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# Patent Pledges for Access to Medicine: Need of the Hour

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## ABSTRACT

*Patent Law gives an exclusive right to the Patent holder to exploit his Patent and thereby create his monopoly. But over a period of time, it has been seen that this monopoly given to the Patent holder interferes with the accessibility to medicine. Though there is an inbuilt Patent law mechanism that helps to strike a balance between public and patent rights, there are a few emerging concepts that are within the rights of the Patent holder and can contribute significantly in providing Access to medicine. One such concept is of Patent pledge that can be of much use. This article aims to outline the concept of Patent pledges. It also elaborates the contribution of different forms of tools like Patent pledges and Patent pool, within the rights of Patent holders in the fight against COVID-19.*

**Keywords:** Patent Pledges, Patent Pooling, COVID-19, Access to medicine.

## I. INTRODUCTION

Access to medicine is one of the most important requirements for people to achieve health. The need for access to medicine has always been felt but the importance of the same has been escalated even more during this pandemic. The year 2019 to 2021, has seen the onset and rage of the Corona Virus pandemic, which has taken the lives of millions across the globe. The vaccines are developed and being supplied to different countries but the distribution or rather the access to the medicine is not uniform. Some countries like the United States of America have initiated their booster dose of vaccination, while many African Countries are waiting for their first dose. It has been said that in order to eradicate corona, there is a need for universal vaccination, where everyone is vaccinated. Even a single person having corona will keep the chain on for further spread. Thus to curb this pandemic, just the invention of curative drugs and vaccines are not enough, there is a need that these vaccines reach to each and every person and there is vaccine equity.<sup>3</sup> Patent Law gives the incentive to innovate and increase the quality of medicine to fight diseases, but at the same time, it gives a monopoly to the Patent holder to

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<sup>3</sup> *No-one is safe until everyone is safe*, WORLD HEALTH ORGANIZATION, (July 20, 2021) <https://www.who.int/news-room/photo-story/photo-story-detail/No-one-is-safe-from-COVID19-until-everyone-is-safe>.

control the flow of the drugs in patented drugs in the market. And based on the previous experience on treatment of another disease, it is feared that the accessibility and affordability of COVID 19 drugs and vaccines will be adversely affected by Patents.<sup>4</sup> At such times, it becomes the duty of the state to ensure that there is a balance between the public interest i.e access to medicine and the interest of the patent holder i.e patent holder's right. In fact, in addition to the state's effort, the patent holders in a different field, ranging from "diagnostics, therapeutic, medical equipment, and vaccine to prevention, tracking, and containment of COVID-19", should make effort to attain vaccine equity<sup>5</sup>. There have been few mechanisms like patent licensing, patent pooling and patent pledging, which while respecting the monopoly of the holder can also be used to provide smooth access to medicine. Out of these, patent licensing and patent pooling are not new, but the concept of patent pledging is an upcoming concept that may prove very effective in providing easy access to medicine.

## II. PATENT PLEDGE

Traditionally, the Patent law provides exclusive rights to the patent holder for a minimum period of 20 years.<sup>6</sup> During this period the patent holder can prevent the third party from making, using, offering for sale, selling, or importing his patent product and using his patent process.<sup>7</sup> Thus it can be said that the Patent holder has the exclusive right to economic exploitation of his patented process and product. He can either engage in the economic exploitation directly or by entering into a license agreement with other manufacturing companies, where the licensed patent can be used to bring the product to market. This helps the patent holder to reap upon the benefits of his invention where he has invested in R&D.<sup>8</sup> But recently the statement given by Elon Musk, the CEO of Tesla motors statement "All our Patent belongs to you," has brought in the limelight, the concept of "Open source movement" or in other words 'Patent Pledges' in field of Patent.<sup>9</sup> The open-source movement is not new in the field of Intellectual Property, in fact, it has been there for a quite long time in the form of

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<sup>4</sup> Olga Gurgula, *Strategic Patenting by Pharmaceutical Companies – Should Competition Law Intervene?*, IIC INTREV IND PROP COPYR LAW, 1, 1-2, (2020)

<sup>5</sup> Contreras J. L. et al. *Pledging intellectual property for COVID-19*, 38 NATURE BIOTECHNOLOGY 1146, 1146, (Oct. 2020).

