togo, Tonga, Trinidad and Tobago, Turkmenistan, Turks and Caicos, Tuvalu, Uganda, Uzbekistan, Vanuatu, Vietnam, Yemen, Zambia and Zimbabwe. Cf. Appendix 1 – Countries in the TDF Territory of the MPP-Gilead License Agreement.

expands the geographic scope by 17 additional countries.<sup>240</sup> Of the added countries, seven are low-middle income states, three are upper middle-income states, two are high-income countries and four are unclassified.<sup>241</sup> In comparison to the 2011 extension of the bilateral Gilead license to the four generic manufacturers<sup>242</sup>, the MPP-Gilead License only exhibits two more TDF territories.

The TDF license includes all low-income countries as well as 96% of people living in lower middle-income countries and 67% of those living in upper middle-income countries.<sup>243</sup> Together, the TDF license covers 87% of people living with HIV/AIDS in low- and middle-income countries. In comparison to the 2006 Gilead license on TDF, coverage has only been widened about less than 2%<sup>244</sup>, which corresponds to 221200 persons infected with HIV/AIDS.<sup>245</sup> In total, the MPP-Gilead TDF license includes 84% of people living with HIV/AIDS worldwide, which refers to more than 26 million persons.<sup>246</sup>

However, in the majority of developing countries, Gilead had not filed patent applications on TDF. When Gilead joined the Pool in 2011, there were no pending applications in 110 countries of the 112 countries covered by the TDF license. Solely in India and Indonesia, patents had been filed.<sup>247</sup> Additionally, one process patent existed in India.<sup>248</sup> The MPP-Gilead License on TDF excludes 45 low- and middle-income countries such as Argentina, Brazil, Chile, Colombia, Malaysia, Peru, Philippines, Ukraine and Uruguay, where no patent on TDF existed, China and Mexico, where patents had been filed respectively granted, and 34 countries, where the patent status was uncertain.<sup>249</sup> The middle-income countries excluded from the license have to spend about 40% more for TDF given limited generic accessibility and

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<sup>240</sup> The additional countries included in the TDF license are Anguilla, Armenia, Aruba, British Virgin Islands, Ecuador, El Salvador, Fiji, Georgia, Kazakhstan, Montserrat, Nauru, Palau, South Sudan, Sri Lanka, Tonga, Turkmenistan, and Turks & Caicos. It should be noted that this count includes South Sudan, a newly recognized country. Cf. Cox, Krista L., *Hastings Science & Technology Law Journal*, 2012, No. 2, p. 307.

<sup>241</sup> Cf. World Bank (2013a).

<sup>242</sup> Cf. Gilead (2011).

<sup>243</sup> Although the vast majority of countries in the MPP-Gilead License are low- or middle-income countries, five high-income countries are also included in the TDF license: Aruba, Bahamas, Equatorial Guinea, Trinidad & Tobago as well as Turks & Caicos.

<sup>244</sup> ITPC/I-MAK state that the 16 additional countries in comparison to the 2006 bilateral license lead to an increase in coverage of 1%. However, if one also includes South Sudan, coverage is more than twice that big (see below). Cf. ITPC/I-MAK (2011a), p. 2 and International HIV/AIDS Alliance (2011).

<sup>245</sup> According to Cox, the number of 93.200 refers to the total number of persons, which could benefit from the new license, no matter whether they already are on ARV treatment or not. The new countries covered by the MPP-Gilead License with a significant number of HIV-positive people are Ecuador with 37.000 infected persons, El Salvador with 34.000 and Kazakhstan with 13.000. In addition to that, it needs to be considered that in South Sudan, 128.000 people infected with HIV/AIDS live. Cf. Cox, Krista L., *Hastings Science & Technology Law Journal*, 2012, No. 2, p. 307 and International HIV/AIDS Alliance (2011).

<sup>246</sup> Cf. Love, James (2011).

<sup>247</sup> Cf. Baker, Brook (2011).

<sup>248</sup> Cf. Medicines Patent Pool (2013i).

<sup>249</sup> Cf. Baker, Brook (2011).

tiered pricing. By receiving access to generic TDF, they could save at least US-\$ 3 million per year.<sup>250</sup> Nine countries, which are included in the geographic scope of the TDF license, are not part of the COBI, EVG and the Quad licenses.<sup>251</sup> This can be referred to the four semi-exclusive licenses Gilead has granted to the four generic manufacturers outside of the MPP in 2011<sup>252</sup>, whereby these nine countries are divided into clearly differentiated sales territories among the manufacturers, offering them protection from competition and more freedom regarding price setting.

The Gilead license on FTC includes the same geographic scope as the TDF license, meaning 112 countries<sup>253</sup> or 87% of people living with HIV/AIDS in low- and middle-income countries. When the license was concluded, patents on FTC already had already been granted in 52 low- and middle-income countries<sup>254</sup> as well as with the African Regional Industrial Property Organization and the African Unions Territory.<sup>255</sup> The MPP-Gilead License on FTC excludes, just as the TDF license, 81 low- and middle-income countries.<sup>256</sup>

The MPP-Gilead License on COBI covers a marginal smaller geographic scope of 103 countries.<sup>257</sup> Just like the TDF/FTC license, the COBI license encompasses all low-income coun-

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<sup>250</sup> Cf. ITPC/I-MAK (2011a), p. 6.

<sup>251</sup> These countries are Botswana, Ecuador, El Salvador, Indonesia, Kazakhstan, Namibia, Sri Lanka, Thailand and Turkmenistan.

<sup>252</sup> Cf. Médecins Sans Frontières (2011), p. 8.

<sup>253</sup> These are 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, Republic Congo, Democratic Republic Congo, 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, People's Democratic Republic Lao, Lesotho, Liberia, Madagascar, Malawi, Maldives, Mali, Mauritania, Mauritius, Republic of Moldova, Mongolia, Montserrat, Mozambique, Myanmar, Namibia, Nauru, Nepal, Nicaragua, Niger, Nigeria, Pakistan, Palau, Papua New Guinea, Rwanda, Saint Kitts and Nevis, Saint Lucia, Saint Vincent & the Grenadines, Samoa, São Tomé and Príncipe, Senegal, Seychelles, Sierra Leone, Solomon Islands, Somalia, South Africa, South Sudan, Sri Lanka, Sudan, Surinam, Swaziland, Syrian Arab Republic, Tajikistan, United Republic of Tanzania, Thailand, Timor-Leste, Togo, Tonga, Trinidad and Tobago, Turkmenistan, Turks and Caicos, Tuvalu, Uganda, Uzbekistan, Vanuatu, Vietnam, Yemen, Zambia and Zimbabwe. Cf. Appendix 1 – Countries in the TDF Territory of the MPP-Gilead License Agreement.

<sup>254</sup> Countries with patents on FTC are Armenia, Benin, Botswana, Burkina Faso, Burundi, Cameroon, Central African Republic, Chad, Republic Congo, Democratic Republic Congo, Côte d'Ivoire, Dominican Republic, Gabon, Gambia, Georgia, Ghana, Guatemala, Guinea, Guinea-Bissau, Honduras, India, Indonesia, Jamaica, Kazakhstan, Kenya, Kyrgyzstan, Lesotho, Madagascar, Malawi, Mali, Mauritania, Republic of Moldova, Nicaragua, Niger, Nigeria, Pakistan, Paraguay, Rwanda, Senegal, South Africa, Sri Lanka, Sudan, Swaziland, Tajikistan, Thailand, Turkmenistan, Togo, Uzbekistan, Zambia and Zimbabwe.

<sup>255</sup> Cf. Appendix 3 – Emtricitabine Patents of the MPP-Gilead License Agreement.

<sup>256</sup> Cf. Baker, Brook (2011).

<sup>257</sup> These are Afghanistan, Angola, Anguilla, Antigua and Barbuda, Armenia, Aruba, Bahamas, Bangladesh, Barbados, Belize, Benin, Bhutan, Bolivia, British Virgin Islands, Burkina Faso, Burundi, Cambodia, Cameroon, Cape Verde, Central African Republic, Chad, Comoros, Republic Congo, Democratic Republic Congo, Côte d'Ivoire, Cuba, Djibouti, Dominica, Dominican Republic, Equatorial Guinea, Eritrea, Ethiopia, Republic of the Fiji Islands, Gabon, Gambia, Georgia, Ghana, Grenada, Guatemala, Guinea, Guinea-Bissau, Guyana, Haiti, Honduras, India, Jamaica, Kenya, Kiribati, Kyrgyzstan, People's Democratic Republic Lao, Lesotho, Liberia, Madagascar, Malawi, Maldives, Mali, Mauritania, Mauritius, Republic of Moldova, Mongolia,

tries.<sup>258</sup> Moreover, 92.8% of people living with HIV/AIDS in lower middle-income countries and 56.4% living in upper middle-income countries are covered. All in all, 85% of people infected with HIV/AIDS living in low-and middle-income countries, respectively 80% of people infected with HIV/AIDS worldwide, which refers to 25 million people, are included in the territory.<sup>259</sup>

In contrast to TDF, the number of pending patent applications for COBI was high when Gilead joined the MPP. The future prospect was that in many countries, including India, patents would probably be granted, because the drug contained a new chemical entity<sup>260</sup> and thus fulfilled patentability criteria. COBI patents had already been granted in 16 of the African Unions Territories and were pending in Bolivia, India, Pakistan, South Africa and Vietnam as well as with 15 countries of the African Regional Industrial Property Organization and five of the Eurasian Patent Organization.<sup>261</sup> However, consequently, there were no patents filed on COBI in 62 of the 104 licensed territories.<sup>262</sup> Moreover, in the 54 states, which are not part of the licensed territory, in Chile, Colombia, Malaysia, Peru, Philippines, Ukraine and Uruguay there were no patents pending, whereas in Argentina, Botswana, Brazil, China, Egypt, Mexico, Morocco, Namibia, Azerbaijan, Belarus, Kazakhstan and Russia, patents had been filed.<sup>263</sup> The MPP-Gilead EVG/Quad license includes 100 countries.<sup>264</sup> Like the other licenses of Gilead, the EVG/Quad License includes all low-income countries.<sup>265</sup> In comparison to the geo-

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Montserrat, Mozambique, Myanmar, Nauru, Nepal, Nicaragua, Niger, Nigeria, Pakistan, Palau, Papua New Guinea, Rwanda, Saint Kitts and Nevis, Saint Lucia, Saint Vincent & the Grenadines, Samoa, São Tomé and Príncipe, Senegal, Seychelles, Sierra Leone, Solomon Islands, Somalia, South Africa, South Sudan, Sudan, Suriname, Swaziland, Syrian Arab Republic, Tajikistan, United Republic of Tanzania, Timor-Leste, Togo, Tonga, Trinidad and Tobago, Turks and Caicos, Tuvalu, Uganda, Uzbekistan, Vanuatu, Vietnam, Yemen, Zambia and Zimbabwe. Cf. Appendix 4 – Countries in the COBI Territory of the MPP-Gilead License Agreement.

<sup>258</sup> Cf. Cox, Krista L., *Hastings Science & Technology Law Journal*, 2012, No. 2, p. 307.

<sup>259</sup> Cf. Love, James (2011).

<sup>260</sup> Cf. Baker, Brook (2011).

<sup>261</sup> Cf. Appendix 2 – COBI Patents of the MPP-Gilead License Agreement.

<sup>262</sup> South Sudan added to the calculations of Baker, Brook (2011).

<sup>263</sup> Cf. Baker, Brook (2011).

<sup>264</sup> The geographic scope encompasses Afghanistan, Angola, Anguilla, Antigua and Barbuda, Armenia, Bahamas, Bangladesh, Barbados, Belize, Benin, Bhutan, Bolivia, British Virgin Islands, Burkina Faso, Burundi, Cambodia, Cameroon, Cape Verde, Central African Republic, Chad, Comoros, Republic Congo, Democratic Republic Congo, Côte d'Ivoire, Cuba, Djibouti, Dominica, Equatorial Guinea, Eritrea, Ethiopia, Republic of the Fiji Islands, Gabon, Gambia, Georgia, Ghana, Grenada, Guatemala, Guinea, Guinea-Bissau, Guyana, Haiti, Honduras, India, Jamaica, Kenya, Kiribati, Kyrgyzstan, People's Democratic Republic Lao, Lesotho, Liberia, Madagascar, Malawi, Maldives, Mali, Mauritania, Mauritius, Republic of Moldova, Mongolia, Mozambique, Myanmar, Nauru, Nepal, Nicaragua, Niger, Nigeria, Pakistan, Palau, Papua New Guinea, Rwanda, Saint Kitts and Nevis, Saint Lucia, Saint Vincent & the Grenadines, Samoa, São Tomé and Príncipe, Senegal, Seychelles, Sierra Leone, Solomon Islands, Somalia, South Africa, South Sudan, Sudan, Suriname, Swaziland, Syrian Arab Republic, Tajikistan, United Republic of Tanzania, Timor-Leste, Togo, Tonga, Trinidad and Tobago, Turks and Caicos, Tuvalu, Uganda, Uzbekistan, Vanuatu, Vietnam, Yemen, Zambia and Zimbabwe. Cf. Appendix 5 – Countries in the EVG-Quad Territory of the MPP-Gilead License Agreement.

<sup>265</sup> Cf. Cox, Krista L., *Hastings Science & Technology Law Journal*, 2012, No. 2, p. 308.

graphic coverage of COBI, the EVG/Quad license excludes three countries: Aruba, a high-income country, the Dominican Republic, an upper-middle income country, and Montserrat, a country not classified.<sup>266</sup> In consequence of their exclusion of the EVG/Quad license, instead of 56.4% of people infected with HIV/AIDS living in upper middle-income countries a slightly smaller percentage of 55% of people in upper middle-income countries is covered by the license.<sup>267</sup> Overall, the EVG/Quad license includes 85% of people infected with HIV/AIDS, who live in low- and middle-income countries. On a worldwide view, 80% of people infected with HIV/AIDS are part of the territory. This means that 25 million people may benefit from the license.<sup>268</sup>

Before the MPP-Gilead License Agreement, patents on EVG had already been granted in India, Nigeria, South Africa and 16 countries of the African Union Territories, whereas some were pending in Bolivia, India, South Africa and Vietnam as well as with several countries of the African Regional Industrial Property Organization and five of the Eurasian Patent Organization.<sup>269</sup> Hence, of the 100 countries covered by the EVG/Quad license, in 59 countries there were no pending patents on the drugs. Of the 57 countries excluded from the licenses, no patent exists in Uruguay, whereas patents for EVG and the Quad were filed or granted in Azerbaijan, Argentina, Azerbaijan, Belarus, Brazil, Botswana, Chile, China, Colombia, Kazakhstan, Malaysia, Mexico, Namibia, Philippines, Peru, Russia, Thailand and Ukraine.<sup>270</sup> Since the Quad is a combination product consisting of all the four ARVs mentioned before, the filing of separate patents is not necessary to protect the drug.

In conclusion, the MPP-Gilead License on TDF, COBI, EVG, the Quad and FTC includes all low-income countries and covers the majority of people infected with HIV/AIDS living in low- and middle-income countries. Since in regard to each of the ARVs at least 25 million people may directly benefit from being provided with access to generics, the MPP-Gilead License exhibits the largest geographic coverage of any voluntary license on adult HIV/AIDS treatment.<sup>271</sup> Nevertheless, about half a million people living in developing countries are excluded from the licensed territories.<sup>272</sup> This exclusion of especially upper-middle income

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<sup>266</sup> Cf. Appendix 4 – Countries in the COBI Territory of the MPP-Gilead License Agreement and Appendix 5 – Countries in the EVG-Quad Territory of the MPP-Gilead License Agreement.

<sup>267</sup> Cf. Cox, Krista L., *Hastings Science & Technology Law Journal*, 2012, No. 2, p. 308.

<sup>268</sup> Cf. Love, James (2011).

<sup>269</sup> Cf. Appendix 2 – EVG Patents of the MPP-Gilead License Agreement.

<sup>270</sup> Cf. Baker, Brook (2011).

<sup>271</sup> Cf. Cox, Krista L., *Hastings Science & Technology Law Journal*, 2012, No. 2, p. 318.

<sup>272</sup> Cf. *Ibid.*, p. 309.

countries has been criticized often.<sup>273</sup> Even the MPP itself has admitted that the geographical scope is “a key area where these licenses could be improved”<sup>274</sup>.

### **The MPP-ViiV Healthcare License**

According to the license agreement between the MPP and ViiV Healthcare, pediatric ABC is allowed to be sold in 118 low- and middle-income-countries.<sup>275</sup> Hence, the ABC license includes more countries than any other license on an ARV the MPP received. In contrast to the MPP-Gilead License on TDF/FTC, which provided the largest geographic scope of the Gilead licenses, Algeria, Argentina, Azerbaijan, Chile, Colombia, Costa Rica, Egypt, Federated States of Micronesia, Iraq, Iran, Korea DPR, Kosovo, Lebanon, Libya, Marshall Islands, Malaysia, Morocco, Panama, Paraguay, Philippines, Tunisia as well as West Bank and Gaza are additionally covered by the MPP-ViiV Healthcare License.<sup>276</sup> Thus, even some Latin American countries, which did not benefit from a MPP License before, are included in the agreement. However, Anguilla, Antigua and Barbuda, Aruba, Bahamas, Barbados, British Virgin Islands, Burundi, Dominica, Kazakhstan, Kyrgyzstan, Montserrat, Saint Kitts and Nevis, Saint Lucia, Saint Vincent and the Grenadines, Surinam, Timor-Leste, Trinidad and Tobago as well as Turks and Caicos, which are part of the TDF/FTC territory, are excluded from the ABC territory.<sup>277</sup> As 98.7%<sup>278</sup>, respectively 3.36 million of all HIV-infected children live in the covered territory, the MPP-ViiV Healthcare License Agreement includes the vast majority of patients.

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<sup>273</sup> Cf. for instance Médecins Sans Frontières (2011), p. 8 and Thai Network of People living with HIV/AIDS (2011).

<sup>274</sup> Cf. Medicines Patent Pool (2011d), p. 4ff.

<sup>275</sup> The approved territories are Afghanistan, Algeria, Angola, Argentina, Armenia, Azerbaijan, Bangladesh, Belize, Benin, Bhutan, Bolivia, Botswana, Burkina Faso, Burundi, Cambodia, Cameroon, Cape Verde, Central African Republic, Chad, Chile, Colombia, Comoros, Congo, Democratic Republic Of The Congo, Costa Rica, Côte d'Ivoire, Cuba, Djibouti, Dominican Republic, E. Timor, Ecuador, Egypt, El Salvador, Equatorial Guinea, Eritrea, Ethiopia, Fiji, Gabon, Gambia, Georgia, Ghana, Guatemala, Guinea, Guinea-Bissau, Guyana, Haiti, Honduras, India, Indonesia, Iran, Iraq, Jamaica, Kenya, Kiribati, Kosovo, Lao, People's Democratic Republic, Lebanon, Lesotho, Liberia, Libya, Madagascar, Malawi, Malaysia, Maldives, Mali, Marshall Islands, Mauritania, Mauritius, Micronesia, Moldova, Republic of Mongolia, Morocco, Mozambique, Myanmar, Namibia, Nauru, Nepal, Nicaragua, Niger, Nigeria, Pakistan, Palau, Papua New Guinea, Panama, Paraguay, Philippines, Republic Kyrgyz, Democratic People's Republic of Korea, Rwanda, Samoa, São Tomé and Príncipe, Sénégal, Seychelles, Sierra Leone, Solomon Islands, Somalia, South Africa, South Sudan, Sri Lanka, Sudan, Swaziland, Syrian Arab Republic, Tajikistan, Tanzania, United Republic of Thailand, Togo, Tonga, Tunisia, Turkmenistan, Tuvalu, Uganda, Uzbekistan, Vanuatu, Vietnam, West Bank and Gaza, Yemen, Zambia and Zimbabwe. Cf. Appendix C of the MPP-ViiV Healthcare-Aurobindo Sublicense Agreement.

<sup>276</sup> Cf. Appendix 1 – Countries in the TDF Territory of the MPP-Gilead License Agreement and Appendix C of the MPP-ViiV Healthcare-Aurobindo Sublicense Agreement.

<sup>277</sup> Cf. Appendix 1 – Countries in the TDF Territory of the MPP-Gilead License Agreement and Appendix C of the MPP-ViiV Healthcare-Aurobindo Sublicense Agreement.

<sup>278</sup> Cf. BUKO Pharma-Kampagne, Pharma-Brief, 2013, No. 3, p. 6.

In most of the approved countries, one of the eight patents covered by the license on pediatric ABC existed.<sup>279</sup> Admittedly, since the MPP-ViiV Healthcare License Agreement does not include middle-income countries like Brazil, China, Mexico, Peru, Venezuela, Uruguay, Ukraine or Russia, the agreement still exhibits deficiencies regarding its geographical scope. By maintaining exclusivity in middle-income countries, 44200 or 1.3% of children infected with HIV/AIDS worldwide are precluded from the MPP-ViiV Healthcare License.<sup>280</sup> In comparison with the 2009 ViiV Healthcare licenses to generic manufacturers, which covered 69 countries<sup>281</sup>, geographic coverage has been significantly increased with the MPP-ViiV Healthcare License Agreement.

### **The MPP-Roche License**

The geographic scope of the MPP-Roche License Agreement on valganciclovir encompasses 138 developing countries.<sup>282</sup> Therefore, 27.7 million people living with HIV/AIDS could benefit from the license.<sup>283</sup> The MPP-Roche License differentiates in that respect from the licenses concluded by the MPP before that it also involves the European states Bosnia and Herzegovina, Latvia, Lithuania, Kosovo, Macedonia and Serbia as well as transitional countries like China. However, since CMV retinitis in high-income countries has decreased strongly during the past 15 years<sup>284</sup>, the inclusion of European countries, especially Latvia and Lithuania, where the prevalence rate of people infected with HIV/AIDS solely amounts 0.7%<sup>285</sup>, respectively 0.1%.<sup>286</sup>, in the territory might not have been necessary.

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<sup>279</sup> Cf. Appendix A of the MPP- ViiV Healthcare-Aurobindo Sublicense Agreement.

<sup>280</sup> Cf. Baker, Brook (2013).

<sup>281</sup> Cf. Médecins Sans Frontières (2013), p. 78.

<sup>282</sup> These are Afghanistan, Albania, Algeria, American Samoa, Angola, Antigua and Barbuda, Argentina, Armenia, Azerbaijan, Bangladesh, Belarus, Belize, Benin, Bhutan, Bolivia, Bosnia and Herzegovina, Botswana, Burkina Faso, Burundi, Cambodia, Cameroon, Cape Verde, Central African Republic, Chad, Chile, China, Comoros, Democratic Republic Congo, Republic Congo, Costa Rica, Cote d'Ivoire, Cuba, Djibouti, Dominica, Dominican Republic, Ecuador, Egypt, El Salvador, Equatorial Guinea, Eritrea, Ethiopia, Fiji, Gabon, The Gambia, Georgia, Ghana, Grenada, Guatemala, Guinea, Guinea-Bissau, Guyana, Haiti, Honduras, India, Indonesia, Iran, Iraq, Jamaica, Jordan, Kazakhstan, Kenya, Kiribati, Democratic Republic Korea, Kosovo, Kyrgyz Republic, Lao PDR, Latvia, Lebanon, Lesotho, Liberia, Libya, Lithuania, Macedonia, Madagascar, Malawi, Malaysia, Maldives, Mali, Marshall Islands, Mauritania, Mauritius, Federal States of Micronesia, Moldova, Mongolia, Montenegro, Morocco, Mozambique, Myanmar, Namibia, Nepal, Nicaragua, Niger, Nigeria, Pakistan, Palau, Panama, Papua New Guinea, Paraguay, Peru, Philippines, Rwanda, Samoa, Sao Tome and Principe, Senegal, Serbia, Seychelles, Sierra Leone, Solomon Islands, Somalia, South Africa, South Sudan, Sri Lanka, St. Lucia, St. Vincent and the Grenadines, Sudan, Suriname, Swaziland, Syrian Arab Republic, Tajikistan, Tanzania, Thailand, Timor-Leste, Togo, Tonga, Tunisia, Turkmenistan, Tuvalu, Uganda, Ukraine, Uzbekistan, Vanuatu, Venezuela, Vietnam, West Bank and Gaza, Republic of Yemen, Zambia and Zimbabwe. Cf. Exhibit B of the MPP-Roche License Agreement.

