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### Patent Pools for Orphan Diseases

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Each year, millions of people living in low and middle-income countries die from treatable and preventable diseases.<sup>1</sup> However, many deaths are the result of inadequate and improper drugs being administered to people in these countries.<sup>2</sup> For example, the most commonly used drug to treat African sleeping sickness, Melarsoprol, is arsenic-based.<sup>3</sup> Melarsoprol kills between three to ten percent of people treated with the drug.<sup>4</sup> Nevertheless, drug companies have little incentive to develop drugs for these “orphan diseases,” such as African sleeping sickness, because the profitability of the market is very small.<sup>5</sup> In fact, drug companies based in the United States only generate five to seven percent of their profits from low to middle-income countries.<sup>6</sup>

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<sup>1</sup> Amy Kapczynski et al., *Addressing Global Health Inequities: An Open Licensing Approach for University Innovations*, 20 BERKELEY TECH. L.J. 1031, 1032 (2005).

<sup>2</sup> *Id.*

<sup>3</sup> *Id.* at 1037-38. See World Health Organization [WHO], African Trypanosomiasis (Sleeping Sickness), <http://www.who.int/mediacentre/factsheets/fs259/en/> (last visited Mar. 22, 2009) (“Melarsoprol: discovered in 1949, it is used in both forms of [Human African Trypanosomiasis]. It derives from arsenic and has many undesired side effects. The most dramatic being a reactive encephalopathy (encephalopathic syndrome) which can be fatal (3% to 10%).”).

<sup>4</sup> WHO, *supra* note 3.

<sup>5</sup> Kapczynski, *supra* 1, at 1038. See Radhika Rao, *Genes and Spleens: Property, Contract, or Privacy Rights in the Human Body?*, 35 J.L. MED. & ETHICS 371, 375 (2007) (“[Orphan diseases] ... affect[] only one in 25,000 births [in the U.S.], so pharmaceutical companies [are] reluctant to invest in research because of the small revenues anticipated from any results.”).

<sup>6</sup> *Id.*

Many people believe market-based incentives for patents inhibit research and development related to orphan diseases.<sup>7</sup> However, a properly constructed patent pool could stimulate orphan disease research and development and improve global public health through access to these drugs.

### I. WHAT IS A PATENT POOL?

Patent pools are not novel, having been widely used since the late 19<sup>th</sup> century.<sup>8</sup> “Today, patent pools are frequently utilized in technology fields that require common standards, such as radio, DVD-video, DVD-ROM and MPEG\_2 compression technology.”<sup>9</sup> The United States Patent and Trademark Office describes a “patent pool” as:

[A]n agreement between two or more patent owners to license one or more of their patents to one another or third parties. Alternatively, a patent pool may also be defined as “the aggregation of intellectual property rights which are the subject of cross-licensing, whether they are transferred directly by patentee to licensee or through some medium, such as a joint venture, set up specifically to administer the patent pool.”<sup>10</sup>

In addition, “a [patent] pool may involve simple cross-licensing among two or more competitors, in order to share a handful of patents necessary for the manufacture and sale of a particular product, or it may involve a large, industry-

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<sup>7</sup> *Id.*

<sup>8</sup> Knowledge Ecology International, *IGWG Submission on Collective Management of Intellectual Property – The Use of Patent Pools to Expand Access to Needed Medical Technologies* (Sept. 30, 2007), [http://www.who.int/phi/public\\_hearings/second/contributions\\_section2/Section2\\_ManonRess-PatentPool.pdf](http://www.who.int/phi/public_hearings/second/contributions_section2/Section2_ManonRess-PatentPool.pdf), at 1.

<sup>9</sup> *Id.* at 2.