<sup>6</sup> The Agreement on Trade Related Aspects of Intellectual Property Rights, Jan 1, 1995, Art. 33. [hereinafter referred as TRIPS Agreement].

<sup>7</sup> TRIPS Agreement, *Id* at Art. 28.

<sup>8</sup> Irene Calboli, "Intellectual Property Exhaustion and Parallel Imports of Pharmaceuticals: A Comparative and Critical Review", in ACCESS TO MEDICINES AND VACCINES, IMPLEMENTING FLEXIBILITIES UNDER INTELLECTUALPROPERTY LAW, 21-25 (Carlos M. Correa and Reto M. Hilty, edn. Springer publication 2022). <http://dx.doi.org/10.2139/ssrn.3853065>.

<sup>9</sup> Elon Musk, *All Our Patent Are Belong To You*, TESLA, (Feb 22, 2022 & 02:15 PM), <https://www.tesla.com/blog/all-our-patent-are-belong-you>.

Open Source Software. Beginning of 1990, large firms in the computing and software industries began to champion Open sources code platforms such as Linux and Android. The early 2000s include IBM's pledge not to assert 500 of its patents against the development, distribution and use of open-source software<sup>10</sup>. And another good example of a non-assertive patent pledge was the free availability of QR technology<sup>11, 12</sup>. Hence, the rise of patent pledges suggests demand for more research.

*“A patent pledge is a publicly announced intervention by patent-owning entities ('Pledgors') to out-license active patents to the restricted or unrestricted public free from or bound to certain conditions for a reasonable or no monetary compensation”.*<sup>13</sup> By relinquishing or restricting their enforcement the Pledgor invites more and more players in the market, with relation to the said technology. As discussed, the pledging of Intellectual Property [IP] is not new in the field of software copyright, their success of the open-source movement for software and the computer-related product has shown that a business model based on monopoly is not the only key to innovation.<sup>14</sup> In fact, the open movement has substantially contributed to further product innovation.

### III. TYPES OF PATENT PLEDGES

Patent Pledges are characterized as public announcements, which can be made in a variety of different settings and formats including website postings, press releases, or even public speeches, as such, they are intended to address the public rather than one or more specific addresses.<sup>15</sup> The best example for this statement was given by Elon Musk for Tesla Patents.<sup>16</sup> The initiation of these pledges are entirely in the discretion of the patent holder, therefore these voluntary Pledges can sometimes be made to the public at are and some time specific to an

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<sup>10</sup> Paul Kallender, *IBM opens 500 patents to open-source developers*, COMPUTERWORLD IDG NEWS SERVICE (Jan 11, 2005 & 01:30 PM) <https://www.computerworld.com/article/2569038/ibm-opens-500-patents-to-open-source-developers.html>.

<sup>11</sup> A QR code is a type of barcode that can be read easily by a digital device and which stores information as a series of pixels in a square-shaped grid. QR codes are frequently used to track information about products in a supply chain and – because many smartphones have built-in QR readers – they are often used in marketing and advertising campaigns. More recently, they have played a key role in helping to trace coronavirus exposure and slow the spread of the virus. See more, Adem Hayes, *Quick Response (QR) Code*, INVESTOPEDIA, (Mar 29, 2021) <https://www.investopedia.com/terms/q/quick-response-qr-code.asp>.

<sup>12</sup> Jonas Fabian Ehrnsperger & Frank Tietze, *Patent pledges, open IP, or patent pools? Developing taxonomies in The thicket of terminologies*, 14(8) PLoS One 1-30, 3, (2019) <https://doi.org/10.1371/journal.pone.0221411>.