<sup>283</sup> Own calculations based on WHO (2013c).

<sup>284</sup> Cf. Ford, Nathan et al., *Clinical Infectious Diseases*, 2013, No. 1, p. 8.

<sup>285</sup> Cf. UNAIDS (2013a).

<sup>286</sup> Cf. UNAIDS (2013b).

With 14% of people infected with HIV/AIDS additionally infected with CMV, prevalence of CMV retinitis is highest in Asia. The Asian countries most affected with CMV retinitis are Myanmar with 25% of HIV/AIDS patients co-infected with CMV, Thailand with 24% of patients, China with 15% of patients and India with 7% of patients.<sup>287</sup> These states are all covered by the MPP-Roche License. In Latin America, prevalence of CMV disease amounts 12% and hence is also quite high.<sup>288</sup> Although several Latin American states are included in the licensed territory, the transitional countries Brazil and Mexico are not part of the license agreement. The lowest number of infections with CMV in people living with HIV/AIDS exists in Africa, where solely 2.2% of people living with HIV/AIDS are affected.<sup>289</sup> However, based on the number of CMV disease patients, the scope of the MPP-Roche License Agreement should incorporate more Asian and Latin American countries. To start discussing future expansions of the license agreement, the MPP has to demonstrate unmet needs of valganciclovir in states, which do not belong to the territory, and request Roche for negotiations.<sup>290</sup>

Altogether the number of countries included in the geographic scope of the license agreements falls between 100 and 139. One needs to be aware of the fact that, to maximize public health benefits and to ensure economies of scale in the production of generics, it is important that the licenses concluded by the MPP and patent holders cover a huge number of countries.<sup>291</sup> Otherwise, economies of scale cannot be realized. Therefore, a restriction of licenses to least-developed or low-income countries would not be reasonable. Since least developed countries do not need to introduce patents for pharmaceuticals until 2016<sup>292</sup>, it is even more important that developing countries, which already have to grant patents on ARVs and other medicines, are involved in the geographic scope of the licenses. Because upper-middle-income countries and transitional countries constitute profitable markets for pharmaceutical companies, they are predominantly not part of the licensed territories. A further reason for excluding such states from the licenses is that the American and the European pharmaceutical market do not grow anymore, whereas transitional economies' markets increase.<sup>293</sup> Through

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<sup>287</sup> Cf. Ford, Nathan et al., *Clinical Infectious Diseases*, 2013, No. 1, p. 3.

<sup>288</sup> Cf. *Ibid.*, p. 8.

<sup>289</sup> Cf. *Ibid.*, p. 3.

<sup>290</sup> Cf. Art. 2.4 of the MPP-Roche License Agreement.

<sup>291</sup> Cf. 't Hoen, Ellen et al., *Journal of the International AIDS Society*, 2011, No. 15, p. 8 and Gold, E. Richard et al. (2007), p. 4.

<sup>292</sup> Cf. Art. 7 of the Doha Declaration on the TRIPS Agreement and Public Health.

<sup>293</sup> Cf. Beyer, Peter (2013), p. 238.

enhancing sales in upper-middle-income and emerging countries pharmaceutical manufacturers aim to increase their profits.

## **5.4 Termination provisions of the license agreements**

### **The MPP-NIH License**

The MPP-NIH License Agreement expires with the last expiring patent, which contains a valid claim, on a country-by-country basis within the approved territories.<sup>294</sup> In case the licensee fails to comply with any material obligation and corrective action has not been taken during 90 days after the receipt of the default in written, the licensor is allowed to terminate the agreement as well.<sup>295</sup> The decision of the licensor can be appealed within 30 days. Thereinafter, the director of the NIH will make a final agency decision, which can be followed by an initiation of available administrative or judicial remedies by the licensee.<sup>296</sup>

### **The MPP-Gilead License**

The MPP-Gilead License Agreement terminates with the expiration or termination of all sublicense agreements, the expiration of the last expiring patent, which contains a valid claim covering the production, use, import, offer for sale or sale of API or products in such country within the territory, or with the date of expiration of the last expiring patent containing a valid claim covering the production, use, import, offer for sale or sale of API or products in India.<sup>297</sup> In case one party breaches the agreement and the deficiency is not corrected within 30 days after receiving written notice, the agreement also terminates.<sup>298</sup> The same applies if the MPP becomes insolvent, makes an assignment, which benefits the creditors, or has a petition in bankruptcy filed for or against it.<sup>299</sup> Moreover, Gilead has the right to terminate the license agreement if control of the MPP, for instance through a shift of ownership, changes. In contrast to that, the MPP always has the right to terminate the license agreement upon 30 days prior written notice to Gilead.<sup>300</sup>

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<sup>294</sup> Cf. Appendix B III of the MPP-NIH License Agreement.

<sup>295</sup> Cf. Art. 7.2 of the MPP-NIH License Agreement.

<sup>296</sup> Cf. Art. 7.6 of the MPP-NIH License Agreement.

<sup>297</sup> Cf. Art. 7.1 S. 1 of the MPP-Gilead License Agreement.

<sup>298</sup> Cf. Art. 7.2 of the MPP-Gilead License Agreement.

<sup>299</sup> Cf. Art. 7.5 of the MPP-Gilead License Agreement.

<sup>300</sup> Cf. Art. 7.4 of the MPP-Gilead License Agreement.

### **The MPP-ViiV Healthcare License**

Regarding the MPP-ViiV Healthcare License Agreement, ViiV Healthcare is allowed to immediately terminate the agreement in case the MPP fails to perform its obligations of the license agreement in accordance with the Prevention of Corruption – Third Party Guidelines by GSK.<sup>301</sup> Furthermore, if the MPP does not comply with the applicable laws and regulations of the territories, where the pool conducts business with ViiV Healthcare and, respectively or, grants sublicenses, ViiV Healthcare may also immediately terminate the license agreement on written notice.<sup>302</sup>

### **The MPP-Roche License**

The MPP-Roche License Agreement already determines an expiry date, which is July 1<sup>st</sup> 2018, but is renewable.<sup>303</sup> Nevertheless, in case a quality-assured generic of valganciclovir, which costs are equal or below, becomes available in one of the approved countries, Roche may terminate the license agreement regarding this country within 90 days.<sup>304</sup> In case a party breaches a provision of the license agreement and does not correct it within 30 days or in case a correction within 30 days is not possible, but the party does not begin with corrections within that period, the observant party is allowed to terminate the agreement within 30 days.<sup>305</sup> In addition to that, if one of the parties becomes bankrupt or insolvent, the other party has the right to immediately terminate the agreement.<sup>306</sup>

The termination provisions of the four license agreements coincide only partially. Whereas the MPP-NIH and the MPP-Gilead License determine among others, that the licenses will end with the last expiring patent, which contains a valid claim in such country within the territory, the MPP-Roche License yet mentions an expiry date, which lies only five years in future from the day the license agreement came into force. However, the MPP-ViiV Healthcare License quotes none of those, but rather refers to infringement of laws by the MPP, which even allows the company to immediately terminate the license agreement. With the right to terminate the license if correction has not taken place within 30, respectively 90 days, or has not been started within 30 days after the receipt of written notice, at least tolerance towards breaches of the

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<sup>301</sup> Cf. Art. 4.3 S. 1 of the MPP-ViiV Healthcare License Agreement.

<sup>302</sup> Cf. Art. 4.3 S. 1 of the MPP-ViiV Healthcare License Agreement.

<sup>303</sup> Cf. Art. 13.1 of the MPP-Roche License Agreement.

<sup>304</sup> Cf. Art. 13.2 of the MPP-Roche License Agreement.

<sup>305</sup> Cf. Art. 13.3 S. 1 of the MPP-Roche License Agreement.

<sup>306</sup> Cf. Art. 13.4 S. 1 of the MPP-Roche License Agreement.

agreements is similar among the licensors. Moreover, in case of bankruptcy or insolvency, the other party may terminate the agreement immediately or within 30 days.

## **6. Sublicensees of the patents licensed to the pool**

### **6.1 Sublicenses granted by the MPP and their licensing terms**

#### **Sublicensees of the NIH patents<sup>307</sup>**

Until today, there is no sublicensee of the darunavir patents licensed to the MPP by the NIH.<sup>308</sup> The reason for this is that the NIH is not the only patent holder regarding darunavir. To allow for the manufacture and sale of the ARV, the subsidiary patents of Tibotec/Johnson & Johnson, the other patent holder, have to be licensed to the MPP. As long as Tibotec does not join the Pool, the company may prevent the production and sale of darunavir.<sup>309</sup> Thus, currently a hold-out problem exists.<sup>310</sup>

However, sublicensees may use the licensed products for research, which involves human subjects and clinical trials in the United States. This research has to be in accordance with specific FDA regulatory provision protecting human subjects.<sup>311</sup> If research shall be conducted outside the United States, the NIH has to be notified at least 60 days in advance.<sup>312</sup>

#### **Sublicensees of the Gilead patents**

Regarding the Gilead license, the MPP has to identify potential generic manufacturers under the requirement that these manufacturers are located in India.<sup>313</sup> Today, a fifth of generic drugs worldwide and 70% of the drugs, which are supplied to developing countries through humanitarian agencies, are manufactured in India.<sup>314</sup> Regarding ARVs, India is the biggest supplier of generics to low- and middle- income countries as developing countries' markets are supplied with 89% of adult formulations produced in the country. In addition to that, even 91% of pediatric ARVs have been manufactured in India.<sup>315</sup> The leading role India plays in generic ARV production can among others be referred to the fact that India did not have to introduce patents for pharmaceuticals before 2005.<sup>316</sup> Furthermore, under Indian patent law,

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<sup>307</sup> For the sake of clarity, the analysis of the license agreements is subdivided according to the individual agreements.

<sup>308</sup> Cf. Medicines Patent Pool (2013c).

<sup>309</sup> Cf. Medicines Patent Pool (2010a), p. 1f.

<sup>310</sup> Cf. Lerner, Josh/Tirole, Jean (2008), p. 159.

<sup>311</sup> Cf. Art. 5.2 S. 1 of the MPP-NIH License Agreement.

<sup>312</sup> Cf. Art. 5.2 S. 2 of the MPP-NIH License Agreement.

<sup>313</sup> Cf. Art. 2.1 MPP-Gilead License Agreement.

<sup>314</sup> Cf. The Economic Times (2012).

<sup>315</sup> Cf. Waning, Brenda/Diedrichsen, Ellen/Moon, Suerie, Journal International AIDS Society, 2010, No. 9, p. 35.

<sup>316</sup> Cf. Art. 65.1 of the TRIPS Agreement.

several patent applications for alleged new substances have been refused due to their lack of increased efficacy, which denies them to be regarded as novel inventions<sup>317</sup> and enabled companies to build up high-quality manufacturing capacities.

However, the intense restriction of potential sublicensees by Gilead to Indian companies can probably not be referred to Indian market leadership in regard to generic ARV manufacture, but rather to the fact that Gilead had a weak patent claim on TDF in India. This patent claim was used to justify the collection of royalties on sales of TDF made in the 110 licensed countries, where TDF received no patent protection. Consequently, the limitation of Gilead sublicensees just to Indian generic manufacturers has been widely criticized.<sup>318</sup> Gilead justifies the restriction of manufacturers to Indian pharmaceutical companies with the fact that such companies generally dispose the necessary manufacturing requirements including EMA, FDA or WHO approval. Moreover, Gilead alleges that, since it already has established relations with Indian pharmaceutical companies via its prior bilateral license agreements, it is convinced of the Indian companies high-quality and cost-efficient manufacturing processes.<sup>319</sup> Nevertheless, according to Cox, Gilead has indicated a willingness to take modifications to the sublicense agreements, namely allowing for the manufacture of products in one particular country outside of India, into consideration.<sup>320</sup> Indeed, this would only be one additional state manufacturing ARVs, whereby problems of poor competition and little opportunities for domestic manufacturing capacity building would still exist.

Six sublicense agreements with Indian sublicensees have been signed, which is the biggest number of sublicensees for one of the MPP's licenses. In September 2011, the Indian manufacturer Aurobindo Pharma, an Indian pharmaceutical company generating most of its revenue through generic ARV production<sup>321</sup>, signed an Amended and Reinstated License Agreement with Gilead.<sup>322</sup> The reason for this was that the pharmaceutical company had concluded a voluntary license agreement on TDF with Gilead in 2006. The sublicenses of the Gilead license base either on the Form Sublicense Agreement or on the Amended and Reinstated License Agreement. Since these are identical regarding their content, the following detailed examination of the Aurobindo sublicense is representative for the terms of the other sublicense agreements.

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<sup>317</sup> Cf. I-MAK (2007).

<sup>318</sup> Cf. Baker, Brook (2011).

<sup>319</sup> Cf. Ibid.

<sup>320</sup> Cf. Cox, Krista L., *Hastings Science & Technology Law Journal*, 2012, No. 2, p. 310.

<sup>321</sup> Cf. IHS (2011).

<sup>322</sup> Cf. Title of the Amended and Restated License Agreement among Gilead Sciences, the Medicines Patent Pool and Aurobindo Pharma. Hereafter MPP-Gilead-Aurobindo Sublicense Agreement.

Aurobindo concluded the first royalty-free, non-exclusive, non-sublicensable, non-transferable API license to make, use, offer for sale and sell API in the field and in India to licensed product suppliers or for internal use.<sup>323</sup> The royalty-bearing, non-exclusive, non-sublicensable, non-transferable product license includes the right to make, use, sell, have sold, offer for sale, export from India and import TDF and combination products, EVG and combination products and the Quad as well as COBI and combination products in the field and in their respective territories.<sup>324</sup> In addition to that, the sublicense also includes FTC, for which Gilead secures not to bring any claim or proceeding for making, using, selling, having sold and export in the territory.<sup>325</sup> The sublicenses also create a one-time technology transfer of know-how on the products, without any obligations of additional royalties.<sup>326</sup>

However, the patent status of the mentioned products differed. Patent applications for COBI and EVG/Quad, which contained a new chemical entity, were granted, respectively pending in India, and the probability of further patents issuance was high.<sup>327</sup> FTC was also patent protected by Gilead in India.<sup>328</sup> In contrast to that, although pending patent applications on TDF existed in the country, claims were weak. Several patent applications for TDF had already been refused in India due to the country's strict patentability criteria.<sup>329</sup> Because Indian manufacturers were able to produce TDF-based medicines without violating the single Indian process patent Gilead has been granted<sup>330</sup>, the necessity to pay royalties on sales in 110 countries was hardly given for sublicensees. Therefore, one day after signing the sublicense agreement, Aurobindo used its right to terminate the sublicense on an API basis.<sup>331</sup> While the rest of the sublicense remained standing, Aurobindo unbundled the Gilead license from TDF.

Opting out of the TDF license meant that TDF-based drugs could still be sold in 111 countries of the licensed territory, because the only country not longer supplyable would be Indonesia in case TDF patents would be granted there in future<sup>332</sup>, which later really took place.<sup>333</sup> Not licensing TDF does not inhibit the sublicensees to co-formulate TDF with other APIs like COBI and EVG licensed by Gilead at the minimum in the COBI and EVG, respectively the Quad territory. Furthermore, the Indian sublicensees could still be chosen as suppliers under a

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<sup>323</sup> Cf. Art. 2.1 S. 1 of the MPP-Gilead-Aurobindo Sublicense Agreement.

<sup>324</sup> Cf. Art. 2.2 of the MPP-Gilead-Aurobindo Sublicense Agreement.

<sup>325</sup> Cf. Art. 7.5 of the MPP-Gilead-Aurobindo Sublicense Agreement.

<sup>326</sup> Cf. Art. 5.4 of the MPP-Gilead-Aurobindo Sublicense Agreement.

<sup>327</sup> Cf. Baker, Brook (2011).

<sup>328</sup> Cf. Appendix 3 – Emtricitabine Patents of the MPP-Gilead License Agreement.

<sup>329</sup> Cf. UNDP (2010), p. 27.

<sup>330</sup> Cf. Baker, Brook (2011).

<sup>331</sup> Cf. Aurobindo (2011).

<sup>332</sup> Cf. Baker, Brook (2011).

<sup>333</sup> Cf. Medicines Patent Pool (2013g).

compulsory license in states, where TDF is patented.<sup>334</sup> This also includes supply under a compulsory import license to Indonesia.

However, since except TDF and FTC the FDA had not approved the other licensed ARVs yet, the generic manufacturers had to secure that they will not administer or sell EVG, the Quad or COBI until Gilead has received the outstanding approval.<sup>335</sup> To further secure quality of produced ARVs, the sublicense agreements oblige the generic manufacturers to produce API and products in consistency with the Indian manufacturing standards and with either the WHO, EMA or FDA standards as well as with national, regional or local standards on a country-by-country basis.<sup>336</sup> Since Indian generic manufacturers generally dispose WHO prequalification or at least have the capacity for approval, this quality requirement demanded by Gilead should not render to be a restriction.<sup>337</sup> Regarding API supply, sublicensees are only allowed to use licensed API, meaning API from Gilead suppliers or licensed API suppliers.<sup>338</sup> Consequently, the restriction on API supply prohibits sublicensees to buy API from cheaper or easier to access suppliers. However, Gilead secures to reasonably assist the sublicensees with being supplied, but limits the supply to the precondition that Gilead's own needs are sufficiently met. In case Gilead's supply is negatively affected by the supply of the sublicensees, the licensor may terminate the agreement.<sup>339</sup> Another influence Gilead takes on the manufacturing process of the sublicensees becomes visible with the provision that sublicensees are solely allowed to sell API to licensed product suppliers in India. Those have been approved by Gilead before.<sup>340</sup> In addition to that, after a notification, Gilead has the right to send an independent public accountant for an audit to the sublicensees. In case a difference of more than 5% of the amount of royalties, which are due, appears, the sublicensee has to take over the costs of the audit as well as to pay the lacking amount of money to Gilead.<sup>341</sup>

To strengthen the difference between Gilead and the sublicensees, the sublicensees do neither have the right to use a Gilead trademark, trade name, logo or service mark, nor the right to use a word, logo or expression which merely resembles any mark of Gilead.<sup>342</sup> Instead of this, the generics sold by the sublicensees shall have a "different trade dress"<sup>343</sup> of which an example has to be provided to Gilead before usage on the market. In case Gilead disagrees with a

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<sup>334</sup> Cf. Baker, Brook (2011).

<sup>335</sup> Art. 2.4 (b) (ii) of the MPP-Gilead-Aurobindo Sublicense Agreement.

<sup>336</sup> Cf. Art. 6.2 (a) S. 1 of the MPP-Gilead-Aurobindo Sublicense Agreement.

<sup>337</sup> Cf. Médecins Sans Frontières (2011), p. 10f.

<sup>338</sup> Cf. Art. 3.1 of the MPP-Gilead-Aurobindo Sublicense Agreement.

<sup>339</sup> Cf. Art. 3.2 and 3.3 of the MPP-Gilead-Aurobindo Sublicense Agreement.

<sup>340</sup> Cf. Art. 2.4 (a) of the MPP-Gilead-Aurobindo Sublicense Agreement.

<sup>341</sup> Cf. Art. 4.6 of the MPP-Gilead-Aurobindo Sublicense Agreement.

<sup>342</sup> Cf. Art. 2.5 (b) of the MPP-Gilead-Aurobindo Sublicense Agreement.

<sup>343</sup> 5.3 (a) of the MPP-Gilead-Aurobindo Sublicense Agreement.

product or its packing, it may though not prohibit the use of the material. Instead of this, solely a discussion about changes shall take place in good faith.<sup>344</sup> The great importance Gilead attaches to a clear distinction between its own “original” products and the generics produced by the sublicensees becomes clear through a further embedding in the sublicense agreements: In a third mentioning, the sublicense agreements quote the prohibition to use the other parties name, logo or trademark without prior consent.<sup>345</sup>

Besides these restrictions, the sublicensees are granted the right to develop pediatric formulations of the licensed products. Solely in case of EVG and combination products, they need Gilead’s prior consent.<sup>346</sup> If the sublicensees receive regulatory approval for a pediatric formulation, they shall strive to make it available in the respective territory of the kind of product. A duty to pay royalties on pediatric formulations developed does not exist.<sup>347</sup> Hence, since pediatric ARVs may be supplied royalty-free, they present an exceptional case to the other ARVs covered in the sublicense agreements. Besides, the agreement provides for one-time technology transfer through forwarding documentation and professional expertise the sublicensees need to develop drug compound manufacturing processes and bioequivalence testing.<sup>348</sup> Albeit, several Indian generic manufacturers are able to reverse engineer ARVs without depending on the transfer of knowledge from the originator company.<sup>349</sup> Despite, technology transfer is indispensable to reduce costs of the production of generics. Since the MPP-Gilead License requires Gilead to waive any data exclusivity rights<sup>350</sup>, generic manufacturers can seek authorization from the drug approval body concerned without having the duty to repeat clinical trials. Hence, sublicensees may rely on the data submitted by Gilead as evidence that the generic versions are safe for human consumption.<sup>351</sup>

The second sublicensee is the Indian company Emcure Pharmaceuticals, which signed a sublicense agreement in January 2012.<sup>352</sup> Emcure is the 14<sup>th</sup> largest pharmaceutical company in India and has been producing ARVs for twelve years, which are sold in more than 40 countries.<sup>353</sup> As mentioned before, the sublicense exhibits the same features like the Aurobindo

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<sup>344</sup> Cf. Art. 5.3 (b) of the MPP-Gilead-Aurobindo Sublicense Agreement.

<sup>345</sup> Cf. Art. 11.3 of the MPP-Gilead-Aurobindo Sublicense Agreement.

<sup>346</sup> This can be referred to the Gilead license on EVG by Japan-Tobacco. Cf. Art. 6.2 (e) of the MPP-Gilead-Aurobindo Sublicense Agreement.

<sup>347</sup> For instance, if the pediatric formulation is mainly a TDF combination product, it has to be made available in the TDF territory. Cf. Art. 6.2 (i) of the MPP-Gilead-Aurobindo Sublicense Agreement.

<sup>348</sup> Cf. Art. 5.4 of the MPP-Gilead-Aurobindo Sublicense Agreement.

<sup>349</sup> Cf. Center for Global Health R&D Policy/The Results for Development Institute (2012), p. 28.

<sup>350</sup> Cf. Medicines Patent Pool (2011d), p. 4.

<sup>351</sup> Cf. Center for Global Health R&D Policy/The Results for Development Institute (2012), p. 26.

<sup>352</sup> License Agreement between Gilead, the Medicines Patent Pool and Emcure Pharmaceuticals. Hereafter MPP-Gilead-Emcure Sublicense Agreement.

<sup>353</sup> Cf. Emcure (2013).

sublicense. Emcure terminated its license on TDF as well; it did even so on the same day the MPP-Gilead-Emcure Sublicense Agreement was signed.<sup>354</sup> Hence, the Emcure sublicense effectively encompasses the same scope as the sublicense of Aurobindo. The same day the sublicense agreement was concluded, the Emcure sublicense has been amended by including the provision that in case the sublicensee terminates the TDF license, Gilead will not bring on a claim against it for the production, use and sale of products containing FTC or TDF in the TDF territory as long as the sublicense agreement is in force.<sup>355</sup> Moreover, the amendment clarifies that the supply of API or products outside the approved territories does not constitute a breach of the sublicense agreement if a compulsory license, which has been issued in the importing country and, respectively or, India has issued a compulsory license for the export of the product concerned, is in effect.<sup>356</sup>

In July 2012, the third sublicense between the MPP, Gilead and the Indian pharmaceutical company Hetero Labs, a company generating most of its revenue through generic ARV production<sup>357</sup>, has been agreed on.<sup>358</sup> Just as Aurobindo and Emcure, Hetero opted out of the TDF license the same day it signed the sublicense agreement.<sup>359</sup>

After the Quad received approval by the FDA in August 2012, the fourth sublicense agreement between the MPP, Gilead and the Indian company Laurus Labs was signed in form of an Amended and Restated License Agreement in September 2012. Laurus did not terminate its license on TDF like the other sublicensees did before. A possible explanation for this could be that the sublicensee wanted to benefit from a technology transfer in regard to the manufacture of TDF.<sup>360</sup>

In February 2013, the Indian pharmaceutical company Shasun Pharmaceuticals became the fifth sublicensee of the Gilead patents in the pool.<sup>361</sup> Because Shasun was already equipped with a existing license on TDF, the company concluded an Amended and Restated License Agreement like Aurobindo and Laurus. Like Laurus, Shasun did not terminate the license on TDF, probably also in order to benefit from a technology transfer.

