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# PATENT POOLS AND ACCESS TO PUBLIC HEALTH

# 1. INTRODUCTION

Patent pools can be defined as "*as an agreement between two or more patent owners to license one or more of their patents to one another or to third parties*" <sup>1</sup> they can be called private arrangements or agreements which enables the parties to work under one another patent rights and centrally administer the pooled rights, which can be then granted in the form of licenses to third parties.<sup>2</sup>

The concept has been discussed from a legal as well as an economic perspective, it has been observed to have had a positive effect on innovation and competition by reducing costs of transaction, development of new products and sharing intellectual property assets.<sup>3</sup>

Various fields of technology have used patent pools, some early examples being sewing machines in the nineteenth century and for aircrafts during World War 1.<sup>4</sup> In recent times they

<sup>&</sup>lt;sup>1</sup> "WORLD INTELLECTUAL PROPERTY ORGANIZATION (WIPO) PATENT ..."

<sup>&</sup>lt;https://www.wipo.int/export/sites/www/ip-competition/en/studies/patent\_pools\_report.pdf> accessed June 12, 2020, p 3.

<sup>&</sup>lt;sup>2</sup> Contreras J, "PATENTS AND CORONAVIRUS – A ROLE FOR PATENT POOLS?" (*infojustice.org*) <http://infojustice.org/archives/42242> accessed June 12, 2020.

<sup>&</sup>lt;sup>3</sup> "WORLD INTELLECTUAL PROPERTY ORGANIZATION (WIPO) PATENT ..."

<sup>&</sup>lt;https://www.wipo.int/export/sites/www/ip-competition/en/studies/patent\_pools\_report.pdf> accessed June 12, 2020.

<sup>&</sup>lt;sup>4</sup> Chon M, Roffe P and Abdel-Latif A, *The Cambridge Handbook of Public-Private Partnerships, Global Intellectual Property Governance, and Sustainable Development* (Cambridge University Press 2018), p 93.

have been associated with the field of information and technology communication, often linked to standard setting under standard setting organizations.<sup>5</sup>

In the twentieth century patent pools have emerged as a possible solution for public health access, however they haven't achieved much commercial success in the biomedical sector<sup>6</sup> as some problems that it faces are lack of market exclusivity in the face of high production costs, regulatory approval of criminal trials, monopoly and control over assets<sup>7</sup> and issues arising out of antitrust law. It is a new model in the field of public health relying on a new type of public private partnership (PPP)<sup>8</sup>.

What this paper seeks to do is understand the concerns that may plague patent pools, its contribution to the biomedical sector and access to public health, and whether a voluntary patent pool may be the answer in the wake of the current pandemic.

## 2. SOME CONCERNS UNDER PATENT POOLS.

#### Competitive concerns

Competition between substitute patents will be eliminated as a result of pooling and this may be seen as a negative effect on competition.<sup>9</sup>

Another issue that may arise is if the licensing policy of the pool is restrictive, or if the members of the pool are not allowed to license their covered patents, the price of the pool may be higher than the available competitive rate.<sup>10</sup> Patent laws already grant exclusivity and restrictions, licensing agreements under patent pools should not impose additional restrictions, meaning a licensing agreement should not be restrictive beyond the rights under intellectual property law, in order to avoid competitive concerns.<sup>11</sup>

<sup>7</sup> Ibid.

<sup>10</sup> Ibid.

<sup>&</sup>lt;sup>5</sup> Ibid.

<sup>&</sup>lt;sup>6</sup> Contreras n2.

<sup>&</sup>lt;sup>8</sup> Chon, Roffe and Abdel- Latif, n4, p 93.

<sup>&</sup>lt;sup>9</sup> "WORLD INTELLECTUAL PROPERTY ORGANIZATION (WIPO) PATENT ..."

<sup>&</sup>lt;https://www.wipo.int/export/sites/www/ip-competition/en/studies/patent\_pools\_report.pdf> accessed June 12, 2020.

<sup>&</sup>lt;sup>11</sup> Ibid.

Anti- competitive effects can be seen in the case of grant back provisions, as improved technologies may need to be shared with the members for free, there would be no incentive to hide developments, and would lead to reduced R and D if the results are not monetized.<sup>12</sup>

There also may additionally be the threat that the members of the pool in collusion may share sensitive information, like pricing, marketing strategies, or R&D development.<sup>13</sup>

#### Beyond competition law

A question that plagues the concept of patent pools is whether it is the least restrictive way of bringing dispersed patents together.<sup>14</sup> Pools were justified to encompass the overlapping patents in diverse enterprises, but under the umbrella of technological fields such as information and communication technologies.<sup>15</sup> Whether steady advancement into new fields of biotechnology and biomedical sciences is supporting the creation of pools rather than patent thickets.<sup>16</sup> "*The pool is as much made to get patents together as patents are taken to get pools together*"<sup>17</sup>

The other concern is whether the argument of reduced transaction cost is lost when it comes to overarching strategies in diffusing new technologies.<sup>18</sup>

Pools may be seen as too broad in the sense that its applicability may extend to all patents attached with a technology, whether they are essential, complementary or particularly advantageous.<sup>19</sup> It can be argued that a less binding patent agreement may be a better solution to a patent pool, also clearing arrangements may be a less restrictive alternative as transaction costs are minimum once the search costs are met.<sup>20</sup>

<sup>15</sup> *Ibid*, p 157.