<sup>10</sup> Jeanne Clark et al., *Patent Pools: A Solution to the Problem of Access in Biotechnology Patents?* (Dec. 5, 2000), [www.uspto.gov/web/offices/pac/dapp/opla/patentpool.pdf](http://www.uspto.gov/web/offices/pac/dapp/opla/patentpool.pdf), at 4 (quoting Joel I. Klein, *AN ADDRESS TO THE AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION, ON THE SUBJECT OF CROSS-LICENSING AND ANTITRUST LAW* (May 2, 1997), available at <http://www.usdoj.gov/atr/public/speeches/1118.htm>).

wide [patent] pool open to anyone, encompassing hundreds of manufacturers and thousands of patents.”<sup>11</sup>

Although there are no formal requirements for patent pools, patent pools generally enable its members to license patents in the patent pool based on standard licensing fees or royalties determined by a pre-set formula or procedure.<sup>12</sup> Additionally, a portion of the licensing fees or royalties is usually allocated to patent owners, who are also members of the patent pool.<sup>13</sup>

## II. PROPOSED FRAMEWORK FOR AN ORPHAN DISEASE PATENT POOL

### A. *The Goal of the Orphan Disease Patent Pool*

The goal of the orphan disease patent pool would be to enhance global public health by enabling the development of cost effective drugs for orphan diseases. Admittedly, an industry-wide orphan disease patent pool would be elaborate.<sup>14</sup> Moreover, it would require extensive cooperation among international drug companies and federal governments.<sup>15</sup> Nevertheless, the pursuit of patent pools is recommended for the development of treatments for orphan diseases that take the lives of millions of people each year.<sup>16</sup>

### B. *The Participants for the Orphan Disease Patent Pool*

The development of an orphan disease patent pool can begin with establishing participants. An orphan disease patent pool can require the

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<sup>11</sup> Knowledge Ecology International, *supra* note 8, at 1.

<sup>12</sup> *Id.*

<sup>13</sup> *Id.*

<sup>14</sup> *Id.* (“A pool may involve ... large, industry-wide pool open to anyone, encompassing hundreds of manufactures and thousands of patents, as well as other intellectual property.”).

<sup>15</sup> *Id.* at 6 (“The Pool [to expand access to needed medical technologies] would simultaneously negotiate agreements with patent holders and national governments. The pool would execute Memoranda of Understanding (MOU) with governments, purchasing agencies and donors in order to generate support for the patent pool model as well as to facilitate cooperation between the numerous interested parties.”).

<sup>16</sup> See Kapczynski, *supra* note 1, at 1032 (“Each year, millions of people in low- and middle-income (LMI) countries die from preventable and treatable diseases.”).

participation of federal governments and drug companies.<sup>17</sup> Federal governments' contributions would include providing incentives to drug companies to participate.<sup>18</sup> Initially, drug companies might be reluctant to participate because patents "provide a competitive advantage in a highly competitive and lucrative environment" such as the drug industry.<sup>19</sup> Moreover, drug companies focus research and development resources on inventions that promise lucrative financial rewards.<sup>20</sup> Accordingly, drug companies typically do not develop drugs for orphan diseases that primarily affect low and middle-income countries because the market is not lucrative.<sup>21</sup> Finding the ideal incentive package to ensure that drug company patent holders participate will be vital to the initial success of an orphan disease patent pool.

### *C. Incentives Needed to Ensure Participation of Drug Companies*

An economic committee would need to determine the ideal incentive package to ensure drug company patent holders participate. Therefore, detailed incentive packages will not be discussed. However, there are two laws codified by the United States government that will be used to illustrate how patent-related incentives may be leveraged.

First, the Bayh-Dole Act allows universities, faculty inventors, and private industry that receive federal funding to obtain ownership of patent rights from

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<sup>17</sup> Knowledge Ecology International, *supra* note 8, at 6 (For example, Memoranda of Understanding (MOU) with governments, purchasing agencies and donors would have to be executed.).

<sup>18</sup> Consumer Project on Technology, The Bayh-Dole Act, <http://www.cptech.org/ip/health/bd/> (last visited Mar. 22, 2009) (The Bayh-Dole Act provides one example of how a government may provide incentives. The Bayh-Dole Act "allows for the transfer of exclusive control over many government funded inventions to universities and businesses operating with federal contracts for the purpose of further development and commercialization.").

<sup>19</sup> Intellectual Asset Management, Building a Strong Patent Portfolio, <http://www.iam-magazine.com/issues/Article.ashx?g=fd9a3044-e7a4-4787-b108-8f85c2906b44> (last visited Mar. 22, 2009).

<sup>20</sup> Consumers International, *Drugs, Doctors and Dinners: How Drug Companies Influence Health in the Developing World*, (Oct. 2007), [http://www.marketingoverdose.org/documents/ci\\_pharma\\_2007.pdf](http://www.marketingoverdose.org/documents/ci_pharma_2007.pdf), at 10.