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<sup>354</sup> Cf. Emcure (2012).

<sup>355</sup> Cf. Art. 3 (b) of the First Amendment to MPP-Gilead-Emcure Sublicense Agreement amending replacing Art. 10.3 (d) of the MPP-Gilead-Emcure Sublicense Agreement.

<sup>356</sup> Cf. Art. 2 of the First Amendment to MPP-Gilead-Emcure Sublicense Agreement.

<sup>357</sup> Cf. IHS (2011).

<sup>358</sup> Cf. Title of the License Agreement between Gilead, the Medicines Patent Pool and Hetero Labs. Hereafter MPP-Gilead-Hetero Sublicense Agreement.

<sup>359</sup> Cf. Hetero (2012).

<sup>360</sup> Cf. Center for Global Health R&D Policy/The Results for Development Institute (2012), p. 33.

<sup>361</sup> Cf. Title of the Amended and Restated License Agreement between Gilead, the Medicines Patent Pool and Shasun. Hereafter MPP-Gilead-Shasun Sublicense Agreement.

The last signee of a sublicense agreement was the Indian pharmaceutical company Shilpa Medicare in May 2013.<sup>362</sup> Since the sublicenses are all identical, Shilpa was also granted an API license to make, use, offer for sale and sell API in the field and in India to licensed product suppliers or for internal use<sup>363</sup> as well as the right to make, use, sell, have sold, offer for sale, export from India and import TDF and combination product, EVG and combination product and the Quad as well as COBI and combination product in the Field and in their respective territories and the possibility to make, use, sell, have sold and export FTC.<sup>364</sup> Nevertheless, Shilpa did not terminate the license on TDF. Hence, it is one of the three sublicensees with a valid license on TDF.

### **Sublicensees of the ViiV Healthcare patents**

ViiV Healthcare does not restrict the MPP in its decision on sublicensees. In contrast to the MPP-Gilead License Agreement, which narrows sublicensees down to Indian pharmaceutical companies, there is no limitation on the country of sublicensed manufacture.<sup>365</sup> Hence, pharmaceutical companies from any territory country may conclude sublicenses with the MPP. Raw materials and products solely need to be in consistency with WHO prequalifications or with the standards of a regulatory authority, which is a member, observer or affiliate to the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). This organization aims to harmonize technical guidelines and requirements for pharmaceutical product registration in Europe, Japan and the United States.<sup>366</sup> In case generic manufacturers have not received approval yet, they need to obtain temporary approval by the WHO Expert Review Panel.<sup>367</sup>

The Indian pharmaceutical company Aurobindo is the only sublicensee until today.<sup>368</sup> The pharmaceutical company was granted a non-exclusive, royalty-free, non-sublicensable, non-transferable license encompassing the production, use, sale, supply, import and export of raw materials for use in the manufacture of products in the territory as well as encompassing the production, use, sale, supply, import and export of the product in the territory.<sup>369</sup> According to the sublicense agreement, the term “products” also includes pharmaceutical combinations and

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<sup>362</sup> Cf. Title of the License Agreement between Gilead, the Medicines Patent Pool and Shilpa. Hereafter MPP-Gilead-Shilpa Sublicense Agreement.

<sup>363</sup> Cf. Art. 2.1 S. 1 of the MPP-Gilead-Shilpa Sublicense Agreement.

<sup>364</sup> Cf. Art. 2.2 and 7.5 of the MPP-Gilead-Shilpa Sublicense Agreement.

<sup>365</sup> Cf. Art. 2.1 of the MPP-ViiV Healthcare-Aurobindo License Agreement.

<sup>366</sup> Cf. ICH (2013).

<sup>367</sup> Cf. Art. 3.2 of the MPP-ViiV Healthcare-Aurobindo Sublicense Agreement.

<sup>368</sup> Cf. Medicines Patent Pool (2013c).

<sup>369</sup> Cf. Art. 2.1 of the License Agreement between ViiV Healthcare, the Medicines Patent Pool and Aurobindo. Hereafter MPP-ViiV Healthcare-Aurobindo Sublicense Agreement.

compositions, which contain ABC.<sup>370</sup> Therefore, the MPP-ViiV Healthcare-Aurobindo Sublicense additionally permits the manufacture and supply of combined products for pediatric use involving ABC.

The license agreement waives any data exclusivity, so that the original test data can be used by the generic manufacturer and clinical trials do not need to be repeated to obtain approval for the generics.<sup>371</sup> Same as with the MPP-Gilead Sublicense Agreements, the MPP-ViiV Healthcare-Aurobindo Sublicense clearly states that the sublicensee has neither the right to use ViiV Healthcare's or their affiliates' trademarks, nor is allowed to try to register a trademark, trade dress, symbol or device related to a product, its packing or marketing material which is identical or similar to one of ViiV Healthcare's or its affiliates'.<sup>372</sup> Instead of this, all material Aurobindo wants to employ needs to be approved by ViiV Healthcare.<sup>373</sup> A further similar controlling right is ViiV Healthcare and the MPP's option to examine Aurobindo's records twice a calendar year.<sup>374</sup>

### **The Roche patents**

So far, no sublicense agreement has been concluded in accordance to the MPP-Roche License. The reason for this is that in contrast to the other license agreements, the MPP does not identify generic manufacturers, but organizations, which Roche will directly supply with valganciclovir.<sup>375</sup> Not before August 2014 Roche will enter into negotiations about licensing and technology transfer to third parties in or outside the territory, if the MPP requests it to do so.<sup>376</sup> Organizations supplied with valganciclovir are for instance non-profit HIV treatment organizations, the Global Fund to Fight AIDS, Tuberculosis and Malaria, the United States Presidents Emergency Plan for AIDS Relief, UNITAID or Médecins Sans Frontières. However, Roche has to accept the organizations proposed by the MPP.<sup>377</sup> If import licenses or else are necessary for supply, the organizations are responsible for receiving such.<sup>378</sup>

After approval and supply, the HIV treatment organizations are solely allowed to use valganciclovir for direct administration to patients, in indication and in the way per product

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<sup>370</sup> Cf. Art. 1.12 of the MPP-ViiV Healthcare-Aurobindo Sublicense Agreement.

<sup>371</sup> Cf. Art. 5.7 of the MPP-ViiV Healthcare License Agreement.

<sup>372</sup> Cf. Art. 9.2 of the MPP-ViiV Healthcare-Aurobindo Sublicense Agreement.

<sup>373</sup> Cf. Art. 9.3 of the MPP-ViiV Healthcare-Aurobindo Sublicense Agreement.

<sup>374</sup> Cf. Art. 10.1 of the MPP-ViiV Healthcare-Aurobindo Sublicense Agreement.

<sup>375</sup> Cf. Art. 1 "Organizations" and Art. 2.1 of the MPP-Roche License Agreement.

<sup>376</sup> Cf. Art. 8.2 of the MPP-Roche License Agreement.

<sup>377</sup> Cf. Art. 1 "Organizations" of the MPP-Roche License Agreement.

<sup>378</sup> Cf. Art. 5.3 of the MPP-Roche License Agreement.

information or package leaflet received in the approved territories.<sup>379</sup> Orders of the product have to be conveyed to Roche or to a designated third party distributor at least three months before delivery.<sup>380</sup> Roche warrants that the products are manufactured, sold and packed in accordance with FDA, EMA or other applicable authorities.<sup>381</sup> The shipment of products takes place according to International Commercial Terms (INCO Terms) 2010<sup>382</sup>, which determine the duties of seller and buyer in international trade transactions.<sup>383</sup> Since transport shall take place in form of Free Carrier Airport Basel, Roche has to deliver the products to the Airport of Basel, where it consigns them to the buyer. Here, the risk passes on to the organization supplied.<sup>384</sup> Same as with the Gilead and the ViiV Healthcare Licenses, the MPP does not have the right to use any of Roche's marks without prior written approval.<sup>385</sup>

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<sup>379</sup> Cf. Art. 2.3 of the MPP-Roche License Agreement.

<sup>380</sup> Cf. Art. 4.1 of the MPP-Roche License Agreement.

<sup>381</sup> Cf. Art. 9.2 of the MPP-Roche License Agreement.

<sup>382</sup> Cf. Annex A of the MPP-Roche License Agreement.

<sup>383</sup> Cf. Springer Gabler Verlag (ed.) (n.y.).

<sup>384</sup> Cf. Deutscher Zoll (n.y.).

<sup>385</sup> Cf. Art. 16.1 of the MPP-Roche License Agreement.

## **6.2 Sourcing of active pharmaceutical ingredients (API)**

### **Sublicensees of the NIH patents**

In the MPP-NIH License Agreement, there are no provisions mentioned regarding the sourcing of API. Consequently, there are no restrictions on API supply and every country, which is part of the approved territory, might be chosen to manufacture and supply them.

### **Sublicensees of the Gilead patents**

In the MPP-Gilead Sublicense Agreements, purchase, sale and use of API in the manufacture of generics are restricted. The royalty-free, non-exclusive, non-transferable API license solely permits sublicensees to make, use, offer to sell and sell API for internal use or for the selling process to licensed product suppliers in the field and in India.<sup>386</sup> Otherwise, API can only be purchased from Gilead suppliers or an API supplier licensed by Gilead.<sup>387</sup> This limitation has been widely criticized.<sup>388</sup> By restricting API supply to Gilead suppliers or licensed API suppliers, potential suppliers from China, which is one of the countries with the major API producers, or from other Asian, Latin American or African countries, are excluded. This might affect free competition among API suppliers and was already part of the most negative features of Gilead's 2006 licenses on TDF.<sup>389</sup> Thereby, since API manufacture is forbidden outside India, developing countries are inhibited to become more self-sufficient through domestic production of ARVs.<sup>390</sup> This is fraught with problems since permitting domestic manufacture would contribute to encourage economic development and build up local capacity.<sup>391</sup> The reason for the harsh restriction might be that Gilead wants to prevent the development of a generics industry in China and aims to impede API production in least developed countries, which benefit from the waiver on patents for pharmaceuticals under the TRIPS Agreement until 2016.<sup>392</sup>

API suppliers are obliged to manufacture in accordance with Indian manufacturing standards as well as either WHO, EMA or FDA standards and with national, regional or local standards on a country-by-country basis.<sup>393</sup> Gilead further justifies its limitation of API suppliers to Indian companies by referring to this provision and mentioning the fact that Indian suppliers

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<sup>386</sup> Cf. Art. 2.1 of the MPP-Gilead-Aurobindo Sublicense Agreement representative for all other sublicense agreements.

<sup>387</sup> Cf. Art. 3.1 of the MPP-Gilead Aurobindo Sublicense Agreement and Art. 1 "Licensed API Supplier" of the MPP-Gilead-Aurobindo Sublicense Agreement.

<sup>388</sup> Cf. Baker, Brook (2011).

<sup>389</sup> Cf. Médecins Sans Frontières (2011), p. 10.

<sup>390</sup> Cf. Baker, Brook (2011).

<sup>391</sup> Cf. Cox, Krista L., *Hastings Science & Technology Law Journal*, 2012, No. 2, p. 310.

<sup>392</sup> Cf. Baker, Brook (2011).

<sup>393</sup> Cf. Art. 6.2 (a) S. 1 of the MPP-Gilead-Aurobindo Sublicense Agreement.

generally dispose the necessary manufacturing requirements. Nevertheless, one could also assume that Gilead aims to benefit from additional economies of scale of its API suppliers. Through additional sales to sublicensees, Gilead's API suppliers then might be able to sell APIs at lower price to Gilead.<sup>394</sup> Regarding the sale of API, sublicensees are only allowed to sell to licensed product suppliers in India, which have been approved by Gilead.<sup>395</sup> By forbidding the sale to non-sublicensees, Gilead prevents Indian API producers from the export of APIs to other countries, where manufacturers could lawfully formulate generics of assured quality.<sup>396</sup>

### **Sublicensees of the ViiV Healthcare patents**

In contrast to the MPP-Gilead License Agreement, which restricts the manufacturing of API to India, the MPP-ViiV Healthcare License includes the freedom to manufacture APIs in different countries. The sublicensees are allowed to “manufacture, use, sell, import and export in the territory raw materials for the use in manufacture of products”<sup>397</sup>. Since the term “raw materials” also includes active ingredients<sup>398</sup>, this provision relates to the production of API. Consequently, the country supplying API can be chosen by the sublicensees, provided that it is one of the 118 territory states. Moreover, to the extent the licensor has the right to grant a sublicense in respect to the non-territory patents, the sublicensees may also manufacture API outside the approved territory to supply it to the territory for the manufacture of products<sup>399</sup> or outside the approved territory for the manufacture of products.<sup>400</sup> Hence, under circumstances, possible countries to source API could even encompass more than 118 states. To enhance competition and to reduce drug prices, such a large number of API suppliers is worthwhile.<sup>401</sup> Same as with the manufacture of generics, API has to be produced in accordance with WHO prequalifications or with standards of a regulatory authority, which is a member, observer or affiliate to the ICH. In case approval has not been received yet, API manufacturers need to obtain temporary approval by the WHO Expert Review Panel.<sup>402</sup>

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<sup>394</sup> Cf. Baker, Brook (2011).

<sup>395</sup> Cf. Art. 2.4 (a) of the MPP-Gilead- Aurobindo License Agreement.

<sup>396</sup> Cf. Baker, Brook (2011).

<sup>397</sup> Cf. Art. 2.1 (a) of the MPP-ViiV Healthcare-Aurobindo Sublicense Agreement.

<sup>398</sup> Cf. Art. 1.13 of the MPP-ViiV Healthcare-Aurobindo Sublicense Agreement.

<sup>399</sup> Cf. Art. 2.2 (b) of the MPP-ViiV Healthcare-Aurobindo Sublicense Agreement.

<sup>400</sup> Cf. Art. 2.2 (c) of the MPP-ViiV Healthcare-Aurobindo Sublicense Agreement.

<sup>401</sup> Cf. Beyer, Peter (2013), p. 241.

<sup>402</sup> Cf. Art. 3.2 of the MPP-ViiV Healthcare-Aurobindo Sublicense Agreement.

## **The Roche patents**

Roche directly supplies HIV treatment organizations with the product valganciclovir.<sup>403</sup> Hence, there are no generic manufacturers, who have to source API. Regarding the original product valganciclovir the companies, which are entrusted with API manufacture, are Corden Pharma Colorado Inc., a company located in the United States, and Roche itself, which is located in Switzerland.<sup>404</sup> However, it cannot be determined further where exactly they manufacture the API necessary to produce valganciclovir.

Consequently, while the NIH and ViiV Healthcare set encompassing provisions, Gilead restricts the supply of API to India. The fact that ViiV Healthcare has not limited API supply to a certain country might be referred to the fact that Gilead arouse harsh criticism for that.

## **6.3 Royalties**

### **Sublicensees of the NIH patents**

Since the MPP-NIH License Agreement solely allows sublicensees to make or use, but not to sell the licensed products<sup>405</sup>, no royalties are demanded. The products shall only be used in low- and middle-income countries, where the NIH has neither been granted, nor applied for patents. Hence, no distribution of products is foreseen in those countries, where patents on darunavir exist or might be granted, wherefore the necessity to pay royalties on any sublicense the MPP may issue is eliminated.<sup>406</sup>

### **Sublicensees of the Gilead patents**

When the MPP-Gilead License Agreement was concluded, Gilead has been obliged to pay 5% of all sublicense revenue the company received per calendar year to the MPP, but not more than US-\$1 million.<sup>407</sup> The fee should be paid for the MPP's efforts in regard to the identification of sublicensees as well as for the administration of the licenses. This means, between 0.15% and 0.25% of the generics' prices was initially set aside for the MPP.<sup>408</sup> The MPP estimated that the revenues it will receive from Gilead will amount about US-\$1500-30000 from 2011 to 2012. Thus, in comparison with the MPP's operating budget, the administrative fee

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<sup>403</sup> Art. 2.1 of the MPP-Roche License Agreement.

<sup>404</sup> Corden's ID/FEI 076470525 and Roche's ID/FEI 482242971. Operation: API MANUFACTURE (0004-0038) (0004-0039). Cf. Med Library (2013).

<sup>405</sup> Cf. Art. 3.1 of the MPP-NIH License Agreement.

<sup>406</sup> Cf. Medicines Patent Pool (2010a).

<sup>407</sup> Cf. Art. 3.1 S. 1 of the MPP-Gilead License Agreement.

<sup>408</sup> Cf. Medicines Patent Pool (2011e), p. 7f.

only constitutes a marginal portion of less than 1%.<sup>409</sup> However, criticism that the duty to pay of 5% of sublicense revenues to the MPP could lead to a conflict of interests, since the MPP as an independent non-profit organization should by definition be free from commercial interests, arose.<sup>410</sup> Moreover, it was apprehended that Gilead could make up for the fee by raising drug prices in middle-income countries, which are not part of the licensed territory<sup>411</sup>, and hence bring along further negative effects for the countries already excluded from the license agreement. Therefore, the obligation of Gilead to pay the share of total revenue to the MPP was removed with the third amendment to the license agreement in July 2012.<sup>412</sup>

Whereas API may be manufactured royalty-free<sup>413</sup>, sublicensees need to pay royalties on a product-by-product and country-by-country basis to Gilead, starting with the first commercial sale of one product. This duty does not terminate before the last expiring patent, which contains a valid claim to produce, use, import, offer for sale and sale API or the products in its territory or in the field and in India, expires.<sup>414</sup> The sublicensees Aurobindo, Emcure, Hetero, Laurus, Shasun and Shilpa have to pay 3% of TDF net sales as well as 3% of the share of TDF combination product net sales, which is attributable to TDF, in the TDF territory to Gilead.<sup>415</sup> Moreover, 3% of the share of TDF in the Quad combination product net sales, which is attributable to TDF component, and 5% of the share of the Quad combination product net sales attributable to EVG and COBI component in the Quad territory have to be paid.<sup>416</sup> Regarding EVG, the sublicensees have the obligation to pay 5% of product net sales as well as 5% of the portion of EVG combination product, which is attributable to EVG component, in the EVG territory to Gilead.<sup>417</sup> Moreover, 5% of COBI product net sales in the COBI territory need to be passed to the company.<sup>418</sup> Regarding COBI combination products except the Quad, 5% of the portion of net sales attributable to COBI component, and, in case such combined products also contain TDF, 3% of the share of the COBI combination product attributable to TDF have to be paid.<sup>419</sup> The same applies to EVG combination products and EVG combination products which also include TDF and COBI component.<sup>420</sup> Solely for pediatric formula-

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<sup>409</sup> Cf. Medicines Patent Pool (2011e), p. 8.

<sup>410</sup> Cf. ITPC/I-MAK (2011b), p. 2.

<sup>411</sup> Cf. ITPC/I-MAK (2011b), p. 4.

<sup>412</sup> Cf. Art. 2 (a) of the Third Amendment to the MPP-Gilead License Agreement.

<sup>413</sup> Cf. 2.1 of the MPP-Gilead-Aurobindo Sublicense Agreement representative for all other sublicense agreements.

<sup>414</sup> Cf. Art. 4.9 of the MPP-Gilead-Aurobindo Sublicense Agreement.

<sup>415</sup> Cf. Art. 4.1. (a) and (b) of the MPP-Gilead-Aurobindo Sublicense Agreement.

<sup>416</sup> Cf. Art. 4.1. (c) of the MPP-Gilead-Aurobindo Sublicense Agreement.

<sup>417</sup> Cf. Art. 4.1. (d) and (e) of the MPP-Gilead-Aurobindo Sublicense Agreement.

<sup>418</sup> Cf. Art. 4.1. (f) of the MPP-Gilead-Aurobindo Sublicense Agreement.

<sup>419</sup> Cf. Art. 4.1. (g) of the MPP-Gilead-Aurobindo Sublicense Agreement.

<sup>420</sup> Cf. Art. 4.1. (e) of the MPP-Gilead-Aurobindo Sublicense Agreement.

tions of the licensed products and FTC component of combination products there is no duty to pay royalties.<sup>421</sup>

In case a patent on TDF or TD will be issued in India, the sublicensees have to pay royalties of 5% instead of 3% for TDF products as well as for all possible combined products.<sup>422</sup> In addition to royalties on net sales, the sublicensees also need to pay the withholding taxes for and on behalf of Gilead to the respective authorities. However, the amount of tax paid may be subtracted from royalties, which are due to Gilead.<sup>423</sup> According to Beyer, the royalty rate demanded by Gilead is solely expected to cover the costs of concluding the license agreement with the MPP. Thus, the company follows a “no-cost no-benefit policy”<sup>424</sup>. Nevertheless, it needs to be noticed that royalties must be paid to Gilead regardless of the patent status in the countries, where the ARVs will be actually marketed.<sup>425</sup>

### **Sublicensees of the ViiV Healthcare patents**

Since the MPP-ViiV Healthcare-Aurobindo Sublicense Agreement is completely royalty-free<sup>426</sup>, ViiV Healthcare may not claim to obtain any fee for sales of generic pediatric ABC. This way, possible cost-savings through the licensing procedure via the MPP are maximized.<sup>427</sup> Nevertheless, a licensor receiving no royalties might be contrary to the MPP’s aim to establish an alternative commercially viable scheme to enhance access to ARVs. Participation in the pool might be less attractive to other patent holders if they get aware of the fact that ViiV Healthcare does not obtain a percentage share of revenue on net sales. Depending on the motivation to join the MPP, not receiving any royalties at all could weaken the incentive to accede to the pool.

### **The Roche patents**

The HIV treatment organizations, which are directly supplied with valganciclovir by Roche, have to pay a unit price of 250 CHF per pack within a month after receipt of invoice.<sup>428</sup> Additionally, the organizations have to pay import and sale taxes -with an exclusion of VAT-, insurances, duties and levies under the license agreement.<sup>429</sup> Since current prices for a pack of

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<sup>421</sup> Cf. Art. 4.1. (h) and (i) of the MPP-Gilead-Aurobindo Sublicense Agreement.

<sup>422</sup> Cf. Art. 4.1. (l) S. 3 of the MPP-Gilead-Aurobindo Sublicense Agreement.

<sup>423</sup> Cf. Art. 4.8 (a) of the MPP-Gilead-Aurobindo Sublicense Agreement.

<sup>424</sup> Beyer, Peter (2013), p. 239.

<sup>425</sup> Cf. Médecins Sans Frontières (2011), p. 12.

<sup>426</sup> Cf. Art. 2.1 and 2.2 of the MPP-ViiV Healthcare-Aurobindo Sublicense Agreement.

<sup>427</sup> Cf. Baker, Brook (2013).

<sup>428</sup> Cf. Art. 7 of the MPP-Roche License Agreement.

<sup>429</sup> Cf. Art. 5.3 of the MPP-Roche License Agreement.

valganciclovir amount about 2500 CHF<sup>430</sup>, the price really constitute a reduction by 90% in comparison to the sale price in Switzerland, just as Roche states.<sup>431</sup> Albeit, according to different sale prices in the territory countries, the price reduction will differ in the territory countries. For instance, in India, the sale price of valganciclovir under the MPP-Roche License Agreement is solely 35% lower than the previous price.<sup>432</sup>

In total, it needs to be highlighted that most patent pools have a royalty structure, where licensees need to pay either a percentage of the licensee's net sales of the licensed products or a flat fee per unit sold to the pool administrator.<sup>433</sup> With Gilead, sublicensees are obliged to pay a 3-5% share of total net sales, which corresponds to the first variant. Opposed to this, there is no need to pay royalties with the NIH and ViiV Healthcare. With Roche, the organizations supplied have to pay a fixed price of 250 CHF per pack to the company. In consequence, there are three different payment methods applied with the pool members, which illustrates the flexibility the MPP offers to licensors. Furthermore, except for the fee initially demanded from Gilead, which was removed one year after the license agreement came into force, the MPP did never require the licensors to pay a part of the royalties they receive to the pool.