<sup>13</sup> *Ibid.*

<sup>14</sup> Contreras L., *Patent Pledges*, 47 ARIZ. ST.L.J.543, 545 (2015) [https://arizonastatelawjournal.org/wp-content/uploads/2015/12/Contreras\\_Final.pdf](https://arizonastatelawjournal.org/wp-content/uploads/2015/12/Contreras_Final.pdf).

<sup>15</sup> Catharina M. & Metzger A., *Playing Nice with Patents: Do Voluntary Non-Aggression Pledges Provide a Sound Basis for Innovation*, 17 N.C. J.L. & TECH. 483, 485 (2016) <https://scholarship.law.unc.edu/cgi/viewcontent.cgi?article=1303&context=ncjolt>.

<sup>16</sup> Ehrnsperger & Tietze, *Supra note* 11, at 3.

individual.

On the basis of Origin, these pledges may be divided into two major categories i.e Unilateral Pledge and Coordinated pledge. *Unilateral Patents* are a commitment made by an individual patent holder on a voluntary basis. Whereas ‘*Coordinated Pledges*’ is made by a member of a defined group like that of a Standard Development Organisation (SDO)<sup>17</sup> according to the pre-determined form or formula, with respect to a defined technology or set of Patents. These coordinated Pledges have some sort of common basic characters. These pledges can be made through contractual Agreements, by-laws and policy of the SDO or even through Letter of Assurances/ licensing declaration or written assurances. “The purpose behind the pledges is that the licensor is not focusing on immediate commercial return for their inventions or creations

Another important classification of the patent pledges is on the basis of the forms in which patent pledges are provided. The first one is *Primary Access commitments* where the patent holder makes a general statement that he is willing to provide access to his Patent technology to the public at large. The patent holder agrees to refrain from starting any infringement proceeding against any person, who engages in manufacturing, sale and import of patented product or process. The holder may also agree to provide license with his patent on FRAND<sup>18</sup> terms to the public at large or a specified group of people who fulfil the set criteria fixed by the patent holder. The Second one is *Royalty Commitments* where the License is given on FRAND Terms but a nominal royalty amount is charged from the licensor. The last one is *Non-Royalty Commitments* where the pledge is limited to the ability of the Patent holder to enforce his patent and maximize rents from the patent.<sup>19</sup> It is notable that in all these cases the Patent Holder lets go his patent privilege or a part of his rights, with or without any direct monetary benefit.

#### IV. BENEFITS OF PATENT PLEDGES

One of the key questions that come with patent pledges is what is the reasoning behind the growth of such Patent Pledges. The traditional theories i.e the incentive theory, the labour theory and the prospect theory, focus on the rights, interest and the economic benefit and

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<sup>17</sup> SDO stands for Standard- Development Organisation. They are typically organized as non-profit trade association, ranging from small firms focusing on single product to multinational companies, having a wide range of products. See also Contreras L. J., *A patent Pledge Taxonomy*, in PATENT PLEDGES GLOBAL PERSPECTIVES ON PATENT LAW’S PRIVATE ORDERING FRONTIER, 7, 7-8, ( Contreras M. & Jacob M ed. 2017).

<sup>18</sup> FRAND stands for ‘Fair, Reasonable and Non-Discriminatory’ term of Licensing. See more Sidak J. Gregory, *A FRAND Contract’s Intended Third-Party Beneficiary*, 1 THE CRITERION JOURNAL ON INNOVATION, 1001,1001(2016) available at <https://www.criterioneconomics.com/docs/a-frand-contracts-intended-third-party-beneficiary.pdf>.