<sup>17</sup> Ibid.

- <sup>19</sup> Ibid.
- <sup>20</sup> Ibid.

<sup>&</sup>lt;sup>12</sup> Ibid.

<sup>&</sup>lt;sup>13</sup> Ibid.

<sup>&</sup>lt;sup>14</sup> Drexl J, *Research Handbook on Intellectual Property and Competition Law* (Edward Elgar 2008), p 156.

<sup>&</sup>lt;sup>16</sup> Ibid.

<sup>&</sup>lt;sup>18</sup> *Ibid*, p 158.

## 3. WHY PATENT POOLS FOR PUBLIC HEALTH ACCESS.

Before we dwell on the contribution and previous efforts made for patent pooling in the biomedical sector for access to public health, we look at some advantages of pooling and compare it with a few other models in the patent regime.

#### **Pro- competitive effects**

The other side of the coin in relation to competitive effects is the positive side, it can be said that assembly of complementary patents in a pool can facilitate efficient production and required inputs can be given in the hands of the most efficient producers.<sup>21</sup> Intellectual property assets can be represented by a pool, to deal with inefficiencies, leading to cross licensing and licensing to third parties, and pool member can also be allowed to license their individual patents, keeping prices under a competitive pressure.<sup>22</sup>

Creation of such pools save money and time that may be spent in litigation over patent rights, which would be beneficial for small businesses and developing countries who may not be able to bear the cost of litigation.<sup>23</sup>

As pools facilitate co ownership of joint technologies transaction costs can be significantly reduced and manufacturers no longer have to bear the burden of multiple patents and licensing fees.<sup>24</sup> It would also reduce the cost payable as royalties for each individual patent or stacking of patents.

To facilitate faster development of technology pooling helps in clearing issues arising out of infringing or blocking patents.<sup>25</sup>

<sup>&</sup>lt;sup>21</sup> "WORLD INTELLECTUAL PROPERTY ORGANIZATION (WIPO) PATENT ..."

<sup>&</sup>lt;https://www.wipo.int/export/sites/www/ip-competition/en/studies/patent\_pools\_report.pdf> accessed June 12, 2020.

<sup>&</sup>lt;sup>22</sup> Ibid.

<sup>&</sup>lt;sup>23</sup> Ibid.

<sup>&</sup>lt;sup>24</sup> *Ibid.* 

<sup>&</sup>lt;sup>25</sup> Ibid.

#### Other models

The article by Heller and Eisenberg have described the problem of anti-commons in intellectual property as-

"too many IP rights in 'upstream' research results that could . . . restrict 'downstream' research and product development by making it costly and burdensome to collect all the necessary licenses."<sup>26</sup>

What this would result in is the underuse of scarce resources as the owners may block each other.<sup>27</sup>

Lack of cooperation among individual patent holders may result in a holdout, each player demanding a separate incentive may significantly increase the cost of the project.<sup>28</sup>

*Open source and compulsory licensing* – the widest access can be achieved by this model as it does away patenting of both materials and improvements, eliminating problems of patent thickets and downstream competitive tensions.<sup>29</sup> Often this model has been used for software products, but in the biotechnology field, subsequent transfers of technology can take place after patenting certain material.<sup>30</sup> It may be a viable option but since the biotechnology field is not the same as the software field, it is limited by the long development timeline, elaborate laboratory infrastructure and imposed regulatory oversight.<sup>31</sup> It can still be used to share biotechnology knowledge.

A compulsory licensing approach may require specified terms and conditions under the World Health Organization and member states for granting licenses and would only be marginally appealing to potential patentees when compared to non- proprietary models.<sup>32</sup>

Compensatory liability- for microbial samples Professor Reichmann proposed a model that

- <sup>30</sup> *Ibid*.
- <sup>31</sup> Ibid.

 <sup>&</sup>lt;sup>26</sup> Beldiman D, "Patent Choke Points in the Influenza-Related Medicines Industry: Can Patent Pools Provide Balanced Access?" (2012) 15 Search Tulane Journal of Technology and Intellectual Property, p 46.
<sup>27</sup> Ibid.

<sup>&</sup>lt;sup>28</sup> *Ibid*.

<sup>&</sup>lt;sup>29</sup> *Ibid*, p 49.