#### **6.4 Ability of sublicensees to supply to countries outside the licensed territory**

##### **Sublicensees of the NIH patents**

There are no provisions on supply outside the territory, for instance under a compulsory license, mentioned in the MPP-NIH License Agreement. Since there are other patent holders, who own patents on darunavir and hence may prohibit production, the license on the NIH darunavir patents does not allow for the manufacture of the ARV.<sup>434</sup> Consequently, no sublicensee will be able to manufacture darunavir, let alone supply under a compulsory license, as long as not all patents necessary for the drug's production are licensed to the pool.

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<sup>430</sup> Cf. for instance Mymedi (2013).

<sup>431</sup> Cf. Roche (2013).

<sup>432</sup> Cf. DNA India (2009).

<sup>433</sup> Cf. Layne-Farrar, Anne/Lerner, Josh, *International Journal of Industrial Organization*, 2011, No. 2, p. 296.

<sup>434</sup> Cf. Medicines Patent Pool (2010a), p. 1f.

### **Sublicensees of the Gilead patents**

According to the sublicense agreements, countries excluded from the licensed territory may import generic ARVs manufactured in India under a compulsory license.<sup>435</sup> A compulsory license for import has to be granted in case sufficient domestic manufacturing capacities do not exist and the drug concerned is necessary to protect public health, but patent-protected in the country concerned.<sup>436</sup> Since the MPP-Gilead License Agreement only allows for API and product manufacture in India, just the drug's patent status in India as the exporting country has to be examined. If no patent exists in India, a compulsory license for export has not to be granted by the Indian government.<sup>437</sup> In case patent protection in India exists, a compulsory license for the export of the relevant drug has to be issued so that sublicensees would be able to manufacture the drug for the other country.<sup>438</sup> A compulsory license for export in India can be granted according to Art. 92A 1 of the Indian Patents Acts, which allows for such a license in case patented pharmaceutical products shall be manufactured for and be exported to a country with insufficient manufacturing capacities to address public health problems. When taking into account the current patent landscape of Gilead's patents, the probability that two compulsory licenses, one for the import into the excluded country and one for the export from India, have to be granted is much higher.<sup>439</sup> Hence, if the necessary compulsory import license, respectively compulsory export license, has been received, countries outside the approved territory can be supplied with generics. This way, the middle-income countries excluded from the licensed territory are yet able to benefit from the MPP-Gilead License.

The concern that Gilead needs to permit sublicensees to manufacture under a compulsory license was overtaken by the second amendment to the license, which replaced the wording of Art. 10.3 of the MPP-Gilead License Agreement. The amendment clarified that supplying under a compulsory license solely has to be in accordance with the scope, geographic range and period of validity of the compulsory license, but that there is no necessity of consent by Gilead.<sup>440</sup> Therefore, compulsory licenses, which are an important flexibility of the TRIPS Agreement to protect public health, might be deployed in case of sublicense agreements as well. In contrast to the 2006 Gilead TDF license, the permission of sublicensees to supply

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<sup>435</sup> Cf. Art. 10.3 (d) of the MPP-Gilead-Aurobindo Sublicense Agreement representative for all other sublicense agreements.

<sup>436</sup> Cf. Art. 2 (a) iii of the Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health – Decision of the General Council of August 30 2003 and Art. 10.3 (d) i of the MPP-Gilead-Aurobindo Sublicense Agreement.

<sup>437</sup> Cf. Cox, Krista L., *Hastings Science & Technology Law Journal*, 2012, No. 2, p. 315.

<sup>438</sup> Cf. Art. 10.3 (d) ii of the MPP-Gilead-Aurobindo Sublicense Agreement.

<sup>439</sup> Cf. Cox, Krista L., *Hastings Science & Technology Law Journal*, 2012, No. 2, p. 315.

<sup>440</sup> Cf. Art. 4 (b) of the Second Amendment to the MPP-Gilead License Agreement.

outside the territory under a compulsory license is a new concession.<sup>441</sup> However, although according to the MPP-Gilead License Agreement responding to a compulsory license request is no breach of agreement and will not lead to the sublicense's termination, it is questionable if generic manufacturers that have signed a sublicense agreement would apply for a compulsory license to export, since this would be a threat to its commercial relationship with Gilead. In contrast to the possibility of supplying outside the licensed territory in consequence of a compulsory license, parallel importation is prohibited by the sublicense agreements even for states, which allow for it. The sublicense agreements attribute the right to terminate the sublicense to Gilead in case ARVs or API made or sold by sublicensees are redirected to countries excluded from the approved territory.<sup>442</sup>

### **Sublicensees of the ViiV Healthcare patents**

A similar regulation of supplying non-territories under compulsory licenses can be found in the MPP-ViiV Healthcare License Agreement. The agreement clearly states that the manufacture, use, sell or supply of products or raw materials, including API, to a non-territory country does not constitute a breach of agreement if the non-territory country has issued a compulsory license on a non-territory patent.<sup>443</sup> The sublicense agreement additionally states that manufacture, use, sell and supply have to be in the scope of the compulsory license. Moreover, the sublicensee needs to be "authorized to supply under a compulsory license"<sup>444</sup>. This probably does not mean an authorization by ViiV Healthcare since, as mentioned above, there was a lot of opposition by civil society groups until a provision on compulsory licenses in the MPP-Gilead License Agreement, which was interpreted in the way that the permission of Gilead was necessary for a sublicensee to supply under a compulsory license, was amended. In all probability, ViiV Healthcare is not interested in raising any similar civil society concerns. Instead of this, the term "authorization" likely rather refers to an authorization by the government of the country, in which the sublicensee is resident, meaning that a compulsory license for export has to be granted in case ABC is patented there. Hence, it can be expected that the license allows the sublicensee to supply outside the territory under compulsory licenses.<sup>445</sup>

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<sup>441</sup> Cf. Cox, Krista L., *Hastings Science & Technology Law Journal*, 2012, No. 2, p. 318.

<sup>442</sup> Cf. Art. 10.3 (b) 2.2 (i) of the MPP-Gilead-Aurobindo Sublicense Agreement.

<sup>443</sup> Cf. Art. 2.4 of the MPP-ViiV Healthcare License Agreement.

<sup>444</sup> Art. 2.3 S. 3 of the MPP-ViiV Healthcare-Aurobindo Sublicense Agreement.

<sup>445</sup> This is also the opinion of Love. Cf. Love, James (2013).

## **The Roche patents**

Roche supplies HIV treatment organizations with valganciclovir for use in the territory itself.<sup>446</sup> The supply of valganciclovir under a compulsory license to a non-territory country would require Roche to agree to manufacture the medicine for export. Thereby, it has to be kept in mind that valganciclovir is not a generic and price reductions are only applied to the territory countries by Roche. Consequently, it might be cheaper if the country excluded from the MPP-Roche License Agreement, is supplied by a generic manufacturer. Nevertheless, in order to prevent generic supply, perhaps Roche would yet again decide to produce valganciclovir and apply the price reduction to the excluded country.

## **6.5 Grant back provisions**

### **Sublicensees of the NIH patents**

Sublicensees of the NIH darunavir patents have to assure that they will not use the licensed products for research regarding human subjects or clinical trials in the United States, which is inconsistent with the American provisions on protection of the human subject while conducting research.<sup>447</sup> If sublicensees want to conduct research outside the United States, they need to comply with the applicable national regulations. Moreover, before research outside America is started, the sublicensees additionally have to inform the NIH about their intent in written.<sup>448</sup> In regard to clinical trials and research involving the human subject, notification has to be sent at least 60 days before research begins.<sup>449</sup> 60 days after the turn of the year a report describing the current status of research has to be delivered to NIH.<sup>450</sup> As the MPP-NIH License Agreement does not contain any provisions on grant backs of improvements, sublicensees are not obliged to relicense such to NIH.

### **Sublicensees of the Gilead patents**

In contrast to the MPP-NIH License, grant back clauses can be found in the MPP-Gilead Sublicense Agreements. Usually, grant back clauses approach the rights the licensor has on the improvements of medicines by the licensee.<sup>451</sup> The sublicensees of the MPP-Gilead License have to grant a non-exclusive, royalty-free, worldwide, sublicensable license to all improvements, methods, modifications and other know-how, which was developed by or on behalf of

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<sup>446</sup> Cf. Art. 2.3 (iv) of the MPP-Roche License Agreement.

<sup>447</sup> Cf. Art. 5.2 S. 1 of the MPP-NIH License Agreement.

<sup>448</sup> Cf. Art. 5.2 S. 2 of the MPP-NIH License Agreement.

<sup>449</sup> Cf. Art. 5.2 S. 3 of the MPP-NIH License Agreement.

<sup>450</sup> Cf. Art. 5.3 of the MPP-NIH License Agreement.

<sup>451</sup> Cf. Beyer, Peter (2013), p. 240.

the sublicensees and are related to API or a product, to Gilead.<sup>452</sup> Self-evidently, the grant back license for improvements is limited to improvements made prior to termination of the licenses. The duty to grant back improvements to the licensed technology does not transfer ownership to Gilead. Since ownership of improvement stays with the sublicensees, they may self-evidently file patent applications for the improvements or share them with third parties.<sup>453</sup> Gilead has no right to transfer improvements to third parties, except for Gilead's affiliates, suppliers as well as Japan Tobacco for the benefit of Gilead or Japan Tobacco.<sup>454</sup> This opportunity to use improvements for the own benefit protects the company's interests, but also promotes competition between the company and the developer of the improvement, respectively third parties licensed by the developer.<sup>455</sup> In addition to grant backs, Gilead has to be provided with a detailed annual report, which also lists patent applications.<sup>456</sup> In case sublicensees fail to provide information about improvements to Gilead, Gilead has the right to terminate the sublicense agreements.<sup>457</sup>

Moreover, sublicensees have the right to develop liquid or dispersible pediatric formulations of TDF, EVG and COBI as well as of combination products of these ARVs for children younger than twelve years. Only regarding EVG and EVG combination products, they need to obtain Gilead's prior approval.<sup>458</sup> In case the sublicensees develop a pediatric formulation, they may apply for regulatory approval and then have to make the formulation available in the territory of the product, of which the pediatric formulation has been invented.<sup>459</sup> If the formulation is approved, the sublicensees have to license the pediatric formulation back to Gilead, other licensed product suppliers or Gilead supplier for sale in the territories, which are not part of the sublicensees' territory.<sup>460</sup> Since sublicensees are required to make the pediatric formulation available in the territory of the corresponding drug, which encompasses at least 100 countries, and the pediatric ARV market is much bigger in the developing than in the developed world, one might assume that the sublicensees will strive for protection in the numerous territory-countries. Otherwise, Gilead has the right to sell in the territories, for which the sublicensees cannot exhibit patent protection. Thereby, a certain market share on the pediatric ARV market is secured to Gilead. In case the sublicensees are not able to make the pedi-

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<sup>452</sup> Cf. Art. 2.3 of the MPP-Gilead-Aurobindo Sublicense Agreement representative for all other sublicense agreements.

<sup>453</sup> Cf. Art. 6.2 (i) of the MPP-Gilead-Aurobindo Sublicense Agreement.

<sup>454</sup> Cf. Art. 5.2 S. 4 of the MPP-Gilead-Aurobindo Sublicense Agreement.

<sup>455</sup> Cf. Cox, Krista L., *Hastings Science & Technology Law Journal*, 2012, No. 2, p. 317.

<sup>456</sup> Cf. Art. 5.2 of the MPP-Gilead-Aurobindo Sublicense Agreement.

<sup>457</sup> Cf. Art. 5.2 S. 3 of the MPP-Gilead-Aurobindo Sublicense Agreement.

<sup>458</sup> Cf. Art. 6.2 (e) S. 1 of the MPP-Gilead-Aurobindo Sublicense Agreement.

<sup>459</sup> Cf. Art. 6.2 (e) S. 2 and 6.2 (i) S. 1 of the MPP-Gilead-Aurobindo Sublicense Agreement.

<sup>460</sup> Cf. Art. 6.2 (iii) a of the MPP-Gilead-Aurobindo Sublicense Agreement.

atric formulations available, Gilead may additionally supply in the sublicensees' territory in exchange for compensation<sup>461</sup> and hence obtain a bigger market share.

### **Sublicensees of the ViiV Healthcare patents**

ViiV Healthcare and the MPP have the right to receive a "perpetual, irrevocable, worldwide, royalty free, non-exclusive license to use any improvement, improvement patent and related know how"<sup>462</sup>. Consequently, the sublicensees may conduct research and apply for patent protection on improvements. The improvements have to be communicated even with the mode of working and the way how to use it to ViiV Healthcare.<sup>463</sup> In case the MPP aims to sublicense the rights obtained from the sublicensees to third parties, it has to enter into good faith negotiations with the sublicensees.<sup>464</sup>

ViiV Healthcare itself however may grant sublicenses to its affiliates, contract manufacturers, distributors or service providers for the commercialization of ViiV Healthcare products without negotiating additional rights.<sup>465</sup> Furthermore, ViiV Healthcare does not need to pay royalties to the sublicensees for commercializing their improvements.<sup>466</sup> This provision is remarkably, since without the possibility to recoup research investments through royalties arising from the commercialization of improvements, sublicensees might be disincentivized to invest in improvements. On the one hand, ViiV Healthcare as the licensor has a strong interest in having access to any improvements on the licensed drug made by the sublicensees. The reason for this is that in case the licensor is excluded from improvements on the ARV, the sublicensees are able to drive the licensor out of the market by selling improved versions of the medicine concerned.<sup>467</sup> On the other hand, sublicensees do not have any incentive to improve the licensed drug if the licensor may commercialize them without any remuneration to the developer of the improvement. Destroying the incentive to conduct research is initially contrary to the aim of ViiV Healthcare, which would also profit from improvements by obtaining a grant back license. To pay a certain amount of royalties for the commercialization of improvements, which of course would be far smaller than the total additional revenue ViiV Healthcare could reach without such a provision, would secure that the monetary rewards of

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<sup>461</sup> Cf. Art. 6.2 (iii) b of the MPP-Gilead-Aurobindo Sublicense Agreement.

<sup>462</sup> Art. 8.2 S. 1 of the MPP-ViiV Healthcare-Aurobindo Sublicense Agreement.

<sup>463</sup> Cf. Art. 8.1 of the MPP-ViiV Healthcare-Aurobindo Sublicense Agreement.

<sup>464</sup> Cf. Art. 8.2 S. 1 of the MPP-ViiV Healthcare-Aurobindo Sublicense Agreement.

<sup>465</sup> Cf. Art. 8.2.1 and 8.2.2 of the MPP-ViiV Healthcare-Aurobindo Sublicense Agreement.

<sup>466</sup> Cf. Art. 8.2 of the MPP-ViiV Healthcare-Aurobindo Sublicense Agreement.

<sup>467</sup> Cf. Beyer, Peter (2013), p. 240.

innovation are also shared among the licensor and the sublicensees. This would incentivize sublicensees to strive for improvements.

### **The Roche patents**

Since Roche manufactures valganciclovir itself and will not enter into negotiations about licenses and technology transfer to third parties in the territory, respectively developing countries outside the territory, before August 2014<sup>468</sup>, there is no provision offering the permission to conduct research on valganciclovir yet.

In conclusion, all license agreements except the MPP-Roche Agreement, which does not provide for sublicenses yet, enable the sublicensees to conduct research under the requirement to provide a detailed report about current status to the licensors. Non-exclusive grant back provisions are part of the MPP-ViiV Healthcare and the MPP-ViiV Healthcare License. Such grant backs represent the most common approach regarding improvements conducted by sublicensees, since they balance both interests and are generally legally permissible due to their pro-competitive effect, too.<sup>469</sup> Gilead and ViiV Healthcare also permit the sublicensees to apply for patent protection. Whereas ViiV Healthcare and affiliates may commercialize improvements without paying royalties, Gilead will only supply outside the territory the sublicensees received patent protection for, or, where sublicensees do not make formulations available to the necessary extent, in exchange for compensation. Nevertheless, to enhance the incentive to improve the licensed medicines even further, grant backs should always be subject to royalties.<sup>470</sup>

## **6.6 Ability to challenge the licensed patents**

### **Sublicensees of the NIH patents**

In the MPP-NIH License Agreement the NIH mentions that it does not warrant the validity of the licensed patents.<sup>471</sup> Since there are no provisions, which prohibit sublicensees from challenging the NIH's darunavir patents, sublicensees shall be allowed to attack the validity of the patents at court. This is important, since pre- and post-grant opposition contributes to maintain a high quality level of patents.<sup>472</sup> Generic manufacturers belong to the most frequent users of patent opposition procedures. Due to the potential lacks of human and financial resources in

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<sup>468</sup> Cf. Art. 8 of the MPP-Roche License Agreement.

<sup>469</sup> Cf. Dykeman, David J. (2006).

<sup>470</sup> Cf. Beyer, Peter (2013), p. 240.

<sup>471</sup> Cf. Art. 6.2 of the MPP-NIH License Agreement.

<sup>472</sup> Cf. Beyer, Peter (2013), p. 241.

patent offices, which prevent such from time-consuming and costly investigations of patent applications, opposition is especially important in developing countries.<sup>473</sup>

### **Sublicensees of the Gilead patents**

There is no prohibition of challenging validity of the licensed patents in the MPP-Gilead License Agreement. A prohibition of patent challenging is anti-competitive and can have a negative impact on affordability of ARVs<sup>474</sup>, for instance in case a weak patent like that of TDF in India is not allowed to be challenged by the sublicensees. In case of the MPP-Gilead License, the unbundling provision, which allows sublicensees to terminate the sublicense on an API or product basis at any time, also secures that weak patents are not protected through the license agreement.

### **Sublicensees of the ViiV Healthcare patents**

The challenge of patents is not explicitly mentioned in the MPP-ViiV Healthcare-Aurobindo Sublicense Agreement. However, since neither pre- or post-grant opposition, nor revocation, which both constitute opportunities to limit patent challenges, are addressed in the agreement, sublicensees seem to be permitted to raise such.<sup>475</sup> As a further argument supporting the permission of pre- and post-grant opposition one could mention the fact that competition policy in numerous jurisdictions particularly prevents the restriction of patent challenges in license agreements, since they are anti-competitive.<sup>476</sup>

### **The Roche patents**

Roche guarantees that it is the owner of the product valganciclovir without violating any law or right of third persons.<sup>477</sup> However, because it would contradict competition if this provision would be seen as a prohibition of any HIV treatment organization, which is supplied with valganciclovir by Roche, to challenge Roche's patents, it has to be presumed that organizations supplied are free to challenge the patents' validity.

In total, all license agreements allow for pre- and post-grant opposition, which secures that participation in the MPP does not represent an opportunity to protect weak patents from being

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<sup>473</sup> Cf. Beyer, Peter (2013), p. 241.

<sup>474</sup> Cf. Medicine Patent Pool (2011d), p. 3f.

<sup>475</sup> The same opinion have Baker and Love. Cf. Baker, Brook (2013) and Love, James (2013).

<sup>476</sup> Cf. Baker, Brook (2013).

<sup>477</sup> Cf. Art. 9.1 S. 1 of the MPP-Roche License Agreement.

challenged, perhaps even connected with royalty payment. Hence, such an arrangement of licensing terms safeguards that competition remains possible.

## **6.7 Termination of the sublicense agreements**

### **Sublicensees of the NIH patents**

Since any sublicense granted shall provide for termination upon termination of the MPP-NIH License Agreement<sup>478</sup>, sublicenses may always be terminated in case the license agreement does not longer exist in consequence of a provision mentioned in Art. 7 of the MPP-NIH License Agreement. Consequently, the sublicenses terminate when the last patent, which contains a valid claim, expires on a country-by-country basis within the approved territories.<sup>479</sup>

### **Sublicensees of the Gilead patents**

Gilead has the right to terminate a sublicense agreement if it is not provided with a detailed annual report, which also lists the patent applications filed.<sup>480</sup> Moreover, if the sublicensees cannot exhibit WHO prequalification, FDA or EMA approval standards at the second anniversary of date the sublicense agreement became effective, Gilead may also terminate the sublicense agreements until correction took place.<sup>481</sup> Furthermore, if one party breaches the sublicense agreement and does not take remedial action within 30 days after receiving written notice, the agreement ends.<sup>482</sup> The same applies in case the sublicensees become insolvent, make an assignment benefitting creditors or have a petition for bankruptcy filed for or against them.<sup>483</sup> Gilead additionally has the right to terminate the sublicense agreements in case control, meaning ownership or else, of the sublicensees changes.<sup>484</sup> Besides, the company is assigned to end the agreements if part of API or product made or sold by the sublicensees has been rolled out of the approved territories, except a compulsory license has been granted there and, respectively or, India has granted a compulsory license for the export of the product concerned, within 30 days after receipt of written notice. If API from outside the approved territories has been used or the sublicensees do not keep minimum quality standards and the sublicensees have not shown that the mentioned issues do not longer exist within 30 days of

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<sup>478</sup> Cf. Art. 4.3 of the MPP-NIH License Agreement.

<sup>479</sup> Cf. Appendix B III of the MPP-NIH License Agreement.

<sup>480</sup> Cf. Art. 5.2 S. 3 of the MPP-Gilead-Aurobindo Sublicense Agreement representative for all the other MPP-Gilead Sublicense Agreements.

<sup>481</sup> Cf. Art. 6.2 (c) of the MPP-Gilead-Aurobindo Sublicense Agreement.

<sup>482</sup> Cf. Art. 10.2 of the MPP-Gilead-Aurobindo Sublicense Agreement.

<sup>483</sup> Cf. Art. 10.6 of the MPP-Gilead-Aurobindo Sublicense Agreement.

<sup>484</sup> Cf. Art. 10.3 (a) of the MPP-Gilead-Aurobindo Sublicense Agreement.

receiving written notice, termination may be the subsequent action as well.<sup>485</sup> Furthermore, in case the Gilead-Japan Tobacco License Agreement on EVG expires, Gilead may terminate the EVG sublicenses.<sup>486</sup>

The sublicensees have the right to terminate the sublicenses on an API basis immediately upon receipt of notice.<sup>487</sup> Hence, on an API basis, the sublicensees can quit the sublicense agreements very fast and without lengthy previous notice. The termination of the sublicense on one product does not affect the license for any other API or product.<sup>488</sup> The provision grants significant flexibility to the sublicensees, which may select only the products they wish to produce or the ones they believe patents represent a barrier regarding their manufacture and sale.<sup>489</sup> Consequently, if patent claims are weak, such as with TDF in India, the sublicensees may take the opportunity to terminate the sublicenses on the product concerned as an alternative to challenge the patents validity. As mentioned before, half of the generic manufacturers unbundled their sublicenses from TDF. Moreover, the sublicensees may always terminate the complete agreements upon 30 days after providing written notice to Gilead.<sup>490</sup>

### **Sublicensees of the ViiV Healthcare patents**

The sublicense agreement between the MPP, ViiV Healthcare and Aurobindo will expire upon the later of the expiration, lapse or invalidation of the last remaining patent in the territory.<sup>491</sup> In case Aurobindo breaches a provision of the sublicense agreement and if such breach is material and not correctable, or if it is correctable, but not corrected within 60 days after the reception of the breach in written, the licensor is allowed to immediately terminate the sublicense agreement.<sup>492</sup> Moreover, if ViiV Healthcare notifies its sublicensee that its right to grant licenses of its patent is challenged or the sublicensee's use of the patents is contrary to patent rights of a third party, the sublicensee may decide within ten business days whether to suspend the license regarding the patent until the issue does not exist anymore.<sup>493</sup> Otherwise, the sublicensee has to approve that it will provide indemnification for any losses of ViiV Healthcare, which occur due to the continued use of the patents.<sup>494</sup> If Aurobindo sells or supplies products without having received the necessary approvals of the WHO or by being a

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<sup>485</sup> Cf. Art. 10.3 (i), (ii), (iii) and (d) of the MPP-Gilead-Aurobindo.

<sup>486</sup> Cf. Art. 10.3 (iv) of the MPP-Gilead-Aurobindo Sublicense Agreement.

<sup>487</sup> Cf. Art. 10.5 S. 1 and 3 of the MPP-Gilead-Aurobindo Sublicense Agreement.