<sup>19</sup> Contreras, *Supra* note 12 at 12-17.

interest of the patent holder<sup>20</sup>, justifying the monopoly in the hands of the Patent holder as a key to future innovation. However, there is also an alternate line of thinking, a different school of thought, according to which patent monopolies are most effective when configured to maximize society's access to technology and innovation. As per this line of thinking, over-protective laws can hinder the development of subsequent innovations by increasing the cost of improving old technologies or by completely banning affiliated works.<sup>21</sup> In fact as per one theory of competition law, when there are more players in the market, they constantly tend to improvise their product, to succeed in the market, paving a way for further innovation in addition to Public access to goods.<sup>22</sup> It says that “while patents are designed to promote innovation through incentivizing the development of new technology, overly restrictive patent protections can limit innovation beyond the original purpose of the patent.”<sup>23</sup>

Patent pledgor on one hand seems to be forgoing their monopoly benefit, but this does not mean that the patent pledgor receives no benefit. On the face it may seem that the patent holder is at loss but “the purpose behind the pledges is that the licensor is not focusing on immediate commercial return for their inventions or creations; rather, they encourage a broad availability of common technology platforms in order to enable long term and market-wide cost savings and efficiencies”.<sup>24</sup> The benefits derived out of Patent pledges can be classified into three heads, benefits to the pledgor, benefit to the society and benefit to the pledgee.

For the Patent Holder, the pledges act as means to create a network, where more and more collaboration can come to the Patent holder. Because of the open nature of the Patent Pledges, it provides assurance to the market at large and not to specific companies, they determine that the pledgor's patents will not be used to prevent the adoption of standards or other common technology platforms. This helps in encouraging more and more companies to rely on the pledges patent and come up with better collaboration and also focus on interoperability standards, which enable further development of different products and services built upon these standards<sup>25</sup>. It may also be used as a marketing tool to show the potential and security of the company in respect of innovation. This further helps in signalling the prospective investors and

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<sup>20</sup> HOLGER HESTERMEYER, HUMAN RIGHTS AND THE WTO, THE CASE OF PATENTS AND ACCESS TO MEDICINE, 30-33, (Oxford University Press 2007).

<sup>21</sup> Nils Tracy, *Patent Pledges: Private Tool For Public Good*, Duke University, 1, 4 (2016), <https://dukespace.lib.duke.edu/dspace/bitstream/handle/10161/11965/Nils%20Tracy%20Masters%20Project.pdf?sequence=1>.

<sup>22</sup> David E. & Abraham H., *Competition Policy and Innovation*, 18(1) OXF.REV.ECO.POL. 63, 66-68, (2002) [https://www.researchgate.net/publication/5216156\\_Competition\\_Policy\\_and\\_Innovation](https://www.researchgate.net/publication/5216156_Competition_Policy_and_Innovation).

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

<sup>24</sup> Catharina & Metzger, *Supra* note 13, at 489.

<sup>25</sup> Joseph Farrell et al., *Standard Setting, Patents, and Hold-Up*, 74 ANTITRUST L.J. 603, 616 (2007).

potential market players about the strong patent portfolio of the patent pledgor.<sup>26</sup> In an empirical study, it came out that public relations and reputation along with decreasing patent uncertainty and patent infringement threat are the additional factors supporting the patent pledge drive.<sup>27</sup> They emphasized that openness leads to research acceleration.

When it comes to the Licensee/pledgee, they take advantage of the pledged patent to develop and further make innovation in their own product. The licensee or the recipient of the pledge gets freedom from constant threats lurking on their head caused by Patent infringement. This gives them the liberty to keep pace with the increased demand for the product and improve their customer relationship. Individuals and companies who take advantage of the pledged patents do so to further innovate and develop their own products.<sup>28</sup>

The benefit derived to society from these pledges is apparent on its face. Such pledges help in the manufacturing of technically standards products less costly and thus make them more valuable and available to the consumers. The enforcement of patents being curtailed for some time will create market competitors, which will ultimately benefit society at large<sup>29</sup>. “Likewise, patent pledges enable market participants to make investments in reliance that the eventually manufactured products and related sales will not be blocked by the patent holder. In turn, this encourages the development of improved products and services built upon access to technology.”<sup>30</sup>