<sup>&</sup>lt;sup>32</sup> Ibid.

"provides an intermediate zone, where Creative Commons licenses are insufficient but exclusive rights and concomitant restrictions on research would impose unnecessary overkill in relation to the still uncertain value of the upstream inputs."<sup>33</sup>

Prospects of commercialization in a strong market this model may not be able to alleviate the problem of patent thickets and remains suited for situations where patent funding plays a less significant role.<sup>34</sup>

#### Pandemic Influenza Preparedness (PIP) and influenza related medicines market (IRM).

Following the H5N1 crisis the WHO in 2011 adopted the framework for PIP, achieving the first effort at widespread access and reasonable prices and access to virus samples.<sup>35</sup> However it couldn't establish an intellectual property governance regime that would have helped in the availability and affordability of IRMs. The effort made to strike a balance between incentives for the private industry and public health needs, but the principles of balance remained at the negotiating table.<sup>36</sup>

To understand if the IRM attracted investment statistics have shown that spending on PIP has tripled from 2007 to 2009 indicative of sufficient interest shown by developers in this field.<sup>37</sup>

Patenting under this framework had issues relating to ambiguity of terms such as qualified recipients of samples, what included the term "materials" since the samples were bound by a single intellectual property right.<sup>38</sup>

TRIPs members states would have control or patents of the derivatives and improvements that arise out of materials and virus samples, giving power to an upstream patentee to block developments made by third parties.<sup>39</sup>

- <sup>34</sup> Ibid.
- <sup>35</sup> *Ibid*, p 34.
- <sup>36</sup> Ibid, p 37.
- <sup>37</sup> *Ibid*, p 39.
- <sup>38</sup> *Ibid*, p 40.
- <sup>39</sup> *Ibid*, p 42.

<sup>&</sup>lt;sup>33</sup> Ibid, p 51.

WHO being the gatekeeper of sample virus under the framework could be part of bargaining asymmetry to the effect of obligating downstream patentees to enter into licensing agreements.<sup>40</sup>

#### The SARS patent pool

Following the outbreak in 2003 institutions for Britain, United States of America and Hong Kong began simultaneously sequencing the virus.<sup>41</sup> The number of prospective patent holders gave rise to concerns that rights to the genomic sequence may be very fragmented<sup>42</sup> and may result in large amount of simultaneous filing. To overcome these concerns cooperative pooling was agreed upon by the holders, combining their technologies and licensing it to third parties in a nonexclusive manner.<sup>43</sup> Although the outbreak was over before the pool was made it can provide for a legal blueprint for formation of similar pools.<sup>44</sup>

#### Patent pool in HIV.

The first patent pool having a streamlined approach to public health mandate was in 2010, following UNITAID's decision, which is a publicly funded initiative under WHO.<sup>45</sup>

The Medicine Patent Pool operates by negotiating licenses with patent holders and further licensing them to manufacturers, who in turn develop the licensed medicine, available in developing countries in exchange for royalties.<sup>46</sup> It operates more as a clearing house or intermediary than a patent pool, but the principle of aggregation and further licensing as seen in pooling is the same. There is undoubted transparency as all licenses are published on its website. This model of transparency has set a new standard in voluntary licensing terms and conditions.<sup>47</sup> MPP has also helped in prioritizing medicine and access in close collaboration with the WHO.<sup>48</sup> These licenses have the potential of achieving the greatest

<sup>43</sup> Ibid.

<sup>47</sup> *Ibid,* p 98.

<sup>&</sup>lt;sup>40</sup> *Ibid,* p 53.

<sup>&</sup>lt;sup>41</sup> *Ibid,* p 57.

<sup>&</sup>lt;sup>42</sup> *Ibid*, p 58.

<sup>&</sup>lt;sup>44</sup> Ibid.

 <sup>&</sup>lt;sup>45</sup> Chon M, Roffe P and Abdel-Latif A, *The Cambridge Handbook of Public-Private Partnerships, Global Intellectual Property Governance, and Sustainable Development* (Cambridge University Press 2018), p 96.
<sup>46</sup> *Ibid.*

<sup>&</sup>lt;sup>48</sup> *Ibid*, p 99.

public health impact by gathering data and needs in collaboration with governments and expanding its geographical scope.<sup>49</sup>

In the case of HIV thirteen generic manufacturers have already supplied 17 million patients in 127 developing countries, enabling a saving of 239 million dollars, through the purchase of affordable treatment, equivalent to the treatment of 6 million people.<sup>50</sup>

It can clearly be observed that cross licensing in the form of patent pools can have a great impact on the public health access model across the globe.

### 4. CURRENT SCENARIO.

Sometime in December 2019 and early 2020 a new disease emerged reported from the regions of China. The outbreak was termed as Public Health Emergency of International Concern on 30<sup>th</sup> January 2020 by the WHO.<sup>51</sup> It was identified as the new coronavirus and on 11<sup>th</sup> February was given the name Covid-19.