<sup>488</sup> Cf. Art. 10.5 (c) of the MPP-Gilead-Aurobindo Sublicense Agreement.

<sup>489</sup> Cf. Cox, Krista L., *Hastings Science & Technology Law Journal*, 2012, No. 2, p. 312.

<sup>490</sup> Cf. Art. 10.4 of the MPP-Gilead-Aurobindo Sublicense Agreement.

<sup>491</sup> Cf. Art. 10.1 of the MPP-ViiV Healthcare-Aurobindo Sublicense Agreement.

<sup>492</sup> Cf. Art. 11.3 of the MPP-ViiV Healthcare-Aurobindo Sublicense Agreement.

<sup>493</sup> Cf. Art. 11.4.2 (i) of the MPP-ViiV Healthcare-Aurobindo Sublicense Agreement.

<sup>494</sup> Cf. Art. 11.4.2 (ii) of the MPP-ViiV Healthcare-Aurobindo Sublicense Agreement.

member, observer or affiliate to ICH, ViiV Healthcare may immediately terminate the agreement.<sup>495</sup> Supplying products or raw materials outside the permitted territory or supplying them to a third party, which might sell products or raw materials outside the approved territory, is a further reason for the complete termination of the sublicense or a termination in regard to the relevant patents by the licensor. The same applies if a third party's patent rights are infringed by the sublicensee's use of the patent in the territory as well as in case ViiV Healthcare loses the right to grant licenses or it expires.

Furthermore, if ViiV Healthcare is demanded to pay royalties for the sale of products or raw materials by the sublicensee and the sublicensee does not fulfill the requirements, or if legal control or ownership of the sublicensee and, respectively or, its affiliates change in a way ViiV Healthcare considers significant, the licensor can also terminate the sublicense agreement completely or in regard to the relevant patent.<sup>496</sup> In case one of the parties is bankrupt or insolvent or goes into liquidation, the other parties have the right to terminate the agreement as well.<sup>497</sup> In addition to that, if the sublicensee does not provide sufficient access to ABC in the approved territories within 180 days after a notification by the licensor, the licensor also has the right to immediately terminate the sublicense agreement.<sup>498</sup> Regarding enforcement, it is the task of the MPP to call on the sublicensee to cure an arisen breach, while providing ViiV Healthcare with a copy. In case the breach is not remedied and ViiV Healthcare requests a termination of the sublicense agreement, the MPP needs to fulfill the termination.<sup>499</sup> However, the sublicense agreement may be terminated by the sublicensee at any time within 30 days after written notification to the licensor.<sup>500</sup>

### **The Roche patents**

Since Roche directly supplies HIV treatment organizations with valganciclovir, there are no sublicense agreements and no provisions on terminations of such.

With all the three licenses in the pool, which have already been sublicensed to generic manufacturers, the number of justifications for termination is far more comprehensive with the sublicense agreements than with the license agreements. Partially, termination provisions of license and sublicense agreement are identical. For instance, both the MPP and the sublicensees

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<sup>495</sup> Cf. Art. 3.4 of the MPP-ViiV Healthcare-Aurobindo Sublicense Agreement.

<sup>496</sup> Cf. Art. 11.5 of the MPP-ViiV Healthcare-Aurobindo Sublicense Agreement.

<sup>497</sup> Cf. Art. 11.7 of the MPP-ViiV Healthcare-Aurobindo Sublicense Agreement.

<sup>498</sup> Cf. Art. 11.9 S. 1 and 2 of the MPP-ViiV Healthcare-Aurobindo Sublicense Agreement.

<sup>499</sup> Cf. Art. 3.2 of the MPP-ViiV Healthcare License Agreement.

<sup>500</sup> Cf. Art. 11.11 of the MPP-ViiV Healthcare-Aurobindo Sublicense Agreement.

may terminate the licenses, respectively sublicense agreements at any time upon 30 days prior written notice to Gilead. The opportunity to quit the sublicense agreement within 30 days also exists for sublicensees of ViiV Healthcare. Moreover, the MPP-Gilead Sublicense Agreements even offer the opportunity to terminate the sublicenses immediately on an API basis, while the rest of the sublicenses remain standing. This provision offers flexibility and concessions to generic manufacturers.

## **7. Effectiveness of the License Agreements**

### **7.1 The MPP-NIH License**

Through being the first patent holder joining the MPP and through being strongly supported to participate by the American government, the NIH as a public institution gave credence to the MPP as a new established organization.<sup>501</sup> The political support of the American government was considered especially promising, since the majority of ARV patent holders can be found in the United States.<sup>502</sup> Moreover, other publicly funded research institutions and patent holders were expected to emulate the NIH.<sup>503</sup>

The patents licensed by the NIH may be used for “treatment and prevention of medical conditions affecting humans”<sup>504</sup> and thus involve a broad field of use. Nevertheless, although additionally all low- and middle-income countries are covered, so that potentially benefits could be provide to more than 29.2 million people, the license only exhibits a marginal practical usefulness. Indeed, the license allows sublicensees to conduct research and development in countries, which provide patent-protection for darunavir to the NIH.<sup>505</sup> But due to the fact that the NIH is not the sole patent holder, the license does not permit for the generic production of darunavir for the benefit of HIV/AIDS patients. To manufacture and sell the ARV, the subsidiary patents of Tibotec, a subsidiary of Johnson & Johnson, are necessary.<sup>506</sup> As long as Tibotec does not license its patents regarding darunavir to the MPP, the company is able to prevent the production and sale of the ARV in the countries concerned.<sup>507</sup> Thus, whilst Tibotec does not join the MPP, a hold-out problem exists.<sup>508</sup>

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<sup>501</sup> Cf. Cox, Krista L., *Hastings Science & Technology Law Journal*, 2012, No. 2, p. 301.

<sup>502</sup> Cf. Mullard, Asher, *Nature Medicine*, 2010, No. 12, p. 1351.

<sup>503</sup> Cf. Medicines Patent Pool (2010a), p. 2.

<sup>504</sup> Appendix B II (a) of the MPP-NIH License Agreement.

<sup>505</sup> Cf. Medicines Patent Pool (2010a), p. 2.

<sup>506</sup> Cf. Medicines Patent Pool (2013j).

<sup>507</sup> Cf. Medicines Patent Pool (2010a), p. 1f.

<sup>508</sup> Cf. Lerner, Josh/Tirole, Jean (2008), p. 159.

At the moment, there are no ongoing negotiations with Tibotec.<sup>509</sup> The company stated that to ensure the availability of darunavir, it has directly concluded voluntary licenses with generic manufacturers.<sup>510</sup> For instance in 2008, Tibotec agreed on a bilateral license for the manufacture of darunavir with the Indian manufacturer Emcure.<sup>511</sup> In addition to the production of darunavir, Emcure may develop fixed-dose combinations and manufacture API as well. The geographic scope of the bilateral license, however, is limited to India, where patent applications on darunavir have been refused later.<sup>512</sup> Therefore, one might also assume that the voluntary license to Emcure was an attempt to circumvent patent opposition. Since royalties with the Tibotec-Emcure License amount 5%, this is almost the amount of royalties a generic sublicensee would probably pay under a MPP License.

Although the ARV is only ranked as Level 2 Priority, it would be very sensible to license darunavir to the pool in order to enhance the effectiveness of the MPP-NIH License. Besides darunavir, with etravirine and rilpivirine are two other ARVs of Tibotec on the MPP's Target Medicines List.<sup>513</sup>

## 7.2 The MPP-Gilead License and associated sublicenses

The MPP-Gilead License Agreement is “far from perfect”<sup>514</sup>. Especially the control of API and product manufacture by Gilead has been criticized for being “problematic and discriminatory”<sup>515</sup>. By only allowing Indian companies to produce API and to manufacture the products, competition is sharply restricted on one country. Additionally, north-south transfer of technology and the possibility to build up manufacturing capacities in developing countries are denied, although this could contribute to strengthen local economic development.<sup>516</sup> Moreover, access to potentially cheaper API through supply by other emerging countries is prohibited.<sup>517</sup> This is also problematic in the way that generic prices would be lower if API could be sourced less expensive. In addition, by excluding any other potential API manufacturer from outside India, market concentration on Indian suppliers is further enhanced.<sup>518</sup> Probably, Gilead applies the restriction on API suppliers to benefit from a decrease in costs of its own suppliers. Additionally, with the limitation on Indian product manufacturers Gilead probably

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<sup>509</sup> Cf. Medicines Patent Pool (2013h).

<sup>510</sup> Cf. Johnson & Johnson/Tibotec (2011).

<sup>511</sup> Cf. Médecins Sans Frontières (2013), p. 79.

<sup>512</sup> Cf. Patent Opposition Database (n.y.).

<sup>513</sup> The Medicines Patent Pool (2013j).

<sup>514</sup> Baker, Brook (2011).

<sup>515</sup> Médecins Sans Frontières (2011), p. 6.

<sup>516</sup> Cf. Cox, Krista L., *Hastings Science & Technology Law Journal*, 2012, No. 2, p. 310.

<sup>517</sup> Cf. ITPC/I-MAK (2011b), p. 8.

<sup>518</sup> Cf. BUKO Pharma-Kampagne, *Pharma-Brief*, 2011, No. 7-8, p. 2.

aimed to create a system requiring the payment of royalties, because patents existed, respectively were pending in the country.<sup>519</sup>

However, since the sublicenses are unbundled, the agreements provide generic manufacturers with sufficient flexibility to circumvent the payment of royalties based on weak patent claims. Sublicensees may choose to terminate the sublicenses for a particular ARV, while using sublicenses for others. Hence, no sublicensee has to pay royalties on generic manufacturers in case there is only a weak patent claim, which will probably be rejected. Because TDF does not receive patent protection in the majority of countries in the licensed territory, several Indian generic manufacturers made use of their API- and product-based termination right and quit their sublicenses on TDF. Since Gilead's TDF patent later has been rejected for sooth, all sublicensees are now able to manufacture and sell TDF without being obliged to pay royalties.<sup>520</sup> However, as mentioned above, Gilead has indicated its willingness to consider the permission of product manufacture in one particular country outside of India in future. Certainly, although generic manufacturers may be located in one additional country then, generic production will still not be permitted in any country of the approved territory, which remains controversial.<sup>521</sup>

The Gilead License at least covers all low-income countries and totally provides access to generic ARVs for about 25-26 million people living with HIV/AIDS in the licensed territories, depending on the respective ARV. In addition for use in regard to HIV/AIDS treatment, TDF may be applied to treat Hepatitis B, too. Moreover, Gilead, which states that 96% of their HIV/AIDS therapy medicines used in low- and middle-income countries is produced and sold by licensing partners<sup>522</sup>, has by licensing five ARVs, which is the highest number of ARVs granted by a company to the MPP until today, proven its willingness to provide access to HIV/AIDS medicines in the developed world. However, in comparison with the MPP-NIH and the MPP-ViiV Healthcare License, several middle-income countries are excluded from the license agreement. For instance Brazil, which represents a key emerging ARV market and even has refused a TDF patent, is not part of the licensed territory. The reason for its exclusion might be that this way Gilead tries to protect its most important future markets.<sup>523</sup> Albeit, one needs to take into account that in contrast to the wide scope of the MPP-Gilead License, the MPP-NIH License does currently not allow for the manufacture of darunavir and the MPP-ViiV Healthcare License solely involves one ARV, which is ABC, but which is only

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<sup>519</sup> Cf. Cox, Krista L., *Hastings Science & Technology Law Journal*, 2012, No. 2, p. 311.

<sup>520</sup> Cf. *Ibid.*, p. 313f.

<sup>521</sup> Cf. *Ibid.*, p. 310.

<sup>522</sup> Cf. Gilead (2013b).

<sup>523</sup> Cf. ITPC/I-MAK (2011b), p. 8.

licensed for pediatric use. Furthermore, the MPP-Gilead License allows for the development of combination products and pediatric formulations, what the MPP-ViiV Healthcare License does not. This seems to make the MPP-Gilead License more effective than the other licenses in regard to the provision of generic ARVs to people infected with HIV/AIDS.

Countries excluded from the licensed territories may still source ARVs from Indian generic producers under a compulsory license. Concerns that a permission to supply under such license by Gilead is necessary have been removed with the Second Amendment to the License Agreement. In case Gilead has valid patent claims on the ARV concerned in India, the supply of generic ARVs outside the licensed territories by an Indian sublicensee depends on a compulsory license for export, which has to be granted by the Indian government. Thus, countries, which are not part of the geographic scope of the MPP-Gilead License, could consider striving for compulsory licenses to increase access to ARVs. Doing so in a coordinated manner would further make patent holders realize that the exclusion of middle-income countries from licenses “will be met with compensatory strategies”<sup>524</sup>.

None of the medicines included in the MPP-Gilead License are currently indicated for pediatric use.<sup>525</sup> However, sublicensees are allowed to develop pediatric formulations, even without the obligation to pay royalties on the sale of the developed formulations, which constitutes a positive concession to generic manufacturers.

### **7.3 The MPP-ViiV Healthcare License and associated sublicenses**

Although the majority of HIV-infected children is included in the MPP-ViiV Healthcare License Agreement, which hence provides access to generic ABC to 3.36 million children living in the licensed territory, the license does not allow to sell ABC to adults. Since adults constitute 90% of all persons infected with HIV worldwide<sup>526</sup>, the MPP-ViiV Healthcare License solely covers a small group of people living with HIV/AIDS. This is especially tragic because most children are infected with HIV/AIDS due to the infection of their parents. ABC is a suitable ARV for co-formulation with lamivudine, which is also available as a generic in many countries but in some states presents a patent-protected combination.<sup>527</sup> Since ViiV Healthcare owns the patents on lamivudine, it prevented the development of a combined product via a generic manufacturer by not granting a license on both drugs to the MPP.

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<sup>524</sup> Baker, Brook (2011).

<sup>525</sup> Cf. ITPC/I-MAK (2011a), p. 3.

<sup>526</sup> Cf. BUKO Pharma-Kampagne, Pharma-Brief, 2013, No. 3, p. 6.

<sup>527</sup> Cf. Baker, Brook (2013).

However, the MPP-ViiV Healthcare License Agreement is better in comparison to the MPP's license with Gilead in regard to its royalty provisions. Because the ViiV Healthcare License includes no royalties and generic manufacturer do not have to make up for royalties they are obliged to pay, generics can be sold as cheap as possible. Moreover, with 118 countries, the ViiV Healthcare License exhibits a wider geographic scope than the MPP-Gilead License. Nevertheless, Gilead licensed five ARVs to the MPP, whereas ViiV Healthcare licensed only one for pediatric use.

According to the Memorandum of Understanding between the MPP and ViiV Healthcare, at the time ViiV Healthcare receives FDA or EMA approval for one of its current pipeline products, which are eligible for pediatric HIV/AIDS treatment, they will be licensed to the MPP with the same geographical scope as ABC.<sup>528</sup> Current HIV pipeline products are dolutegravir and 1265744, which are integrase inhibitors<sup>529</sup> featuring reduced side effects and requiring lower dosages, which could contribute to lower costs<sup>530</sup>, as well as a fixed-dose combination of dolutegravir, ABC and lamivudine.<sup>531</sup> Although the Memorandum of Understanding is not binding, this declaration of intent might lead to additional licenses on patents by ViiV Healthcare in future.

#### **7.4 The MPP-Roche License**

Valganciclovir is the only drug of that licensed to the MPP, which is not an ARV usable for direct HIV/AIDS treatment. Instead of this, with the MPP-Roche License, a frequent co-infection of HIV/AIDS is tackled. 138 countries are part of the license agreement, wherefore 27.7 million people infected with HIV/AIDS can benefit from access to cheaper medicines in case they become diseased by CMV retinis. The disease is predominantly prevalent with people infected with HIV/AIDS living in Asia and Latin America. Since numerous countries of these regions are included in the license agreement, the majority of people the most likely to report ill health can benefit from cheaper access to the drug.

Nevertheless, until now, since Roche directly supplies HIV treatment organizations with valganciclovir, no sublicenses have been granted so far. Not before one year after the license agreement came into force, Roche and the MPP will enter into negotiations about licensing and technology transfer to third parties in the territory, or outside the approved territory<sup>532</sup>, to

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<sup>528</sup> Cf. Art. 1 (b) of the Memorandum of Understanding between the MPP and ViiV Healthcare.

<sup>529</sup> Cf. GSK (2013), p. 1.

<sup>530</sup> Cf. Baker, Brook (2013).

<sup>531</sup> Cf. GSK (2013), p. 1.

<sup>532</sup> Cf. Art. 8.2 of the MPP-Roche License Agreement.

guarantee low-cost supply of valganciclovir.<sup>533</sup> Hence, there will not be any negotiations about licenses before August 2014. The impossibility of generic manufacture prevents sale prices of drugs, which are below the 250 CHF per pack Roche demands now, as well as the up building of local manufacturing capacities. Consequently, regarding access to valganciclovir, dependence on developed countries and the patent holder remains to the same extent.

A recent study on CMV prevalence in people infected with HIV/AIDS showed that there is an urgent need to improve the detection of the disease.<sup>534</sup> This is something, which is not tackled by the MPP-Roche License. However, if screening methods will not be improved, people infected with HIV/AIDS and CMV retinitis, who even live in countries covered by the license, will not be able to benefit from increased and cheaper access to valganciclovir, because their co-infection with CMV disease will probably not be detected then.

As the MPP obviously recognized a “significant medical need”<sup>535</sup> for licensing saquinavir in developing countries, Roche entered into negotiations with the MPP about a license on that ARV<sup>536</sup> and hence people infected with HIV/AIDS might in future additionally benefit from access to low-cost saquinavir. Furthermore, in case the MPP requests Roche to widen the approved territory for supply of valganciclovir due to unmet needs in excluded countries, Roche holds out the prospect that then it will discuss in good faith with the MPP about expanding the territory.<sup>537</sup>

In conclusion, the licenses in the Pool partially strongly differ regarding the licensing terms. The possible fields of use, the territory they cover, the number of ARVs patents are licensed on, the obligation to pay royalties or not, the scope of grant back provisions and the possibility to terminate the licenses and sublicenses vary among the different licensors. However, besides their disparities, the Gilead, the ViiV Healthcare and the Roche License instantaneously provide the opportunity to facilitate access to cheaper ARVs. Even without generic supply, the MPP-Roche License cuts the sale price of valganciclovir, which only costs 250 CHF per pack in the licensed territories, by up to 90%. Only regarding the NIH License, the accession of the subsidiary patent holder to the MPP is required, before generics may be manufactured. In reference to the Roche License, for sure generic competition is a more sustainable

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<sup>533</sup> Cf. Art. 8.1 of the MPP-Roche License Agreement.

<sup>534</sup> Cf. Ford, Nathan et al., *Clinical Infectious Diseases*, 2013, No. 1, p. 10.

<sup>535</sup> Art. 3 of the MPP-Roche License Agreement.

<sup>536</sup> Cf. Medicines Patent Pool (2013): *Target Medicines*.

<sup>537</sup> Cf. Art. 2.4 of the MPP-Roche License Agreement.

method to substantially decrease prices ARVs.<sup>538</sup> However, in August 2014, negotiations about licenses from Roche to third parties in the territory can be started.

## **8. Participation of patent holders in the MPP**

### **8.1 Motives for patent holders to participate in the patent pool<sup>539</sup>**

Since royalty rates are relatively low, patent holders probably not join the MPP due to financial incentives. There are other reasons for the decision to license patents to the Pool. The most important reason for pharmaceutical companies to voluntarily join the MPP seems to be public pressure to enhance access to medicines in the developing world.<sup>540</sup> Due to their market presence and mainstream fame, especially large companies face such public and political expectations. In the past ten years, companies received rising attention by the public. This can especially be referred to the strong mobilization of media by NGOs, but also to the adoption of the Doha Declaration in 2001. Participating in the MPP represents an opportunity for pharmaceutical companies to yield the pressures from the global health community. In turn for licensing their patents, the patent holders might be regarded as assuming corporate social responsibility.<sup>541</sup> Hence, joining the MPP might be a strategy of pharmaceutical companies to avoid bad publicity and gain prestige, because taking such pro-active measures to enhance access to medicines could lead to a reputational boost.<sup>542</sup> Most contributors to the MPP state that they aim to improve global health. For instance, Dr Dominique Limet, the CEO of ViiV Healthcare, stated that ViiV Healthcare has committed to play “our part to address the gaps in care and treatment of pediatric HIV”<sup>543</sup>. Gilead and Roche mention similar statements.<sup>544</sup> Publicly participating in the Pool shows consumers and NGOs that the company seriously pursues its intentions.<sup>545</sup> The satisfaction of the demands of customers in industrial countries in turn secures turnovers in important markets. Moreover, the goodwill the pharmaceutical companies may receive through participation in the MPP could lead to extra sales and profits in developed countries.

Institutions like the Access to Medicines Foundation with its Access to Medicines Index might additionally have contributed to incentivize companies’ participation in the Patent Pool.

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<sup>538</sup> Cf. Waning, Brenda et al., *Globalization and Health*, 2010, No. 9, p. 13.

<sup>539</sup> Unfortunately, when directly approached the patent holders, which have already licensed patents on ARVs to the MPP, refused to make statements regarding their incentives to participate in the pool.

<sup>540</sup> Cf. Wagner-Ahlf, Christian (2013): Interview.

<sup>541</sup> Cf. Dionisio, Daniele, *Transnational Biomedicine*, 2011, No. 1, p. 3.

<sup>542</sup> Cf. Bermudez, Jorge/t Hoen, Ellen, *The Open AIDS Journal*, 2010, No. 1, p. 39.

<sup>543</sup> ViiV Healthcare (2013).

<sup>544</sup> Cf. Gilead (n.y.) and Roche (2013).

<sup>545</sup> Cf. Mullard, Asher, *Nature Medicine*, 2010, No. 12, p. 1351.

The Index strives to “stimulate positive change by publicly encouraging pharmaceutical companies to step up their efforts to improve access to medicine”<sup>546</sup>. The receipt of a good rating, which could be used for promotion and reputation gains, might be an incentive to enhance efforts regarding the facilitation of access to ARVs in the developing world through licensing patents to the MPP. The monitoring by the Index is much more effective than a commitment of a pharmaceutical company to respect its own voluntary guidelines, which normally have a less comprehensive scope. Besides, it usually contradicts the interest of firms to consistently monitor and evaluate their performance based upon self-imposed codes of conduct, because this is linked to high monitoring costs.<sup>547</sup> After its accession to the MPP, the Access to Medicines Index ranked Gilead by far first in the category “Patents & Licensing” in 2012.<sup>548</sup> Furthermore, through participation in the MPP pharmaceutical companies can avoid political costs of patent-related conflicts like the risk of the granting of compulsory licenses.<sup>549</sup> Membership in the Pool might be used to demonstrate that the patent system does not hamper access to ARVs in developing countries and that there is no need for compulsory licenses, whereby pharmaceutical companies could achieve a policy win.<sup>550</sup> Making their patents available through the MPP might appear more attractive to patent holders than being exposed to the threat of non-voluntary measures like compulsory licenses and patent oppositions, which can come along with reputational loss. Furthermore, with compulsory licenses’ royalty rates of 0.5% to 5%<sup>551</sup>, royalties could be even higher with licenses via the MPP.<sup>552</sup> The criticism of pharmaceutical companies’ rather superficial interventions like non-enforcement of patents or donation of drugs as being unsustainable and harmful could be overcome by licensing to the Pool as well.<sup>553</sup>

Technically, pharmaceutical companies, which are vertically integrated, meaning that they conduct research and development as well as manufacture products and have patents and downstream operations at their disposal, more likely join patent pools.<sup>554</sup> This can be referred to the fact that these companies do not completely depend on licensing royalties like firms, which are not vertically integrated and just conduct research. Since Gilead, ViiV Healthcare and Roche are vertically integrated companies, this assumption seems to apply to the MPP,

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<sup>546</sup> Cf. Access to Medicines Index (2012b).

<sup>547</sup> Cf. Grover, Anand et al., *Journal of Law, Medicine & Ethics*, 2012, No. 2, p. 242.

<sup>548</sup> Cf. Access to Medicines Index (2012a), p. 57.

<sup>549</sup> Cf. Bermudez, Jorge/t Hoen, Ellen, *The Open AIDS Journal*, 2010, No. 1, p. 39.