<sup>21</sup> *Id.*

inventions stemming from federal dollars.<sup>22</sup> It also allows these parties the ability to license the inventions to other parties for economic gain.<sup>23</sup> However, the federal government reserves “march-in” rights, whereby under limited circumstances the government may license the invention to third parties without the consent of the patent holder or the original licensee.<sup>24</sup>

Second, the Orphan Drug Act of 1983 provides marketing exclusivity, tax incentives, and research grants for companies engaging in research on orphan diseases.<sup>25</sup> The Act provides, “[a seven]-year marketing exclusivity to sponsors of approved orphan products, a tax credit of [fifty] percent of the cost of conducting human clinical testing, and research grants for clinical testing of new therapies to treat orphan diseases.”<sup>26</sup> Exclusive marketing rights prevent other companies from marketing the same version of the drug.<sup>27</sup> Currently, the Orphan Drug Act is limited in scope to orphan diseases that affect the American population.<sup>28</sup>

As will be discussed, the orphan disease patent pool may benefit from some of the features of these Acts already codified by the United States government.

#### *D. An Example of an Orphan Disease Patent Pool*

The following example outlines one possible framework of an orphan disease patent pool, which incorporates features of the Bayh-Dole Act and the Orphan Drug Act of 1983.

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<sup>22</sup> Kapczynski, *supra* note 1, at 1063; *see* Bayh-Dole Act, 35 U.S.C. §§ 200-12 (2006).

<sup>23</sup> *Id.*

<sup>24</sup> Consumer Project on Technology, *supra* note 18.

<sup>25</sup> Colleen Chien, *Cheap Drugs at what Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation?*, 18 BERKELEY TECH. L.J. 853, 866 (2003); *see* Orphan Drug Act of 1983, 21 U.S.C. § 360ee (2006).

<sup>26</sup> Department of Health and Human Services, Office of Inspector General, *The Orphan Drug Act Implementation and Impact*, May 2001, <http://www.oig.hhs.gov/oei/reports/oei-09-00-00380.pdf>, at 1.

<sup>27</sup> *Id.*

<sup>28</sup> *Id.*

The orphan disease patent pool initially may be populated with relevant patents owned by member drug companies.<sup>29</sup> Members would be granted nonexclusive license rights to these patents for the sole purpose of advancing the goal of developing and producing cost effective drugs for orphan diseases that affect low to middle-income countries.<sup>30</sup> Of course, the members would pay a reasonable licensing fee designated by the patent pool.<sup>31</sup> In addition, as with the Orphan Drug Act of 1983, governments could provide marketing exclusivity, tax incentives, and research grants to incentivize drug companies to participate.<sup>32</sup> However, similar to the Bayh-Dole Act, governments that provide these incentives to members could reserve march-in rights under pre-defined circumstances.<sup>33</sup>

Additionally, similar to the government's role in the Bayh-Dole Act, a patent pool governing body, elected by member drug companies, could prioritize orphan drug research and development and direct funds to member drug companies to conduct the research and development on priority orphan drugs.<sup>34</sup> However, in contrast to the Bayh-Dole Act, members of the patent pool would not have the ability to obtain exclusive licenses.<sup>35</sup> Rather, the patents generated from patent pool funding would further populate the patent pool.

As the orphan disease patent pool progresses, members would begin producing drugs for orphan diseases. Members' profits directly related to licensing would be split in two proportions designated by the patent pool: the first part of the profits would compensate the patent owner for its ingenuity, and the second part of the profits would be returned to the patent pool for the benefit of all members to fund future efforts. Over time, the patent pool would increasingly become self-sufficient by funding itself through patent pool profits. In addition,

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<sup>29</sup> Knowledge Ecology International, *supra* note 8, at 6.

<sup>30</sup> *Id.*

<sup>31</sup> *Id.*

<sup>32</sup> See Chien, *supra* note 25, at 866.

<sup>33</sup> Consumer Project on Technology, *supra* note 18.

<sup>34</sup> See Kapczynski, *supra* note 1, at 1063.

<sup>35</sup> See *Id.*

the patent pool could allow member drug companies to use their patents without licensing fees.