In the wake of the global pandemic it has been proposed that a patent pool be formed and in March 2020 the Health Minister of Costa Rica requested that the WHO

"undertake an effort to pool rights to technologies that are useful for the detection, prevention, control and treatment of the COVID-19 pandemic."

Proposing the pool

"should include existing and future rights in patented inventions and designs, as well rights in regulatory test data, know-how, cell lines, copyrights and blueprints for manufacturing diagnostic tests, devices, drugs, or vaccines. It should provide for free access or licensing on reasonable and affordable terms, in every member country."

<sup>&</sup>lt;sup>49</sup> Ibid.

<sup>&</sup>lt;sup>50</sup> Ibid, p 101.

<sup>&</sup>lt;sup>51</sup> "Coronavirus Disease (COVID-19) - Events as They Happen" (World Health Organization)

<sup>&</sup>lt;https://www.who.int/emergencies/diseases/novel-coronavirus-2019/events-as-they-happen> accessed June 12, 2020

The request has been endorsed by WHO as well as UNITAID following which the MPPs board has authorized

"temporary expansion of MPP's remit to include any health technology where licensing could improve access for low- and middle-income countries."

This may make it seem that countries in North America, Europe and Asia where the pandemic has hit hard may not be the beneficiaries of these expansions.

UNITAID have supported the move and have called for non- exclusive and global voluntary licensing for providing equitable access not just for Covid -19 but tuberculosis and hepatitis, also stating that intellectual property is not the problem but the issue lies in how they are used.<sup>52</sup>

While the US and China played the blame game leading European countries have pledged that innovative tools, therapeutics and vaccines and knowledge thereof shall be equally shared.<sup>53</sup> However what is to be seen is that countries with major pharmaceutical companies have argued that they would need to rely on patents to recover their research and development costs.<sup>54</sup> These have been seen in earlier attempts to break drug and vaccine monopoly for the sake of public health (in the case of HIV AIDS).<sup>55</sup>

There may have been general disappointment on how the resolution has been worded, but the 73<sup>rd</sup> World Health Assembly, but it is important to see that its has addressed the response to the pandemic through

"existing mechanisms for voluntary pooling and licensing of patents to facilitate timely, equitable and affordable access to them, consistent with the provisions of relevant international treaties including the provisions of the TRIPS agreement and the flexibilities as confirmed by the Doha Declaration on the TRIPS Agreement and Public Health"<sup>56</sup>

 <sup>&</sup>lt;sup>52</sup> "Unitaid Backs WHO and Costa Rica Call to Action on Pooling of Knowledge and Rights for COVID-19 Global Public Goods" (*Unitaid*) <a href="https://unitaid.org/news-blog/unitaid-backs-who-and-costa-rica-call-to-action-on-pooling-of-knowledge-and-rights-for-covid-19-global-public-goods/#en> accessed June 12, 2020.</a>
<sup>53</sup> Boseley S, "US and UK 'Lead Push against Global Patent Pool for Covid-19 Drugs'" (*The Guardian* May 17, 2020) <a href="https://www.theguardian.com/world/2020/may/17/us-and-uk-lead-push-against-global-patent-pool-">https://www.theguardian.com/world/2020/may/17/us-and-uk-lead-push-against-global-patent-pool-</a>

for-covid-19-drugs> accessed June 12, 2020.

<sup>&</sup>lt;sup>54</sup> Ibid. <sup>55</sup> Ibid.

<sup>&</sup>lt;sup>56</sup> (World Health Organization) <https://apps.who.int/gb/e/e\_wha73.html> accessed June 12, 2020.

# 5. CONCLUSION

Significant economic and technological efficiency can be achieved by patent pools and relying on the discussions above it can be a viable option even in the biomedical sector. The constraints that encompass it are outweighed by the positives it can achieve in the intellectual property regime as opposed to individual patenting. The proposal of cross licensing in the form of patent pools can strengthen existing framework to achieve accessibility and affordability.<sup>57</sup> There may be a loss to the profit potential but will reduce the risk of not being able to commercialize, and would bring a larger number of players in the market.<sup>58</sup>

Keeping in mind the previous efforts and the existing framework, if countries can look past the private monopoly granted under the patent regime and look ahead into the benefits of equitable health access especially in the wake of the current pandemic, keeping in mind the flexibilities guaranteed by the international agreements, form a national intellectual property regime, that can alleviate the problems of high costs through compensatory liability or prize funds. It would then become easier for countries to actively partake in pooling resources and granting licenses with keeping public health concerns over research and development concerns that plague major pharmaceutical companies.

<sup>&</sup>lt;sup>57</sup> Beldiman, n 26, p 60.

<sup>58</sup> Ibid.