<sup>550</sup> Cf. Gold, E. Richard et al. (2007), p. 38.

<sup>551</sup> Cf. Center for Global Health R&D Policy/The Results for Development Institute (2012), p. 16.

<sup>552</sup> Cf. *Ibid.*, p. 30.

<sup>553</sup> Cf. Gold, E. Richard et al. (2007), p. 38.

<sup>554</sup> Cf. Layne-Farrar, Anne/Lerner, Josh, *International Journal of Industrial Organization*, 2011, No. 2, p. 294.

too. However, although the NIH is a pure research facility, it did also join the Pool. This may follow from the fact that the NIH is a public authority funded by taxes, which does not absolutely depend on licensing fees. Besides, the NIH's objective to benefit the public imposes the responsibility to carefully make use of intellectual property, which might be a further reason for the NIH's accession to the MPP.

A survey of the OECD showed that small and large companies tend to engage more often in licensing as licensee or licensor than medium-sized companies.<sup>555</sup> Although the licensors and licensees of the MPP are rather large companies, one could imagine that in future also small companies become pool members. Small companies are frequently more flexible and willing to experiment with novel business models than large ones.<sup>556</sup> Furthermore, small pharmaceutical companies, which do either have worldwide presence, nor distribution canals, can make use of licensing schemes as distribution networks. Agreements with generic manufacturers in the developing world could be developed into partnerships, where generic producers contribute their local expertise about ARV registration, procurement, supply chain management as well as logistics in the respective country.<sup>557</sup>

Royalty provisions additionally influence, whether firms participate in a patent pool or not.<sup>558</sup> In classical patent pools value proportional rules, which imply that royalties are distributed in accordance to a patent's value and fit into traditional economic thinking, motivate companies to join the pool.<sup>559</sup> The MPP also allows for such a way of value-based royalty-setting: When drawing up the license agreement, the patent holders are able to decide on individual royalty amounts for each ARV licensed. For instance, Gilead has determined that different shares of total net sales of generic ARVs, which vary between 3% and 5%, have to be paid to the company. In contrast to that, pool members may also waive royalties, such as ViiV Healthcare did, when deciding not to demand any royalties for net sales on pediatric ABC. A third possibility was applied by Roche, which determined a certain fixed price at which it will supply HIV treatment organizations with valganciclovir. Hence, the MPP offers long-range flexibility regarding royalties to patent holders.

Besides, the participation in the Pool might offer access to new markets as well as to information about those markets to pharmaceutical companies.<sup>560</sup> Being provided with essential

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<sup>555</sup> Cf. Pluvia Zuniga, Maria/Guellec, Dominique (2009), p. 3.

<sup>556</sup> Cf. Gold, E. Richard et al. (2007), p. 40.

<sup>557</sup> Cf. Janssen (2011), p. 3.

<sup>558</sup> Cf. Layne-Farrar, Anne/Lerner, Josh, *International Journal of Industrial Organization*, 2011, No. 2, p. 296.

<sup>559</sup> Cf. *Ibid.*, p. 269.

<sup>560</sup> Cf. Sukkar, Elizabeth, *British Medical Journal*, 2009, No. 7701, p. 975 and Bermudez, Jorge/'t Hoen, Ellen *Open AIDS Journal*, 2010, No. 1, p. 39.

information on the environmental conditions of these markets is important because, due to the insecure market potential, research on drugs adapted to the needs of developing countries is rarely conducted.<sup>561</sup> This does also applies regarding market size: Since it is easier to anticipate the size of the developing world markets for new formulations and fixed-dose combinations of ARVs as a licensor, companies participating in the MPP can reach a higher level of certainty and more reliable sources of revenues.<sup>562</sup>

## **8.2 Rejection of patent holders to join the pool<sup>563</sup>**

Seven out of eight pharmaceutical companies holding patents on ARVs grant voluntary licenses on bilateral basis, which get even more expanded in regard to territories and medicines covered.<sup>564</sup> However, if there is such participation in voluntary licensing of patents on ARVs, but there are at least three companies, which are not willing to enter into negotiations about participation in the MPP<sup>565</sup>, there need to be several reasons, which prevent pharmaceutical companies to join the MPP. In general, due to the voluntary nature of patent pools, one half to two-thirds of eligible firms chose not to join a patent pool.<sup>566</sup> Therefore, the rate of refusal to start negotiating about membership of one third is even lower with the MPP.<sup>567</sup>

Most of all, the issue of whether to join or not to join a patent pool is a matter of maximizing a firm's profits.<sup>568</sup> Pharmaceutical companies' most important premise in course of business is to maximize gains. The reason to file a patent for an invention is to protect the own discovery and to recuperate research and development investments through the commercialization of the patented invention.<sup>569</sup> Therefore, one of the primary concerns of patent holders regarding participation in the pool is the loss of control of their intellectual property.<sup>570</sup> Since with most pharmaceutical companies business activities are based on patent rights, the loss of secrecy and exclusivity is connected with far-reaching consequences. Because the MPP is a new and complex institution, mistrust towards the pool might prevail on the patent holders' sight. Lim-

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<sup>561</sup> Cf. Gebauer, Thomas (2008), p. 10.

<sup>562</sup> Cf. Gold, E. Richard et al. (2007), p. 39f.

<sup>563</sup> Unfortunately, when directly approached, the patent holders, which have not licensed patents on ARVs to the MPP until now, refused to make statements regarding the reason for their refusal of participation in the pool.

<sup>564</sup> Cf. Beyer, Peter (2013), p. 242.

<sup>565</sup> Cf. Abbott (2011); Johnson & Johnson/Tibotec (2011) and Merck (2011).

<sup>566</sup> Cf. Layne-Farrar, Anne/Lerner, Josh, *International Journal of Industrial Organization*, 2011, No. 2, p. 300.

<sup>567</sup> Three of nine companies did not start negotiations about accidence to the MPP yet. Cf. *Medicines Patent Pool* (2013a).

<sup>568</sup> Cf. Layne-Farrar, Anne/Lerner, Josh, *International Journal of Industrial Organization*, 2011, No. 2, p. 296.

<sup>569</sup> Cf. Verbeure, Birgit et al., *Trends in Biotechnology*, 2006, No. 3, p. 118.

<sup>570</sup> Cf. Wagner-Ahlf, Christian (2013): Interview and van Zimmeren, Esther et al., *Trends in Biotechnology*, 2011, No. 11, p. 574.

ited experience and the low number of empirical research may also contribute to that.<sup>571</sup> The Moreover, with the MPP, current pool members solely obtain a small amount of revenues according to net sales of generics produced or granted royalty-free licenses. Due to the freedom to set prices and circumvent competition outside the pool, profits are higher for patent holders, when they keep their monopolistic position.<sup>572</sup> The ARV market had an estimated value of US-\$ 835 million in 2010, which included an US-\$ 659 million market for adult first-line ARVs, a US-\$ 95 million market for adult second-line ARVs as well as an US-\$ 81 million market for pediatric ARV<sup>573</sup>, and there are increasingly more manufacturers and formulations.<sup>574</sup> Therefore, patent holders may decide to rather try to hold their own on the market through high-price sales instead of voluntarily approving a drop in profits due to losing several country markets. In addition to that, some firms are reluctant to join the MPP because they fear that the low-price generics manufactured may re-enter high-income markets.

Companies, which only conduct research and development, but do not manufacture on their own, solely receive revenues through licensing fees they obtain for their patents.<sup>575</sup> These pure inventors strive to maximize royalty income.<sup>576</sup> If it is possible to earn higher royalties outside the Patent Pool, it is the best option for firms focused on research and development not to join the pool. Nevertheless, this does not apply to public research institutions, which are tax-funded and independent of licensing fees. To pursue their public benefit approach, they should rather participate in the Pool. Furthermore, holders of blocking patents, which may prevent the manufacture of an ARV, are economically better off than companies, which already have licensed their patents on the ARV concerned to the Pool, since they are still able to set prices without restriction.<sup>577</sup> This might explain, why Johnson & Johnson/Tibotec is not willing to participate in the MPP.

Moreover, pharmaceutical companies might refuse to license their patents to the MPP because this way, they would diminish their power.<sup>578</sup> Patents are sublicensed to generic manufacturers, who could build up expertise, which could potentially provide them with an advantage constituting a risk for participating companies.<sup>579</sup> Patent holders might fear that they create their own future competitors and lose their competitive advantage and market leadership in

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<sup>571</sup> Cf. van Zimmeren, Esther et al., Trends in Biotechnology, 2006, No. 3, p. 573.

<sup>572</sup> Cf. Rodriguez, Victor, The Open AIDS Journal, 2010, No. 1, p. 63.

<sup>573</sup> Cf. UNITAID (2012), p. 8.

<sup>574</sup> While 17 manufacturers produced 82 formulations in 2005, 26 manufacturers produced 274 formulations in 2011. Cf. UNITAID (2012), p. 8.

<sup>575</sup> Cf. Layne-Farrar, Anne/Lerner, Josh, International Journal of Industrial Organization, 2011, No. 2, p. 296.

<sup>576</sup> Cf. Lerner, Josh/Tirole, Jean (2008), p. 172.

<sup>577</sup> Cf. Lerner, Josh/Strojwas, Marcin/Tirole, Jean (2005), p. 5.

<sup>578</sup> Cf. OECD (2011), p. 20.

<sup>579</sup> Cf. Gold, E. Richard et al. (2007), p. 40.

developed countries in consequence of license agreements. In addition to that, originator companies apprehend that patent pooling could lead to an unbalanced surge of innovation, development and research activities undertaken by middle-income countries' manufacturers from India, China, Brazil, South-Africa and Thailand.<sup>580</sup>

During the last years, different voluntary approaches to enhance access to medicines in the developing world have been used by pharmaceutical companies: Beside tiered pricing and donations, non-enforcement as well as no filing of patents in least developed countries represent strategies pursued.<sup>581</sup> In addition to that, as mentioned before, a huge number of pharmaceutical companies, which hold patents on ARVs, grant voluntary licenses on bilateral basis. And bilateral licenses get even more expanded in regard to their territories and the medicines covered.<sup>582</sup> These measures can be quoted as examples of current company efforts to enhance access to ARVs in the developing world and used to justify refusal to participate in the Pool. Since the trend to voluntarily license patents on ARVs has risen even further with the creation of the MPP<sup>583</sup>, bilateral licenses might however also be used as a tool to circumvent participation in the pool. Moreover, the pharmaceutical companies Johnson & Johnson/Tibotec as well as Merck & Co., which both deny to enter into negotiations with the MPP<sup>584</sup>, initiated the HIV Medicines Alliance in May 2012.<sup>585</sup> Although the alliance has been criticized for its narrow scope and remaining control of patent holders, it could also be used as a justification for non-membership in the MPP.

Additionally, several companies apprehend that the MPP could be expanded from ARVs to lucrative medicines for cancer or heart diseases.<sup>586</sup> Companies, which did not conclude voluntary licenses on ARVs before might be detained from participation in the MPP by the complexity and costs of negotiations and drafting the licensing contracts.<sup>587</sup> Different corporate company cultures are also mentioned as reasons, why Gilead and ViiV Healthcare were willing to license to the MPP, but other companies, which hold ARV patents, are not, for instance AbbVie.<sup>588</sup> The strong criticism of early licenses, especially that of Gilead received in regard

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<sup>580</sup> Cf. Lunt, Susie, *Pharmafocus*, 2012, p. 22.

<sup>581</sup> Cf. International Federation of Pharmaceutical Manufacturers and Associations (2010), p. 10ff.

<sup>582</sup> Cf. Beyer, Peter (2013), p. 242.

<sup>583</sup> Cf. WHO/WIPO/WTO (2012), p. 180.

<sup>584</sup> Cf. Johnson & Johnson/Tibotec (2011) and Merck (2011).

<sup>585</sup> Cf. BUKO Pharma-Kampagne, *Pharma-Brief*, 2012, No. 6-7, p. 3.

<sup>586</sup> Cf. Gold, E. Richard et al. (2007), p. 40.

<sup>587</sup> Cf. Pluvia Zuniga, Maria/Guellec, Dominique (2009), p. 18.

<sup>588</sup> Cf. Center for Global Health R&D Policy/The Results for Development Institute (2012), p. 30.

to its limited geographic scope, might further reduce the incentive to become a pool member, if potential licensors anticipate to receive similar criticism.<sup>589</sup>

Additionally, many pharmaceutical companies are reluctant to join the MPP because they fear a sharp decrease in profits of the brand-name industry in middle-income countries.<sup>590</sup> In middle-income states like India and China, a significant percentage of the population is able to afford out-of-pocket spending: With 300 million people, 24.9% of the inhabitants of India, and with 800 million people, 59.4% of the Chinese population are able to pay the original sale price set by the manufacturer.<sup>591</sup> Besides, the Asian pharmaceutical market is expected to grow further due to economic development and growing demand.<sup>592</sup> This is a fact that pharmaceutical companies strive to exploit. However, although the MPP aims to include all low- and middle-income countries in the license agreements, since it negotiates licensing terms individually with every licensor, there is no compulsion to include every middle-income country in the licensed territory. Gilead, ViiV Healthcare and Roche have excluded several middle-income countries from the geographic scope of the licenses. Thereby, the drop in sales does not turn out that strong.

In total, even the patent holders, which have not been willing to start negotiations about participating in the MPP yet, did not voice a definite “No”.<sup>593</sup> Since the MPP is a new mechanism, there are always frontrunners willing to satisfy access demands in a new way, but also companies that keep distance at first and will not participate until more experience is built up. Therefore, there is the possibility that time will eliminate currently existing concerns and yet again persuade patent holders to become pool members.

### **8.3 Motives to become a sublicensee**

An advantage of the MPP is that generic manufacturers may obtain sublicenses on several ARVs, while just concluding one sublicense agreement. If the generic manufacturers would license the patents outside the Pool, they might have to negotiate individual licenses with several patent holders. Moreover, participation in the MPP presents an opportunity for generic manufacturers to license all the patents necessary for the manufacture of an ARV just from one entity, since the MPP tries to collect all the patents being indispensable for the manufac-

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<sup>589</sup> Cf. Center for Global Health R&D Policy/The Results for Development Institute (2012), p. 4.

<sup>590</sup> Cf. Medicines Patent Pool (2013f).

<sup>591</sup> Own calculations based on Statista (2013a); Statista (2013b) and Dionisio, Daniele, *Transnational Biomedicine*, 2011, No. 1, p. 3.

<sup>592</sup> Cf. Lunt, Susie, *Pharmafocus*, 2012, p. 22.

<sup>593</sup> Cf. Abbott (2011); Johnson & Johnson/Tibotec (2011) and Merck (2011).

ture of a certain ARV. In its function as a “one-stop-shop”<sup>594</sup>, the Pool exhibits the ability to offer all the necessary patents from different patent holders to the generic producer. Thereby, transaction costs can be comprehensively reduced for the sublicensees.<sup>595</sup> Besides, in contrast to voluntary bilateral licenses generic manufacturers may conclude directly with the patent holders, sublicenses granted by the MPP generally provide better terms to generic manufacturers, since patent holders do lose the possibility to sharply restrict licensing terms this way. Hence, with sublicenses via the MPP predominantly royalties are lower, the sublicenses allow for research and development and the geographic scope is wider.<sup>596</sup> Consequently, in contrast to bilaterally concluded license agreements sublicensing from the pool allows for higher profits, research and economies of scale.

Outside the Pool and apart from being granted a voluntary bilateral license of a pharmaceutical company, generic manufacturers are only permitted to manufacture ARVs, which are still patent-protected, if a compulsory license has been issued. Albeit, the problem of compulsory licenses is that they are granted on a country-by-country basis.<sup>597</sup> Sublicenses via the MPP however encompass territories of up to 118 countries.<sup>598</sup> As a consequence of the lower number of generics needed under a compulsory license, generic manufacturers are hardly able to achieve economies of scale through compulsory licenses. Additionally, in comparison to the MPP, compulsory licenses lead to higher transaction costs and greater uncertainty for generic producers.<sup>599</sup> This can be referred to bureaucratic hurdles as well as to the costs of obtaining regulatory approval for the production of generics, their production and remuneration as well as to their shipping and the adoption of measures to prevent re-export in case of a compulsory export license. As a consequence, via compulsory licenses, the generic manufacturer might not yield any profit except recoup its costs.<sup>600</sup> In addition to that, the process from granting the compulsory license until the manufactured generics can be transported to the destination country is very time-consuming. Hence, in comparison to sublicensing patents on ARVs via the MPP, compulsory licenses are a more cost-intensive and time-consuming mechanism for generic manufacturers.

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<sup>594</sup> Medicines Patent Pool (2013b).

<sup>595</sup> Cf. Bermudez, Jorge/t Hoen, Ellen, *The Open AIDS Journal*, 2010, No. 1, p. 38.

<sup>596</sup> Cf. Park, Chan et al. (2012).

<sup>597</sup> Cf. Art. 31 S. 1 of the TRIPS Agreement.

<sup>598</sup> Indeed, the MPP-Roche License encompasses a territory of 138 countries, but it does not allow for generic manufacture today.

<sup>599</sup> Cf. Bermudez, Jorge/t Hoen, Ellen, *The Open AIDS Journal*, 2010, No. 1, p. 39.

<sup>600</sup> Cf. Tsai, George, *Virginia Journal of International Law*, 2009, No. 4, p. 1081.

## 9. Critical evaluation of the MPP's effectiveness

### 9.1 Advantages

The MPP offers several advantages and possibilities to improve access to ARVs in developing countries compared to the current situation. The most striking advantage of the Pool is the facilitation of generic competition regarding HIV/AIDS treatment in the developing world. This provides the opportunity to decrease prices for ARVs. Since there are no research and development costs, which have to be recouped, generics prices are closer related to actual production costs and hence much lower. Moreover, by granting sublicenses on patented ARVs to several generic manufacturers, the MPP constitutes a remedy to increase competition in the ARV market.<sup>601</sup> Being exposed to competitors further restricts the profit margins of generic companies. The resulting lower sale price of generics makes them more affordable for people infected with HIV/AIDS living in poorer settings.<sup>602</sup> Hence, the MPP can contribute to close the accessibility gap in regard to ARVs, which exists between developed and developing countries.<sup>603</sup> This strongly differs from the current situation where, due to ARVs being patented by just a few pharmaceutical companies, almost monopolies exist.<sup>604</sup>

Besides, since there is a legitimate concern that first- and second-line ARVs might obtain patent protection in countries like India, which is the most important generic manufacturer in the world, during the next years<sup>605</sup>, the MPP constitutes a mechanism to ensure that ARVs can still be manufactured at low cost and sold in the developing world. Through facilitating price reductions, the MPP serves a pro-competitive purpose<sup>606</sup> and in so far represents an alternative to exclusive single-firm production and bilateral licensing.<sup>607</sup> Moreover, since for instance Gilead has even licensed products to the MPP, which had not been approved by the FDA yet<sup>608</sup>, the license agreements may even allow for early generic competition. Despite the lack of approval, sublicensees can immediately start preparing to market the drugs. Hence, developing country patients will benefit from access to the newest ARVs, in cost-less generic form, without delay.<sup>609</sup> Because predominantly the license agreements are valid as long as

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<sup>601</sup> Cf. Gold, E. Richard et al. (2007), p. ii.

<sup>602</sup> Cf. Corrick, Fenella/Watson, Robert/Budhdeo, Sanjay, *Philosophy, Ethics, and Humanities in Medicine*, 2011, No. 13, p. 2.

<sup>603</sup> Cf. Zakus, David et al., *The Open AIDS Journal*, 2010, No. 1, p. 25.

<sup>604</sup> Cf. Corrick, Fenella/Watson, Robert/Budhdeo, Sanjay, *Philosophy, Ethics, and Humanities in Medicine*, 2011, No. 13, p. 2.

<sup>605</sup> Cf. Center for Global Health R&D Policy/The Results for Development Institute (2012), p. 3.

<sup>606</sup> Cf. Nagaoka, Sadao (2004), p. 147.

<sup>607</sup> Cf. van Zimmeren, Esther et al., *Trends in Biotechnology*, 2011, No. 11, p. 570.

<sup>608</sup> Cf. Medicines Patent Pool (2011b).

<sup>609</sup> Cf. Cox, Krista L., *Hastings Science & Technology Law Journal*, 2012, No. 2, p. 305.

patents are, it is also secured that the manufacture of generics via the MPP is possible for all the years monopolistic rights exist.

Through voluntary licenses obtained by patent holders and sublicensed to generic manufacturers, the MPP allows for the production of patented ARVs. Just as standard-setting pools, the Pool comes along with the opportunity of one stop shopping. Instead of individual agreements only one license agreement, which determines all the patents licensed as well as the licensing terms has to be concluded with the patent holder. The same applies to sublicenses: Just one sublicense agreement has to be concluded by generic manufacturers to sublicense patents on several ARVs. This is less time-intensive and bureaucratic and hence reduces the transaction costs, which arise from search and negotiations.<sup>610</sup> Thus, the MPP has a slimming and simplifying effect in regard to the licensing process.<sup>611</sup>

The license agreements concluded by the MPP do not only bring along added value in regard to affordability of ARVs, but also in regard to availability, since license agreements partially permit generic manufacturers to produce locally. Therefore, the MPP also contributes to build up local manufacturing capacities in developing countries.<sup>612</sup> Although not all licensors allow for manufacture in every territory country, the NIH and ViiV Healthcare do. This represents an opportunity for developing states that still lack the necessary technological capacity and infrastructure to produce ARVs on their own to improve their abilities. For instance South Africa is a country, where sustainable local manufacturing capacities arose after making use of voluntary licenses.<sup>613</sup> The establishment of local manufacturing capacities does not only improve access to ARVs, but also streamlines domestic procurement systems, which comes along with the potential to create jobs and improve infrastructure.<sup>614</sup>

Additionally, the MPP facilitates collaborative research so that improved and pediatric formulations as well as fixed-dose combinations can be developed. This is important regarding that especially the market for new ARVs is hardly competitive and evolves only slowly.<sup>615</sup> The MPP has the ability to mitigate the problem of the anti-commons, which arises from the fragmentation of patent rights. The problem of the anti-commons refers to related inventions being patented by numerous companies and thus leading to a patent thicket, which can impede

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<sup>610</sup> Cf. Gallini, Nancy (2011), p. 24.

<sup>611</sup> Cf. Wagner, Christian (2008), p. 124.

<sup>612</sup> Cf. Corrick, Fenella/Watson, Robert/Budhdeo, Sanjay, *Philosophy, Ethics, and Humanities in Medicine*, 2011, No. 13, p. 2.

<sup>613</sup> Cf. Osewe, Patrick L./Nkrumah, Yvonee K./Sackey, Emmanuel K. (2008), p. 37.

<sup>614</sup> Cf. Corrick, Fenella/Watson, Robert/Budhdeo, Sanjay, *Philosophy, Ethics, and Humanities in Medicine*, 2011, No. 13, p. 2.

<sup>615</sup> Cf. Waning, Brenda et al., *Globalization and Health*, 2010, No. 9, p. 1.

the development of new products.<sup>616</sup> Such patent thickets have been observed for pharmaceuticals.<sup>617</sup> The overlapping patent rights exacerbate the commercialization of new innovations<sup>618</sup> because the multitude of negotiations necessary to obtain licenses from every patent holder is not solely time-consuming and associated with high transactions costs, but probably also engenders the problem of royalty stacking.<sup>619</sup> Royalty stacking means that each holder of a complementary patent demands a royalty which seems to be reasonable from an isolated point of view, but which is an unacceptable burden in overall view.<sup>620</sup> By boosting research and development through granting access to the relevant patents, the MPP is able to facilitate the circulation of knowledge and makes it possible to pursue the technology transfer objective of a patent system.<sup>621</sup> As the costs and risks of research and development can be reduced by the pool, the costs for the final product paid by the end users can be lowered significantly as well.<sup>622</sup>

In addition to that, the pool complies with FRAND terms, which is a licensing obligation for standard-setting pools.<sup>623</sup> This means that the MPP provides fair, reasonable, and non-discriminatory access to the patents for every company, which strives for a sublicense. Moreover, sublicensees can operate freely, which also underlines the beneficial and pro-competitive impact of the MPP.<sup>624</sup> The Pool's ability to increase welfare also becomes clearly through the non-exclusive licenses it grants.<sup>625</sup> To ensure equality between the contributors and to avoid recurring negotiations with every patent holder, standard form agreements with identical licensing, geographic coverage and royalty provisions, such as applied by Gilead, are useful as well.<sup>626</sup> Furthermore, generic manufacturers, that do neither command capacity, nor skill to negotiate licensing terms on their own, benefit from the MPP's intermediary position.<sup>627</sup> Besides, as license and sublicense agreements as well the negotiation status with different patent holders are public, the pool is a very transparent institution.