## V. PATENT PLEDGE AS A GLIMPSE OF HOPE IN PANDEMIC

In the current pandemic, the world has seen an unprecedented loss of life. To date, 5,358,978 lives have been lost due to corona infection<sup>31</sup>. Research shows that the chance of getting affected by the COVID-19 virus is higher in those of unvaccinated.<sup>32</sup> Even if the vaccines are invented, they are not available uniformly to every country. This vaccine inequity has led to a resurgence of different variants of the virus, time and again, further increasing the mortality count. One of the reasons for non-uniform access to medicine by the people of different nations is considered to be the IP restrictions. Therefore a joint proposal was made by South Africa

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<sup>26</sup> Larissa Long, *Patent Signals*, 69 U. CHIC. L. REV. 625, 656 (2002).

<sup>27</sup> Jonas Fabian Ehrnsperger & Frank Tietze, *Motives for Patent Pledges: A Qualitative Study*, 11 CTM WORKING PAPER SERIES UNL OF CAM., (2019), [https://www.repository.cam.ac.uk/bitstream/handle/1810/301782/jonas\\_frank\\_final\\_working%20paper\\_dec\\_2019.pdf?sequence=4&isAllowed=y](https://www.repository.cam.ac.uk/bitstream/handle/1810/301782/jonas_frank_final_working%20paper_dec_2019.pdf?sequence=4&isAllowed=y).

<sup>28</sup> Catharina & Metzger, *Supra* note 13, at 492.

<sup>29</sup> Langinier C & Moschini M. *The Economics of Patents: An Overview*, Center for Agricultural and Rural Development (Feb, 2002), <https://www.card.iastate.edu/products/publications/pdf/02wp293.pdf>.

<sup>30</sup> Catharina & Metzger, *Supra* note 13, at 492.

<sup>31</sup> WHO CORONAVIRUS (COVID-19) DASHBOARD, <https://covid19.who.int/>.

<sup>32</sup> *COVID-19 Cases, Hospitalizations, and Deaths by Vaccination Status*, Washington State Department of Health, 1, 3, (2021), <https://www.doh.wa.gov/Portals/1/Documents/1600/coronavirus/data-tables/421-010-CasesInNotFullyVaccinated.pdf>.

and India, for the waiver of certain provisions of the TRIPS Agreement, so that there is access to medicines for all<sup>33</sup>. However, due to lack of unanimity<sup>34</sup> and constant postponement of the Ministerial Conference 12 of WTO meeting<sup>35</sup>, the proposal is left in abeyance with no formal conclusion to date. Though the mechanism of Compulsory license is available in the TRIPS as assured by the DOHA declaration<sup>36</sup>, the same has not been used to its full extent by the countries, because of pressure from developed countries.<sup>37</sup>

Thus considering the need of the hour many companies have pledged their patent, by entering into Open COVID Pledges. The Open COVID Pledge is a private pledge that intellectual property owners have signed, donating their intellectual property to fight the COVID-19 pandemic.<sup>38</sup> Different companies from different areas of technology like software, manufacturing, medical etc, have voluntarily relinquished their patents in the field of vaccine technology to contact tracing etc for the global good to fight against COVID-19 and curtail the effect of the virus on human life.<sup>39</sup> The Open COVID Pledge Platform was the initiative of ten founding pledgors namely, Facebook, Microsoft, Amazon, Intel, IBM, Hewlett Packard,

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<sup>33</sup> The joint proposal made by India and South Africa in Oct 2020 was revised in May 25, 2021. This revised Proposal requests the WTO council for waiver of implementation of Sections 1, 4, 5 and 7 of Part II of the TRIPS Agreement and enforcement of these Sections under Part III of the TRIPS Agreement. The proposal aims for waiver of the patent, in relation to health products and technologies for the prevention, treatment or containment of COVID-19. The proposal is for a period of 3 years, with subsequent yearly revival, if required. See also *Waiver From Certain Provisions Of The TRIPS Agreement For The Prevention, Containment And Treatment of COVID-19*, COUNCIL FOR TRADE- RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS, (May 25, 2021) <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669R1.pdf&Open=True>.