### III. BENEFITS AND A CRITIQUE OF THE ORPHAN DISEASE PATENT POOL

The orphan disease patent pool offers a number of benefits that could enhance global public health by enabling the development of cost effective drugs for orphan diseases.<sup>36</sup> The following are the three primary benefits of the orphan disease patent pool, followed by a common critical response.

#### A. *The Orphan Disease Patent Pool Eliminates the Problems Caused by “Blocking” Patents*

Patent pools eliminate “blocking” patents.<sup>37</sup> Companies that hold patents on an industry’s core technology may prevent, or “block,” others from using that core technology to bring other products to market.<sup>38</sup> By including blocking patents in the orphan diseases patent pool, member drug companies may efficiently license all patents in the patent pool, including blocking patents, necessary to produce a particular orphan drug.<sup>39</sup>

#### B. *The Orphan Disease Patent Pool Reduces Licensing Transaction Costs*

Patent pools may reduce licensing transaction costs.<sup>40</sup> For example, members of the orphan disease patent pool can reduce or eliminate the need for litigation over patent rights, because the members will be able to settle, or even avoid, litigation through the creation of the patent pool.<sup>41</sup> In addition, members will be able to efficiently obtain the licenses for technology encompassed by the

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<sup>36</sup> See Clark, *supra* note 10, at 8.

<sup>37</sup> *Id.*

<sup>38</sup> *Id.*

<sup>39</sup> *Id.*

<sup>40</sup> *Id.*

<sup>41</sup> *Id.*

orphan diseases patent pool.<sup>42</sup> In essence, the patent pool creates one-stop licensing, because a member will be able to obtain one license for all patents in the patent pool.<sup>43</sup> As a result, licensing becomes more efficient and streamlined.<sup>44</sup>

### C. *The Orphan Disease Patent Pool Distributes Risks*

Patent pools distribute the financial risk and cost associated with research and development of new drugs.<sup>45</sup> Depending on how the patent pool is setup, all members could receive a set income based upon a percentage of the patent pool's royalties.<sup>46</sup> In addition, a portion of the profits associated with a drug could be returned to the patent pool to fund future research. Therefore, the success of one member of the patent pool could result in research funding for all members.

### D. *Critique of the Orphan Disease Patent Pool*

Critics primarily argue that patent pools may be susceptible to anticompetitive effects.<sup>47</sup> In particular, critics argue that there are "dangers that the [patent] pool group might possess market power in the industry, artificially inflating prices, or that other patents might shield invalid patents, since they are sold as a package."<sup>48</sup> In response, the Justice Department set guidelines to help patent pools avoid anticompetitive effects.<sup>49</sup> The Justice Department's guidelines specify: "(1) the patents in the pool must be valid and not expired, (2) no aggregation of competitive technologies and setting a single price for them, (3) an independent expert should be used to determine whether a patent is essential to complement technologies in the pool, (4) the pool agreement must not disadvantage competitors in downstream product markets, and (5) the pool

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<sup>42</sup> Clark, *supra* note 10, at 9.

<sup>43</sup> *Id.*

<sup>44</sup> *Id.*

<sup>45</sup> *Id.*

<sup>46</sup> *Id.*

<sup>47</sup> May Mowzoon, *Access Versus Incentive: Balancing Policies in Genetic Patents*, 35 ARIZ. ST. L.J. 1077, 1101 (2003).

<sup>48</sup> *Id.* at 1102.

<sup>49</sup> *Id.*

participants must not collude on prices outside the scope of the pool.”<sup>50</sup> Accordingly, the orphan disease patent pool should follow the Justice Department’s guidelines to avoid anticompetitive effects.

#### IV. CONCLUSION

Patent pools could stimulate research and development on orphan disease drugs and enhance global access to resulting drugs. In order to ensure participation, federal governments would have to help administer the orphan disease patent pool and provide adequate incentives to encourage private drug companies to participate. The incentives, in addition to details of the patent pool, would have to be thoroughly studied before an effective orphan disease patent pool could be established. In addition, the orphan disease patent pool would have to ensure no anticompetitive effects, on a country-by-country basis. Nevertheless, the social and economic benefits stemming from orphan disease research and development, and global access to related drugs, outweigh for-profit interests and is well worth the endeavor.

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<sup>50</sup> Clark, *supra* note 10, at 7.