Although the MPP is focused on the needs of developing countries, HIV/AIDS-patients in middle- and high income countries may benefit from increased innovation arising from the

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<sup>616</sup> Cf. Cox, Krista L., *Hastings Science & Technology Law Journal*, 2012, No. 2, p. 296.

<sup>617</sup> Cf. WHO/WIPO/WTO (2012), p. 135.

<sup>618</sup> Cf. Lerner, Josh/Strojwas, Marcin/Tirole, Jean (2005), p. 2.

<sup>619</sup> Cf. van Zimmeren, Esther et al., *Trends in Biotechnology*, 2011, No. 11, p. 570.

<sup>620</sup> Cf. Lerner, Josh/Tirole, Jean (2008), p. 159.

<sup>621</sup> Cf. Gallini, Nancy (2011), p. 24 and van Zimmeren, Esther et al., *Trends in Biotechnology*, 2011, No. 11, p. 570.

<sup>622</sup> Cf. van Zimmeren, Esther et al., *Trends in Biotechnology*, 2011, No. 11, p. 570.

<sup>623</sup> Cf. Lexology (2012).

<sup>624</sup> Cf. OECD (2011), p. 18.

<sup>625</sup> Cf. Lerner, Josh/ Tirole, Jean (2004), p. 38.

<sup>626</sup> Cf. Gold, E. Richard et al. (2007), p. 24.

<sup>627</sup> Cf. Center for Global Health R&D Policy/The Results for Development Institute (2012), p. 35.

pool as well. This can be referred to the possibility that combination products developed by sublicensees will probably also become available in more developed markets.<sup>628</sup> In addition, the license agreements also guarantee that the supply of countries, which are not part of the approved territory, under compulsory licenses is always feasible for the sublicensees.

By being organized and managed by the reputable and experienced organization UNITAID, the MPP is able to ensure credibility to patent holders as well as to generic manufacturers. Another advantage of the MPP is that no change in international or national law is required for the pool to start working.<sup>629</sup> This guarantees that there are no time delays because of bureaucratic or parliamentary processes.

## 9.2 Analysis of costs and benefits

The MPP has tried to induce every pharmaceutical company, which holds patents on target ARVs, to join the Pool. In three years the MPP obtained license agreements on seven ARVs of four different pharmaceutical companies. Of its target products, the MPP obtained two of six of its Level 1 Priority medicines. Level 1 Priorities have high clinical importance and exhibit high market barriers.<sup>630</sup> Moreover, the MPP received licenses on two of its nine Level 2 Priority medicines, which feature medium importance in regard to clinical need and market structure.<sup>631</sup> This corresponds to success rates of 33% for Level 1 Priority ARVs, respectively 22% for Level 2 Priority ARVs.<sup>632</sup>

Regarding the four Level 3 Priorities, the MPP has not concluded a license agreement yet. However, there are several ongoing negotiations with patent holders: There are ongoing negotiations about two Level 1 Priority ARVs, about two Level 2 Priorities as well as with all the four Level 3 Priority ARVs. Additionally, negotiations take place on three ARVs, which do not have priority due to little patent barriers.<sup>633</sup> In total, the MPP has either obtained or is in negotiations about 67% of Level 1 Priorities, 44% of Level 2 Priorities and 100% of Level 3 Priorities.<sup>634</sup> Keeping in mind that the Pool was founded in July 2010, this is a respectable result.

Until today, when negotiations have been started they have never been abandoned before a license agreement was concluded.<sup>635</sup> Hence, the fact that negotiations about licenses on eight

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<sup>628</sup> Cf. Noehrenberg, Eric, *The Open AIDS Journal*, 2010, No. 1, p. 69.

<sup>629</sup> Cf. 't Hoen, Ellen et al., *Journal of the International AIDS Society*, 2011, No. 15, p. 8.

<sup>630</sup> Cf. Medicines Patent Pool (2013j).

<sup>631</sup> Cf. Medicines Patent Pool (2013j).

<sup>632</sup> Own calculations.

<sup>633</sup> Cf. Medicines Patent Pool (2013j).

<sup>634</sup> Own calculations.

<sup>635</sup> Cf. Medicines Patent Pool (2013j).

ARVs are ongoing should give the confidence that licenses on numerous other needed ARVs will be concluded in future. In addition to the negotiations with the pharmaceutical companies, which already have licensed patents to the Pool, the MPP currently also negotiates with companies, which have not joined the Pool yet. These are Bristol-Myers Squibb, which takes into consideration to license atazanavir, a Level 1 Priority, and didanosine, a Level 3 Priority. Boehringer-Ingelheim considers a license on nevirapine, a Level 2 Priority.<sup>636</sup> Both companies are negotiating about all its Priority medicines the MPP is interested in.

Within the three years the MPP is working, eleven license and sublicense agreements have been concluded. Negotiations about the license agreement took half a year with Gilead<sup>637</sup>, about one year with ViiV Healthcare<sup>638</sup> and about one and a half year with Roche.<sup>639</sup> Only with the NIH, the license agreement was immediately signed in September 2010.<sup>640</sup> The period of time needed from the point in time the license agreements came into effect until a sublicense agreement was agreed on took between seven months and two and a half years. With the sublicensees of the Gilead patents from the day of signing the license agreement, the conclusion of the sublicense agreements took two months with Aurobindo<sup>641</sup>, five months with Emcure<sup>642</sup>, one year and two months with Hetero and Laurus<sup>643</sup>, one year and seven months with Shasun<sup>644</sup> and one year and nine months with Shilpa.<sup>645</sup> Regarding the ViiV Healthcare patents, the conclusion of the sublicense with Aurobindo took four months.<sup>646</sup> Hence, sublicenses predominantly have been concluded within a few months. As the complete accomplishment of an in- and outlicensing process did not take more than two years and three months, the time expenditure for licensing patent rights in and licensing them out to a generic manufacturer again was rather small.

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<sup>636</sup> Cf. Medicines Patent Pool (2013j).

<sup>637</sup> Negotiation started in the end of 2010; the MPP-Gilead License Agreement was concluded in July 2011. Cf. Medicines Patent Pool (2013j) and Medicines Patent Pool (2011b).

<sup>638</sup> Negotiations started not before January 2011; the MPP-Roche License Agreement was concluded in February 2013. Cf. Medicines Patent Pool (2013j) and Medicines Patent Pool (2013e).

<sup>639</sup> Negotiations started not before March 2011; the MPP-Roche License Agreement was concluded in August 2013. Cf. Medicines Patent Pool (2013j) and Medicines Patent Pool (2013e).

<sup>640</sup> Cf. Medicines Patent Pool (2010b).

<sup>641</sup> The MPP-Gilead-Aurobindo Sublicense Agreement was concluded in September 2011. Cf. S. 1 of the MPP-Gilead-Aurobindo Sublicense Agreement.

<sup>642</sup> The MPP-Gilead-Emcure Sublicense Agreement was concluded in January 2012. Cf. S. 1 of the MPP-Gilead-Emcure Sublicense Agreement.

<sup>643</sup> The MPP-Gilead-Hetero Sublicense Agreement and the MPP-Gilead-Laurus Sublicense Agreement were concluded in September 2012. Cf. S. 1 of the MPP-Gilead-Hetero Sublicense Agreement and S. 1 of the MPP-Gilead-Laurus Agreement.

<sup>644</sup> The MPP-Gilead-Shasun Sublicense Agreement was concluded in February 2013. Cf. S. 1 of the MPP-Gilead-Shasun Agreement.

<sup>645</sup> The MPP-Gilead-Shilpa Sublicense Agreement was concluded in May 2013. Cf. S. 1 of the MPP-Gilead-Shilpa Agreement.

<sup>646</sup> The MPP-ViiV Healthcare-Aurobindo Sublicense Agreement was concluded in June 2013. Cf. S. 1 of the MPP-ViiV Healthcare-Aurobindo Agreement.

One has to be aware of the fact that several ARVs, on which patents were licensed to the Pool, had not received FDA approval yet. So the possibility to supply generics further depends on the receipt of approval of the licensed ARV by the licensor. Although there are six sublicense agreements on the Gilead patents, only TDF, FTC and the Quad can be manufactured at the moment.<sup>647</sup> Since ViiV Healthcare received FDA approval for ABC in 1998<sup>648</sup>, Aurobindo as the sublicensee could immediately start to produce the drug.

The geographic scope of the licenses ranges between covering all low- and middle-income countries, which are 139 states<sup>649</sup>, and coverage of all low-, but only part of middle-income countries, which are at least 100 states.<sup>650</sup> Hence, access to the single generic ARVs is at the very least provided to 85% of people, respectively 98.7% of children infected with HIV/AIDS, who live in low- and middle-income countries.

Regarding the costs of establishing and running the MPP in comparison to the benefits the pool offers, it has to be adhered that the MPP is completely subsidized. From July 2010 to June 2011, US-\$ 4.43 million, consisting of US-\$ 2.68 million for one-time arising costs of building the MPP and US-\$ 1.75 million of operating costs, were given to the Pool by UNITAID.<sup>651</sup> The MPP has completely expended its budget for the first year of activity. Following, it can be assumed that an amount of money similar to US-\$ 1.75 million for running the MPP will occur every year. Since attempts of the Pool to charge a fee of 5% of royalties the licensors obtain for services rendered through the agreements were removed after concerns about a conflict of interest, the MPP's ability to reach self-sustainability like the Business Plan planned for<sup>652</sup> cannot be reached this way.

Until now, only scarce research on the proportionality of the costs of the MPP establishment and administration in relation to the benefits it offers has been concluded.<sup>653</sup> However, the MPP exhibits advantages regarding its operational efficiency and feasibility.<sup>654</sup> Although subsidies of US-\$ 1.75 million per year will be needed to run the Pool, the MPP is still a low-cost model to increase access to ARVs.<sup>655</sup> The reason for this is that the MPP pursues an approach

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<sup>647</sup> TDF received approval in 2001, FTC in 2003 and the Quad in 2013. Cf. FDA (2013); FDA (2003) and The Wall Street Journal (2012).

<sup>647</sup> Gilead (2013c).

<sup>648</sup> Cf. FDA (2002).

<sup>649</sup> Cf. Art. 3.1 of the MPP-NIH License Agreement.

<sup>650</sup> Cf. Appendix 5 – Countries in the EVG-Quad Territory of the MPP-Gilead License Agreement.

<sup>651</sup> Cf. Supra note 7 1.5 of Annex B – Detailed Budget Medicines of the Medicines Patent Pool Foundation Memorandum of Understanding.

<sup>652</sup> Cf. Supra note 7 1.6 of Annex B – Detailed Budget Medicines of the Medicines Patent Pool Foundation Memorandum of Understanding.

<sup>653</sup> Cf. van Zimmeren, Esther et al., Trends in Biotechnology, 2011, No. 11, p. 575.

<sup>654</sup> Cf. WHO (2010), p. 74.

<sup>655</sup> Cf. WHO (2010), p. 75.

of generic competition. Through the manufacture of low-cost generic versions of original ARVs and their sale at low price in the approved territories, market needs are fulfilled economically more effectively than with the patent holders being the only one supplying in monopolistic positions. Although generics prices are much lower, generic manufacturers are still able to achieve profits, because they do not need to recoup research and development expenditures. Moreover, since sublicenses are granted to several manufacturers, they cannot act as monopolists.

In comparison to the potential savings, which might take place until patent rights expire, meaning over a decade or a similar period, the running costs are probably far compensated by the benefits the MPP brings along. Just the acceleration of generic market entry through the MPP is connected with potential savings of US-\$ 16.9 million.<sup>656</sup> Besides, for instance in case the Pool will lead to the development of a pediatric (fixed-dose) combination, this will bring along savings of US-\$ 4.1 million. Since in total about US-\$ 23 million can be saved and 25-29 million people infected with HIV/AIDS living in the developing world can be provided with access to generic ARVs for years by the MPP, every HIV treatment organization, which spends money on the purchase of ARVs, is able to benefit from the savings that the Pool creates over time. Thus, the investment into the MPP by UNITAID is a sensible and sustainable one.

### **9.3 The Medicines Patent Pool in comparison with other measures to enhance access to ARVs in the developing world**

Other initiated measures to encourage access of people infected with HIV/AIDS to ARVs in developing countries could be donations and differential pricing, bilateral licenses, compulsory licenses or the HIV Medicines Alliance. Donations and differential pricing to developing countries are measures, which are conducted by several HIV treatment organizations as well as by pharmaceutical companies. In 2008, US-\$15.6 billion has been spent on AIDS programs in low- and middle-income countries.<sup>657</sup> Nevertheless, donations to enhance access to ARVs can be problematical due to underdeveloped local health systems, which can prevent an appropriate distribution of products. Voluntary price differentiations could only be effective if measures, that prevent the re-exportation of ARVs to industrial states' markets, are taken.<sup>658</sup> Otherwise the cheaper medicines may be diverted to developed countries. Even if the risk of

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<sup>656</sup> Cf. I-MAK/ITPC (2011), p. 2.

<sup>657</sup> Cf. Hecht, Robert et al., *Health Affairs*, 2009, No. 6, p. 1597.

<sup>658</sup> Cf. Johnson, Hilde, *Brown Journal of World Affairs*, 2005, No. 1, p. 172.

larceny and smuggling is reduced, differential pricing does not enable the development of fixed-dose combinations or pediatric medicines.<sup>659</sup> The same applies to donations.

Besides, the temporal limitation of such measures restricts their effect. In contrast to the manufacture of generics via the MPP, which is predominantly possible as long as the patents concerned contain a valid claim in a territory country, donations and differential prices could take place only once or for a limited period of time. The dependence of donations on the economic situation constitutes a further issue. Due to the financial crisis, not only private donations, but also funding for ARVs by the Global Fund declined because of budget shortages.<sup>660</sup> A further problem is that due to the increasing number of people infected with HIV/AIDS eligible for treatment, future funding needed could reach US-\$35 billion annually by 2031, which is two and a half times the current level<sup>661</sup> and would afford an immense increase in donations. Furthermore, donations and price differentiation do not allow for local manufacture, whereas developing countries dependence on donors remains. Beyond that, the price of generics is far lower than that of price-reduced original products.<sup>662</sup> Moreover, the MPP allows for a slow return to the self-regulation of the market. With donations and differential pricing, generic manufacturers are not able to enter the market, so patent holders are still the only one supplying their drugs. Therefore, donations and differential pricing can never be as effective as generic competition.<sup>663</sup>

Although seven out of eight pharmaceutical companies, which hold patents on ARVs, grant voluntary licenses on bilateral basis<sup>664</sup> and bilateral licenses get even more expanded in regard to their territories and the medicines covered, the MPP represents a more efficient process. This can be underlined by the fact that instead of individually negotiating licensing terms with each generic manufacturer, one single form license agreement can be used for numerous sub-licenses via the MPP. This sharply reduces the effort arising from negotiations. Moreover, an empirical analysis by Park et al. shows significant differences in voluntary licensing practices: The geographic scope of the licenses ranges from one to 112 countries, the number of licensees ranges from one to unlimited, royalty rates amount from 0-5% of the price of the generic drug, freedom to use the patents to develop combination products ranges from none to unlimited and access to technology transfer and regulatory data ranges from minimal to exten-

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<sup>659</sup> Cf. 't Hoen, Ellen (2009), slide 13.

<sup>660</sup> Cf. Mara, Kaitlin, Africa Health, 2012, No. 2, p. 20.

<sup>661</sup> Cf. Hecht, Robert et al., Health Affairs, 2009, No. 6, p. 1591.

<sup>662</sup> Cf. 't Hoen, Ellen et al., Journal of the International AIDS Society, 2011, No. 15, p. 4.

<sup>663</sup> Cf. 't Hoen, Ellen (2009), slide 13.

<sup>664</sup> Cf. Beyer, Peter (2013), p. 242.

sive.<sup>665</sup> In consequence of a probable smaller geographic scope and more restrictions on pursuing further development of ARVs, sublicenses granted by the MPP may provide better terms for people infected with HIV/AIDS in the developing world.

The MPP additionally confers the advantage that it can pressure pharmaceutical companies to offer their patent rights sooner than they would do with bilateral licenses.<sup>666</sup> Additionally, instead of guaranteeing public access to license agreements like the MPP does, bilateral licenses are generally kept confidential. Thus, bilateral voluntary licenses might not have the same effective power as sublicenses via the MPP. However, since the trend to voluntarily license patents on ARVs has rose even further with the creation of the MPP<sup>667</sup>, bilateral licenses might also be used as a tool to circumvent participation in the Pool. Patent holders facing much public pressure to join the pool might decide that bilateral licenses outside the pool are preferential to them, since this way, they have more freedom to determine (and probably restrict) licensing terms. Furthermore, there would not be a third negotiation partner like the MPP, which could provide support to the generic company, that wants to license the patents.

Compulsory licenses are an important TRIPS flexibility. They have been used 24 times from 1995 to 2011, of which 16 concerned ARVs, and issued in 17 countries. With Brazil and Thailand being the most frequent users, activity in compulsory licensing has been stronger in upper-middle income countries than in low-income countries.<sup>668</sup> With royalty rates of between 0.5% and 5%<sup>669</sup>, compulsory licenses may partially even allow for cheaper generics than under a license of the MPP. Nevertheless, although the waiver of Art. 31 (f) TRIPS strived to enhance access to medicines, bureaucratic constraints and the inefficiency of compulsory licenses have often been criticized.<sup>670</sup> Since in case of compulsory licenses allowing for the import of a patented drug the generic manufacturer has to bear the costs of production, remuneration, shipping as well as for measures to prevent re-export<sup>671</sup>, the waiver of Art. 31 (f) TRIPS has only been used twice.<sup>672</sup>

Compulsory licenses are also rarely used due to political pressure on developing countries not to make use of this TRIPS flexibility.<sup>673</sup> Issuing a compulsory license might be connected with retaliation measures for the country concerned. After Thailand granted a compulsory

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<sup>665</sup> Cf. Park, Chan et al. (2012).

<sup>666</sup> Cf. Center for Global Health R&D Policy/The Results for Development Institute (2012), p. 54.

<sup>667</sup> Cf. WHO/WIPO/WTO (2012), p. 180.

<sup>668</sup> Cf. Beall, Reed/Kuhn, Randall (2012).

<sup>669</sup> Cf. Center for Global Health R&D Policy/The Results for Development Institute (2012), p. 16.

<sup>670</sup> Cf. Thapa, Rojina, *Journal of Intellectual Property Rights*, 2011, No. 6, p. 474.

<sup>671</sup> Cf. Tsai, George, *Virginia Journal of International Law*, 2009, No. 4, p.1081.

<sup>672</sup> Cf. Thapa, Rojina, *Journal of Intellectual Property Rights*, 2011, No. 6, p. 473.

<sup>673</sup> Cf. Hermann, Rachel Marusak (2011).

license to manufacture Abbott's ARV Kaletra (a combination of lopinavir and ritonavir) in 2007, the company declared that it will no longer register new drugs for sale Thailand as long as the compulsory license is in effect.<sup>674</sup> Besides, the USA included Thailand on the Special 301 Priority Watch List<sup>675</sup>, whose members can be imposed with trade sanctions. This also explains why countries, which made clear that they have the intention to grant a compulsory license, but in the end did not, benefitted from price reductions for drugs through discounts or bilateral licenses. Compulsory licensing will never be able to control the prices of ARVs like generic competition, since the time frame of a compulsory license is strictly limited.<sup>676</sup> Furthermore, the amount of generics needed under a compulsory license is far smaller than that producible under the MPP for supply in numerous developing countries. Because a high amount of generics manufactured allows sublicensees to benefit from economies of scale, generics prices are much lower with a sublicense granted by the MPP as well.

The pharmaceutical companies Johnson & Johnson/Tibotec as well as Merck & Co., which both did not enter into negotiations with the MPP yet<sup>677</sup>, initiated the HIV Medicines Alliance in May 2012, which should also enhance access to ARVs in the developing world.<sup>678</sup> However, the alliance implies that patent holders remain in control of choice of generic manufacturers, distribution and price. Opportunities to conduct research and development are not offered to the licensees. Besides, in contrast to the MPP, only least developed, low-income and sub-Saharan African countries may receive ARVs at lower prices.<sup>679</sup> In contrast to that, the MPP allows for more encompassing licensing terms and ensures that patent holders do not completely remain in control regarding the completion of generic supply. Due to its marginal effect on human health, the HIV Medicines Alliances is accused of just being a damage-limitation tool used to ensure business success in transitional countries.<sup>680</sup>

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<sup>674</sup> Cf. Aidsmap (2007).

<sup>675</sup> Cf. Office of the US Trade Representative (2007), p. 11.

<sup>676</sup> Cf. Johnson, Hilde, *Brown Journal of World Affairs*, 2005, No. 1, p. 171.

<sup>677</sup> Cf. Johnson & Johnson/Tibotec (2011) and Merck (2011).

<sup>678</sup> Cf. BUKO Pharma-Kampagne, *Pharma-Brief*, 2012, No. 6-7, p. 3.

<sup>679</sup> Cf. Baker, Brook (2012).

<sup>680</sup> Cf. BUKO Pharma-Kampagne, *Pharma-Brief*, 2012, No. 6-7, p. 4.

## 9.4 Disadvantages

Some critics state that the success of the MPP has “been more on paper than in lives saved”<sup>681</sup>. They conclude that the MPP’s working mechanism is not suffice to fundamentally improve access to ARVs.<sup>682</sup> The reason for this is that the success of the MPP completely depends on the collaboration and participation of pharmaceutical companies and generic manufacturers as its stakeholders.<sup>683</sup> To work effectively, the MPP needs to obtain a critical mass of patents. Albeit, in contrast to standard-setting patent pools, where patent holders cannot refrain from initiating or collaborating with the pool due to their dependence on licenses for the invention of other products<sup>684</sup>, there is not such dependence with the MPP. Patent holders and generic manufacturers voluntarily decide if they want to become licensors, respectively sublicensees. In case they are not interested in joining the pool, the MPP is not able to apply any coercive measures to enhance participation, since as a non-profit organization it does not command any power of disposal.

This is especially disadvantageous because in regard to pharmaceutical companies like AbbVie, which possesses patents on Level 1 Priority ARVs the MPP is strongly interested in, but which is obviously not considering to grant any licenses.<sup>685</sup> Besides, as seen with the MPP-NIH License, the MPP does not have the ability to solve the outsider problem, which arises in case there is another patent holder, whose patents are indispensable to allow for the manufacture of a certain ARV. Then, patents already licensed to the pool only have limited effectiveness. Tibotec, which is the holder of patents complementary to those of the NIH in the pool, refuses to enter into negotiations with the MPP.<sup>686</sup> Thereby, the company is able to restrict attainable profits of the Pool. Hence, it might be doubtful whether voluntary participation in the MPP is able to generate a critical mass of high quality patents.

In addition to that, there is the concern that pharmaceutical companies might keep the more valuable patents out of the MPP and solely contribute less lucrative patents to the Pool.<sup>687</sup> Certainly, Gilead licensed all the ARVs being part of the MPP’s Priority Lists.<sup>688</sup> In contrast to that, ViiV Healthcare only licensed one ARV, whose field of use is even restricted to pediatric HIV/AIDS treatment, although there are three other ARVs the company holds patents on, which the MPP aims to license. Since dolutegravir, one of ViiV Healthcare’s ARVs, even

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<sup>681</sup> Gold, E. Richard/Morin, Jean-Frédéric, *The Lancet*, 2009, No. 9698, p. 1330.

<sup>682</sup> Cf. BUKO Pharma-Kampagne, *Pharma-Brief*, 2012, No. 5, p. 6.