<sup>34</sup> *Countries obstructing COVID-19 patent waiver must allow negotiations to start*, MÉDECINS SANS FRONTIÈRES (MSF) (Mar. 9, 2021), <https://www.msf.org/countries-obstructing-covid-19-patent-waiver-must-allow-negotiations>.

<sup>35</sup> *General Council decides to postpone MC12 indefinitely*, WORLD TRADE ORGANIZATION (Nov 26, 2021), [https://www.wto.org/english/news\\_e/news21\\_e/mc12\\_26nov21\\_e.htm](https://www.wto.org/english/news_e/news21_e/mc12_26nov21_e.htm).

<sup>36</sup> The World Trade Organisation's (WTO) November 2001 declaration of the Fourth Ministerial Conference in Doha, Qatar, is famous as DOHA Declaration for Public health. In this declaration WTO members stressed upon the importance of implementing and interpreting the text of TRIPS Agreement in light of Art 7 and 8 of the Agreement for promoting access to medicines as well as for research and development into new medicines. See also: *Declaration on the TRIPS agreement and public health*, WORLD TRADE ORGANIZATION (Nov. 20 2001) [https://www.wto.org/english/thewto\\_e/minist\\_e/min01\\_e/mindecl\\_trips\\_e.htm](https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm).

<sup>37</sup> Aswathy Asok, *Compulsory Licensing For Public Health And USA's Special 301 Pressure: An Indian Experience*, 24 JIPR 125, 126-129, (2019) <http://nopr.niscair.res.in/bitstream/123456789/54321/1/JIPR%2024%285-6%29%20125-131.pdf>.

<sup>38</sup> OPEN COVID PLEDGE, <https://opencovidpledge.org/about/>.

<sup>39</sup> Clay M., *Patent Pledging Problems: The Open Covid Pledge And Long-Term Solutions To Licensing Intellectual Property in Global Emergencies*, MINNESOTA LAW REVIEW (Mar 23, 2021) [https://minnesotalawreview.org/2021/03/23/patent-pledging-problems-the-open-covid-pledge-and-long-term-solutions-to-licensing-intellectual-property-in-global-emergencies/?utm\\_source=rss&utm\\_medium=rss&utm\\_campaign=patent-pledging-problems-the-open-covid-pledge-and-long-term-solutions-to-licensing-intellectual-property-in-global-emergencies](https://minnesotalawreview.org/2021/03/23/patent-pledging-problems-the-open-covid-pledge-and-long-term-solutions-to-licensing-intellectual-property-in-global-emergencies/?utm_source=rss&utm_medium=rss&utm_campaign=patent-pledging-problems-the-open-covid-pledge-and-long-term-solutions-to-licensing-intellectual-property-in-global-emergencies).



Unified Patents<sup>40</sup>, and Fabricators Foundation<sup>41</sup> with another twenty-three foundations as additional members. All these members have pledged to provide their patent to combat the effect of COVID-19. It is notable that these pledges are not directly related to the pharmaceutical industry, but these patent pledges are very much related to diagnostic, preventive, and other modes of controlling the Pandemic.