<sup>683</sup> Cf. Mara, Kaitlin, *Africa Health*, 2012, No. 2, p. 23

<sup>684</sup> Cf. van Zimmeren, Esther et al., *Trends in Biotechnology*, 2011, No. 11, p. 573.

<sup>685</sup> Cf. Abbott (2011).

<sup>686</sup> Cf. Johnson & Johnson/Tibotec (2011).

<sup>687</sup> Cf. BUKO Pharma-Kampagne (n.y.).

<sup>688</sup> Cf. Medicines Patent Pool (2013j).

constitutes a Level 1 Priority<sup>689</sup>, the concern of solely licensing patents less valuable patents, or only licensing valuable patents with a limited field of use, might be eligible. Nevertheless, there are still negotiations ongoing for the three ARVs, which have not been licensed until now. Roche just licensed valganciclovir, which, as a treatment of a HIV co-infection, is not even part of the MPP's Priority Lists. Indeed, the MPP is interested in Roche's saquinavir, a Level 3 Priority medicine, which was not licensed. In the MPP-Roche License Agreement, the company solely stated that it will enter into negotiations about this ARV<sup>690</sup>, which also took place so far.

A further problem is that the MPP is not able to prevent partially harsh restrictions on usage of the licensed patent rights. For instance limitations on the place of API and product manufacture prevent the full effects of competitive pressure by generic competition.<sup>691</sup> It needs to be taken into account that, in case of the MPP-Gilead License Agreement, where API and generics need to be produced in India, the MPP decentralizes manufacture away from the countries in need.<sup>692</sup> Indeed, it might be doubtful whether a developing country is able to manufacture ARVs in an economically successful way, which is able to compete with large-scale international producers through creating economies of scale and ensuring cost efficiency.<sup>693</sup> Nevertheless, by not allowing for improvement or installation of local manufacture, the Pool restricts investments in developing countries' own capability by improving production facilities, technology and human capital. Besides reducing developmental opportunities, the decentralization of manufacture could also be an obstacle to supply security and consistency.<sup>694</sup> To the extent that the MPP decentralizes production away from the countries in need, their dependence on imports increases, wherefore self-sufficiency cannot be enhanced. Thus, license agreements, which provide access to medicines through a mix between locally manufactured and imported ARVs would be more sustainable in the long term.<sup>695</sup> Nevertheless, the Pool has to decide sensitively during the negotiations of the licensing terms with the patent holder whether there is still negotiation range, or if the company will cancel negotiations if it is further pushed to agree on less restricted licensing terms regarding the production of API and products.

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<sup>689</sup> Cf. Medicines Patent Pool (2013j).

<sup>690</sup> Cf. Art. 3 of the MPP-Roche License Agreement.

<sup>691</sup> Cf. 't Hoen, Ellen (2009), slide 13.

<sup>692</sup> Cf. Stavros Nicolaou, *The Open AIDS Journal*, 2010, No. 1, p. 60.

<sup>693</sup> Cf. Wilson, Kinsley Rose/Kohler, Jillian Clare/Ovtcharenko, Natalia, *Global Health*, 2012, No. 20, p. 6.

<sup>694</sup> Cf. Stavros Nicolaou, *The Open AIDS Journal*, 2010, No. 1, p. 60.

<sup>695</sup> Cf. *Ibid.*

One of the biggest critiques of the MPP's licenses centers around (upper) middle-income countries left out of the agreements.<sup>696</sup> Several critics state that the licenses need to include all developing countries, whether low- or middle-income. This is due to the fact that especially middle-income countries command manufacturing capacities for generics. In addition to that, making licenses applicable to a larger number of countries means that production would become more economically attractive for potential sublicensees. If there is more competition between the sublicensees, the price of the generics would decrease further and this in turn would facilitate to provide access to generic ARVs to a higher number of patients.<sup>697</sup> Nevertheless, by tracking the development of licenses the MPP has concluded over time, it becomes visible that the geographic scope has been enlarged more and more. Whereas not more than 112 countries may benefit from the MPP-Gilead License, 118 are able to benefit from the MPP-ViiV Healthcare License and 138 from the MPP-Roche License.<sup>698</sup> The license agreements partially also mention the possibility of future enlargements of territories. Moreover, the MPP can always request the licensors to include further middle-income countries to the approved territory, just as it has been done successfully with the inclusion of South Sudan in the geographic scope of the Gilead licenses by the first amendment.

Since the MPP is a cooperative agreement, it brings along the potential of suppressing competition in case it harbors weak or invalid patents.<sup>699</sup> The TDF license of Gilead, which requires to manufacture API and product in India, where a weak patent claim existed, has strongly been criticized for being a strategy to defend the patent at the expense of consumer welfare. Because the MPP includes the TDF patent, which is likely to be held invalid, it could, instead of enhancing competition, even extend monopoly power.<sup>700</sup> Therefore, several critics demand that the MPP should perform a gatekeeper function to ensure that the licensed patents are probably valid and enforceable. In addition to that, thereby a situation, where the pool member is exposed to the risk of cost-intensive litigation procedures with an uncertain outcome, could be prevented.<sup>701</sup> Certainly, the MPP-Gilead License allows for unbundling, wherefore sublicensees may immediately terminate the license on TDF. Half of sublicensees have already exerted this right and quit their licenses on TDF. Consequently, the incorporation of the weak TDF license did not make the MPP an anti-competitive entity.

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<sup>696</sup> Cf. Médecins Sans Frontières (2011), p. 8 and Thai Network of People living with HIV/AIDS (2011).

<sup>697</sup> Cf. Childs, Michelle, *The Open AIDS Journal*, 2010, No. 1, p. 36.

<sup>698</sup> 139 countries are able to benefit from the MPP-NIH License. Nevertheless, the license does not allow for the manufacture and sale of generics until now, since the complementary patents of Tibotec need to be licensed to the MPP before.

<sup>699</sup> Cf. Gallini, Nancy (2011), p. 2f.

<sup>700</sup> Cf. Gold, E. Richard et al. (2007), p. 23.

<sup>701</sup> Cf. van Zimmeren, Esther et al., *Trends in Biotechnology*, 2011, No. 11, p. 570.

Additionally it is questionable, which implications the MPP will have on innovation. There is the concern that participation in the MPP might remove the economic incentive to create innovation on ARVs from patent holders. The discontinuation of clinical research would bring along serious negative effects: Due to the continuous mutation of the HI-virus and growing resistances to existing drugs, innovation in ARV development is crucially important to control HIV/AIDS in the future, too.<sup>702</sup> However, future patents of the licensors are not automatically part of the Pool. Therefore, it cannot be expected that the MPP does have a negative impact on innovation regarding ARVs. Indeed, it even promotes innovation in ARV development through allowing sublicensees to conduct research and development on new or pediatric formulations. Through providing the ability to license several combinable patents, the pool additionally facilitates the development of fixed-dose combinations.<sup>703</sup> Albeit, a difficulty in this regard are grant back provisions, which allow the licensor to commercialize the sublicensees's inventions without providing for royalties. If inventions of the sublicensees may be exploited without compensation, there is no incentive to invest in research.

Furthermore, it is criticized that updates of negotiation processes and draft license agreements should be shared with interested civil society groups by the MPP, so that interested groups might comment on them. This way, transparency and accountability of the licensing procedures could be improved.<sup>704</sup> MSF additionally criticizes too little civil society input through consultations.<sup>705</sup> However, while evaluating these criticisms one has to be aware of the fact that all license and sublicense agreements are publicly available on the MPP's website. Moreover, the current negotiation status with the patent holders of the target medicines and several written replies to requests for participation are published.<sup>706</sup> This distinguishes the MPP favorably from the conclusion of bilateral licenses agreements by patent holders, where licensing terms and else are generally kept completely secret.

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<sup>702</sup> Cf. Noehrenberg, Eric, *The Open AIDS Journal*, 2010, No. 1, p. 67.

<sup>703</sup> Cf. *Ibid.*, p. 68.

<sup>704</sup> Cf. ITPC/I-MAK (2011b), p. 2.

<sup>705</sup> Cf. Médecins Sans Frontières (2011), p. 14.

<sup>706</sup> Cf. Medicines Patent Pool (2013h).

## 10. Possible improvements

### 10.1 Enhancing participation

As described above, some points of criticism regarding the MPP can be invalidated. However, there are several areas with room for improvement. Regarding the MPP's Priority ARVs, the only company, which licensed all products the MPP was interested in to the Pool, was Gilead. Presently, the MPP aims to license patents of AbbVie, Boehringer-Ingelheim, Bristol-Myers Squibb, Johnson & Johnson/Tibotec, Merck & Co. as well as additional patents of Roche and ViiV Healthcare.<sup>707</sup> Negotiations are ongoing with Boehringer-Ingelheim, Bristol-Myers Squibb, Roche and ViiV Healthcare.<sup>708</sup>

An important question is how patent holders, who believe that it is more profitable for them to stay out of the MPP, can be convinced to participate in the Pool. Inducing companies like AbbVie, which is the patent holder two Level 1 Priority ARVs the MPP is strongly interested in, but which is obviously not considering to grant any licenses<sup>709</sup>, to participate in the MPP would enhance access to cost-less generics further. Moreover, the participation of Tibotec, which possesses complementary patents to those of the NIH already licensed to the pool, but which is also unwilling to participate<sup>710</sup>, is indispensable to make the MPP-NIH License effective. Current incentives to participate in the Pool are obviously not yet strong enough to encourage all patent holders to join the Pool.

Hence, it has to be reflected upon how patent holders like AbbVie, Johnson & Johnson/Tibotec and Merck can be persuaded to license lopinavir and ritonavir (AbbVie), etravirine, rilpivirine and darunavir (Johnson & Johnson/Tibotec), respectively raltegravir and efavirenz (Merck) to the Pool. While AbbVie has not concluded any bilateral licenses on the desired ARVs until today, Johnson & Johnson/Tibotec and Merck have concluded such on every ARV the MPP aims to license. Johnson & Johnson/Tibotec concluded bilateral royalty-free licenses on etravirine with two generic manufacturers in 2009, which cover Sub-Saharan African and least developed countries. Furthermore, the company granted bilateral licenses on the manufacture and marketing of rilpivirine as a single agent and as part of fixed-dose combinations to five generic manufacturers in 2011. These licenses are royalty-bearing and cover 112 countries, including sub-Saharan African and least developed countries as well as India. Johnson & Johnson/Tibotec also concluded bilateral royalty-free licenses with two generic manufacturers on darunavir in 2007, which cover 65 countries, which are sub-Saharan Afri-

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<sup>707</sup> Cf. Medicines Patent Pool (2013j).

<sup>708</sup> Cf. Medicines Patent Pool (2013j).

<sup>709</sup> Cf. Abbott (2011).

<sup>710</sup> Cf. Johnson & Johnson/Tibotec (2011).

can states, least developed countries and India.<sup>711</sup> Merck issued bilateral licenses on raltegravir to two generic manufacturers in 2011, which cover 60 countries, including sub-Saharan African and low-income countries. Moreover, the company has also granted bilateral royalty-free licenses to seven generic manufacturers regarding the production of efavirenz since 2007, which cover South Africa, as there are no patents in sub-Saharan countries.<sup>712</sup> Regarding royalty provisions and geographic scope, the terms of the bilateral licenses are partially very patient-friendly and similar to licenses the MPP already has concluded. Hence, Johnson & Johnson/Tibotec and Merck need to be convinced to grant voluntary licenses via the MPP in addition or as replacement to the licenses they already have concluded bilaterally. AbbVie however has to be persuaded to generally grant voluntary bilateral licenses.

Since the Pool is voluntary mechanism, the application of coercive action is not possible. Instead of forcing patent holders to participate in the MPP, the Pool has to rely on other incentives to enhance participation. Due to the companies' intention to strive for profit maximization, the provision of new financial incentives as additional motivations to join the MPP seems to be promising. An approach could be that developed states encourage patent holders to join the MPP with favorable treatment under national law. Patent holders on ARVs, who licensed their patents to the pool, could be rewarded with partial tax exemptions for the royalties obtained from the sale of generics produced by sublicensees. In the USA, Australia and Canada pharmaceutical companies, which offer donations and discounts on medicines to developing countries, are rewarded with deductions in tax.<sup>713</sup> By applying tax exemptions to the MPP as well, the patent holders joining the Pool would effectively obtain more money for licensing their patents and hence be able to recoup more of their expenses. Indeed, this way of enhancing participation in the Pool is partially criticized for relieving pharmaceutical companies, which receive tax revenues for conducting research activities, from their tax liabilities.<sup>714</sup> However, since the amount of money, which corresponds to the tax exemptions for royalties received, is not scheduled in the national budget, there is no real monetary loss.

Market commitments, meaning pledging guarantees to purchase large volumes of products, or the guarantee to buy ARVs developed via the MPP at a distinct price for a limited number of years after investment by governments or international procurement agencies could also be created.<sup>715</sup> However, it needs to be critical reviewed if market commitments would not gamble away the MPP's advantage of leading back to a more self-regulating market, which coun-

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<sup>711</sup> Cf. Médecins Sans Frontières (2012).

<sup>712</sup> Cf. Ibid.

<sup>713</sup> Cf. Internal Revenue Service (2012); Australian Taxation Office (2010) and Blumberg, Mark (2008).

<sup>714</sup> Cf. Wagner-Ahlf, Christian (2013): Interview.

<sup>715</sup> Cf. Noehrenberg, Eric, *The Open AIDS Journal*, 2010, No. 1, p. 68 and UNITAID (2012), p. 16.

terbalances demand and supply. Moreover, another advantage of the Pool is that less drugs need to be bought by HIV treatment organizations or governments to be supplied to people infected with HIV/AIDS in developing countries, which cannot afford them on their own. While issuing guaranteed purchases, the ability of the ARV market to regulate itself through generic competition is ignored. The same applies to a fixed price, at which new developed ARV might be purchased. This again overlooks the advantages of generic competition the MPP enables for, which is more efficient than fixing prices.

It has also been suggested that if the MPP is not able to meet its goal on the basis of obtaining voluntary licenses from patent holders, it could consider to ask countries to grant compulsory licenses regarding the ARVs of certain patent holders, who refuse to join the pool, after a reasonable period of time.<sup>716</sup> An increasing threat of compulsory licenses would probably enhance the willingness to participate in the Pool. If a higher number of compulsory licenses is issued, on which patent holders cannot exert influence with respect to the field of use or royalty provisions, they might prefer to license via the MPP, where they have the possibility to influence the licensing terms. Nevertheless, one need to keep in mind the limited geographic scope of compulsory licenses, which have to be granted on a country-by-country basis and the fact that states making use of such licenses have been imposed with retaliation measures. To really persuade patent holders to become a pool member, which would probably be connected with licensed territories of at least 100 countries, the number of compulsory licenses granted needs to be very large-sized. Furthermore, there need to be numerous countries and generic manufacturers, which are willing to expose themselves to retaliation measures. Therefore, the approach to rely on compulsory licenses to enhance the willingness to participate in the Pool is not very auspicious.

In contrast to that, membership could be rather raised by political authorities exerting pressure in a diplomatic way on the pharmaceutical companies to join the pool.<sup>717</sup> To prevent a situation, where diplomatic conversations fizzle out without any results, in addition to political authorities, public pressure should be exerted on the companies.<sup>718</sup> Civil society groups should for instance undertake media campaigns, which ensure that pharmaceutical companies have to pay attention to the Pool's licensing mechanism and cannot flinch from their stakeholder's demand of participation. In addition to exerting leverages on the pharmaceutical companies, they should be provided with detailed information about the benefits of the col-

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<sup>716</sup> Cf. Gold, E. Richard et al. (2007), p. v.

<sup>717</sup> Cf. Gold, E. Richard/Morin, Jean-Frédéric, *The Lancet*, 2009, No. 9698, p. 1330 and Noehrenberg, Eric, *The Open AIDS Journal*, 2010, No. 1, p. 67.

<sup>718</sup> Cf. Wagner-Ahlf, Christian (2013): Interview.

laborative licensing model and be demonstrated the added value they are able to obtain through joining the MPP. Hence, in conclusion, there are two promising ways to encourage the willingness of patent holders, who refused to join the MPP until now, to become a pool member. These are tax exemptions as well as increasing pressure by the political authorities and the public.

## **10.2 Widening of the licenses' scope**

To widen the geographic scope of the licenses, which has especially been strongly been criticized in regard to (upper-) middle-income countries, the MPP could evidence that an exclusion of particular countries from the license agreement would contradict the respective company's interests.<sup>719</sup> To advert to the possibility of generic manufacturers to attain economies of scale by widening the approved territory, which would in turn lead to lower prices of generics, could for instance be an incentive to consider enlargements. To enhance the geographic scope, civil society interventions may also lead to an improvement of licensing terms. Civil society groups could not only put pressure on pharmaceutical companies to start negotiations with the MPP, but also on companies, which already concluded license agreements.

Compulsory licenses constitute the only possibility of countries excluded from a license's territory to be supplied with generics. In case countries excluded would issue compulsory licenses in a cooperating manner within a narrow time frame, this could present an incentive for patent holders to include such states in the license agreements. In contrast to trying to enhance the willingness to participate in the MPP this way, compulsory licenses seem to be useful to widen the scope of licenses, which have already been granted to the Pool. The reason for this is that the extension of the territories concerns a much smaller number of countries, so that the coordinated issuance of compulsory licenses in these countries does not represent an impossible task.

Moreover, one could think of charging higher royalties on sublicensees for sales in upper-middle-income countries, which would in turn lead to higher sale prices of generics there. Since purchasing power is higher in upper-middle-income states and patent holders would also charge higher sale prices there, this seems to be a reasonable approach. Albeit, measures to effectively prevent parallel imports from countries with lower sale prices need to be established then.

Cox suggests connecting the Prize Fund to Support Innovation and Access for Donor Supported Markets for HIV/AIDS, a proposal of the governments of Bangladesh, Barbados, Bo-

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<sup>719</sup> Cf. Cox, Krista L., *Hastings Science & Technology Law Journal*, 2012, No. 2, p. 319.

livia and Suriname presented to the WHO in 2009<sup>720</sup>, with the MPP.<sup>721</sup> The Prize Fund is a reward system for, and only for licenses, which encompass all developing countries. Funding could be provided by fractions of donor drug purchasing budgets from the Global Fund, UNITAID or other programs. Since the share a licensor would obtain should depend on the priority the licensed products have, the amount of money paid to the licensor would be proportional to its patents' impact on improving access to ARVs. The reward system should work together with the MPP, since the monetary reward to patent holders joining constitutes an additional incentive for companies to license their products.<sup>722</sup> Although the MPP will allow for the supply of cost-less generic ARVs in a way that organizations like the Global Fund could reduce their ARV purchasing activities and spend money on such a reward mechanism, it does not seem reasonable to additionally provide companies with monetary rewards for a wide territory. The reason for this is that through generic competition, the ARV market in developing countries may become more and more self-regulated. The reward however would destroy the possibility to turn the market into a "healthy" one.

Therefore, the hint on economies of scale, civil society pressure, making use of compulsory licenses and higher royalties for upper-middle-income countries present the more appropriate measures. Albeit, one has always to keep in mind that licenses are granted completely voluntary by patent holders, who are not legally obliged to participate in the Pool. An all or nothing mentality, for instance requiring the coverage of all low- and middle-income countries, comes along with the risk that patent holders terminate the negotiations, which would bargain away any possible positive impact on people living with HIV/AIDS in the developing world.<sup>723</sup> Negotiations involve a balance between competing objectives, meaning that the aim to expand the geographic scope of the licenses might only be reached by agreeing on less favorable provisions in other areas of the agreement.<sup>724</sup>

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<sup>720</sup> Cf. Proposal by Barbados, Bolivia, Suriname and Bangladesh (2009).

<sup>721</sup> Cf. Cox, Krista L., *Hastings Science & Technology Law Journal*, 2012, No. 2, p. 320.

<sup>722</sup> Cf. *Ibid.*, p. 322.

<sup>723</sup> Cf. Cox, Krista L., *Hastings Science & Technology Law Journal*, 2012, No. 2, p. 318.

<sup>724</sup> Cf. *Ibid.*, p. 309.

## 11. Conclusion

This Master thesis aimed to examine the licensing terms and the effectiveness of the Medicines Patent Pool. The MPP definitely exhibits the potential to improve access to ARVs for millions of people infected with HIV/AIDS, who live in the developing world. This is due to the fact that the pool allows for generic competition through sublicensing patents on ARVs it has obtained from patent holders. Generic competition is the only proven method, which results in sustainable and substantial price reductions of ARVs.<sup>725</sup> Due to the price reductions of urgently needed, but due to monopolistic supply unaffordable medicines, those are made available for people in the developing world. Hence, through negotiating license agreements from a public health perspective, the MPP provides for “shared responsibility and global solidarity”<sup>726</sup>.

Taking into account the numerous ongoing negotiations, the MPP has either obtained or is negotiating about 67% of its Level 1 Priority ARVs, 44% of its Level 2 Priorities and 100% of its Level 3 Priorities.<sup>727</sup> The MPP’s success can be referred to a strong public demand of the uptake of corporate social responsibility by patent holders. Besides public pressure, the Access to Medicines Index and the opportunity to avoid the risk of the issuance of compulsory licenses have contributed to the willingness of patent holders to conclude license agreements with the MPP, too.

Advantageously, the sublicense agreements the Pool grants permit the sublicensees to conduct research. This allows for the development of new, pediatric and combined ARVs and contributes to secure medicinal and therapeutical progress. Moreover, the Pool provides for one-stop-shopping regarding licenses and sublicenses, which comprehensively reduces transaction costs for generic manufacturers and patent holders. As license agreements may include the possibility of domestic generic manufacture in the territory countries, the MPP additionally conduces to build up local capacities and enhance economic development in developing countries. Besides, the Pool secures that generics can be produced all the time the respective patents are in force, which encompasses a period of several years. The flexible composition of royalty provisions ensures that patent holders have an incentive to join the Pool. Furthermore, the manufacture of generics enables for a cut back of donations and voluntary price reductions of ARVs, since cost-less generics are directly affordable for people living with HIV/AIDS in the developing world. Consequently, the production of generic ARVs through the MPP brings along the opportunity to eventuate in a self-regulated ARV market.

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<sup>725</sup> Cf. Waning, Brenda et al., *Globalization and Health*, 2010, No. 9, p. 13.

<sup>726</sup> Buse, Kent/Martin, Greg, *Globalization and Health*, 2012, No. 26, p. 1.

<sup>727</sup> Own calculations.

However, although the MPP exhibits numerous advantages, there are several areas with room for improvement. For instance, the MPP has not been successful to persuade all patent holders, who own patents on target products, to enter into negotiations with the Pool. To incentivize these patent holders to become pool members, it seems to be most promising to put increasing public pressure on them through governments and civil society groups. Aside from that, new incentives to participate in the Pool, like tax exemptions for royalties obtained by the sublicensees, should also be considered to further enhance the effectiveness of the MPP.

In order to widen the scope of the licenses, the coordinated issuance of compulsory licenses represents an opportunity to enlarge the number of territory countries, since patent holders are exposed to a lack of influence regarding royalties, scope or other compulsory licensing terms then. Thus, they might prefer to voluntarily grant licenses, but with being able to influence the licensing terms. Furthermore, to secure supply consistency, generic manufacture should be allowed in as many territory countries as possible. This would additionally increase competition among sublicensees, which provides the opportunity of further price reductions. Nevertheless, since the licenses concluded by the Pool are voluntary, one has to be aware of the fact that licensing terms will unavoidably involve trade-offs, where the MPP has to relent with some terms, while successfully push through its objectives with other terms.<sup>728</sup>

In conclusion, the MPP is a mechanism, which exhibits the ability to overcome the problems of access to ARVs for people infected with HIV/AIDS living in the developing world as well as to enhance innovation on needed new formulations and combination products. However, the Pool must be seen as a complement to other measures.<sup>729</sup> Policies, which support technology transfer and the functioning of local health care systems, are the indispensable basis for the Medicines Patent Pool's ability to work effectively.<sup>730</sup>

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<sup>728</sup> Cf. Cox, Krista L., *Hastings Science & Technology Law Journal*, 2012, No. 2, p. 317.

<sup>729</sup> Cf. 't Hoen, Ellen et al., *Journal of the International AIDS Society*, 2011, No. 15, p. 9.

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