Pharmaceuticals have not come up directly and relinquished all of their Patent enforcement rights but there are few instances when the pharmaceutical companies have conditionally pledged their patent rights with respect to drugs and vaccine technology. A multinational company Moderna Inc<sup>42</sup> has pledged its patented m-RNA technology and declared that it will not enforce its rights against those who use their technology to make a vaccine for COVID-19. They have also agreed to enter into voluntary licenses to combat this pandemic.<sup>43</sup> The aim behind this was that more market participants will help ‘*drive the diffusion*’ of the new mRNA technology into the drug development ecosystem and help ‘*build infrastructure*’ for *mRNA-based technologies*<sup>44</sup> within that new ecosystem.<sup>45</sup> Another pharmaceutical giant AbbVie<sup>46</sup> also pledged that it “will not enforce global patent rights on all formulations of HIV medicine *Kaletra* (Aluvia) as the drug is being evaluated to treat severe COVID-19 in several clinical trials”<sup>47</sup>. The re-known pharmaceutical company Roche suspended its patent for the production of the drug *Tocilumab* in low- and middle-income countries which was declared by World Health Organization [WHO] as a COVID treatment Drug.<sup>48</sup>

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<sup>40</sup> “Unified Patent is a 200+ international membership organization that seeks to improve patent quality and deter unsubstantiated or invalid patent assertions in defined technology sectors (Zones) through its activities. Its actions are focused broadly in Zones with substantial assertions by Standards Essential Patents holders and/or Non-Practicing Entities...Unified works independently of its members to achieve its deterrence goals.” See UNIFIED PATENTS, <https://www.unifiedpatents.com/faq>.

<sup>41</sup> *Supra* note 36.

<sup>42</sup> “Moderna Incorporation is a Massachusetts United States-based biotechnology company established in 2010 that focuses on the development of mRNA technology for development of medical facilities, drugs and vaccines based on the same”. Recently Moderna has come up on m-RNA based vaccine for COVID-19. See more MODERNA, <https://www.modernatx.com/about-us>.

<sup>43</sup> Dan Shores, *Breaking Down Moderna’s COVID-19 Patent Pledge: Why Did They Do It?* IP WATCHDOG (Nov. 11, 2020) <https://www.ipwatchdog.com/2020/11/11/breaking-modernas-covid-19-patent-pledge/id=127224/>.

<sup>44</sup> mRNA technology stands for Messenger Ribo-Nuclie Acid Technology. Messenger RNA, or mRNA, plays a fundamental role in human biology, for transferring the instructions stored in DNA to make the proteins required in every living cell. This technology use biotechnologically altered mRNA medicines to prevent, treat, or cure disease at the cellular level itself. See more, MODERNA <https://www.modernatx.com/modernas-mrna-technology>.

<sup>45</sup> Shores, *Supra*, note 41.

<sup>46</sup> AbbVie Inc. is a US based pharmaceutical Company founded in 2013. They are involved in R&D process for improvement of standard of care through innovative new therapies. Their portfolio include oncology, immunology, neuroscience, eye care, virology, and our Allergan Aesthetics. See more ABBVIE, <https://www.abbvie.com/our-company.html>.

<sup>47</sup> Kyle Blankenship, *AbbVie gives up patent rights to HIV med Kaletra amid COVID-19 tests: Report*, FIERCE PHARMA (Mar 23, 2020 & 3.05 PM) <https://www.fiercepharma.com/pharma/abbvie-gives-up-patent-rights-to-hiv-med-kaletra-amid-covid-19-tests-report>.

<sup>48</sup> Kerry Cullian, *Roche Suspends Patents on Tocilizumab in LMICs After WHO Recommends it as Treatment*

## VI. PATENT POOLING AS A COVID-19 COMBATANT

In addition to Patent Pledge, another mechanism of licensing, i.e Patent Pool<sup>49</sup> has also come up as a mechanism, to facilitate the production of COVID drugs and their supply in under-developed and developing countries. By sharing IP and know-how through voluntary agreements and patent pooling the developers of COVID-19 health products can facilitate scale up the production multiple folds. These patent pools assist in unleashing the manufacturing and innovating capacity of the Patent pool members to scale up production.<sup>50</sup> WHO has also initiated a platform for Medical Patent Pool (MPP), with the aim to “increase access to, and facilitate the development of, life-saving medicines for low- and middle-income countries through an innovative approach to voluntary licensing and patent pooling.”<sup>51</sup> As per the data available on the official website, MPP has signed agreements with thirteen patent holders, involving thirteen HIV antiretroviral drugs, an HIV technology platform, three direct-acting antiviral drugs for hepatitis-C, one tuberculosis treatment, two long-acting antiretroviral drugs and two experimental oral antiviral treatments for COVID-19 and a COVID-19 serum antibody diagnostic test.<sup>52</sup> These technologies that have been pooled are further used to give licenses to a third party member, for escalating the supply of these drugs.

Recently Merck Sharp & Dohme<sup>53</sup> entered into an agreement with the MPP for the development of its COVID-19 oral drug ‘*Molnupiravir*’ (MK-4482/ EIDD-2801).<sup>54</sup> Even Pfizer Inc<sup>55</sup> has entered into an agreement with the MPP, for the production of its oral COVID-19 treatment drug *Ritonavir*<sup>56</sup>. “The agreement will enable MPP members to facilitate

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for Severe COVID-19, HEALTH POLICY WATCH INDEPENDENT GLOBAL HEALTH REPORTING, (July 08, 2021), <https://healthpolicy-watch.news/roche-suspends-patents-on-tocilizumab-for-lmics-after-who-recommends-it-as-treatment-for-severe-covid/>.

<sup>49</sup> “Patent pools can be defined as an agreement between two or more patent owners to license one or more of their patents to one another or to third parties.... In a patent pool, patent rights are aggregated amongst multiple patent holders. Then, the pooled patents are made available to member and non-member licensees and typically the pool allocates a portion of the licensing fees it collects to each member in proportion to each patent’s value.” See also “Patent Pools And Antitrust – A Comparative Analysis”, WORLD INTELLECTUAL PROPERTY ORGANIZATION, (Mar. 2014), [https://www.wipo.int/export/sites/www/ip-competition/en/studies/patent\\_pools\\_report.pdf](https://www.wipo.int/export/sites/www/ip-competition/en/studies/patent_pools_report.pdf).

<sup>50</sup> WHO COVID-19 Technology Access Pool, WORLD HEALTH ORGANIZATION, <https://www.who.int/initiatives/covid-19-technology-access-pool>.

<sup>51</sup> MEDICAL PATENT POOL, <https://medicinespatentpool.org/>.

<sup>52</sup> *Ibid*.

<sup>53</sup> Merck Sharp & Dohme, (MSD), is a US-based Pharmaceutical company. MSD, <https://www.msd.com/>

<sup>54</sup> *The Medicines Patent Pool (MPP) and Merck Enter Into License Agreement for Molnupiravir, an Investigational Oral Antiviral COVID-19 Medicine, to Increase Broad Access in Low- and Middle-Income Countries*, MERK, (Oct 27, 2021 & 6.00 AM), <https://www.merck.com/news/the-medicines-patent-pool-mpp-and-merck-enter-into-license-agreement-for-molnupiravir-an-investigational-oral-antiviral-covid-19-medicine-to-increase-broad-access-in-low-and-middle-income-countries/>.

<sup>55</sup> Pfizer is a leading research-based biopharmaceutical company, having its offices in different nations. See also PFIZER, <https://www.pfizer.com/>.

<sup>56</sup> *Pfizer and The Medicines Patent Pool (MPP) Sign Licensing Agreement for COVID-19 Oral Antiviral*

additional production and distribution of the investigational antiviral, finalization of the pending regulatory authorization or approval, by granting sub-licenses to qualified generic medicine manufacturers, with the goal of facilitating greater access to the global population”<sup>57</sup>. It is notable that both these licences by Merck and Pfizer are royalty-free, for the sales in low-income countries, as long as the Pandemic is considered as a Public Health Emergency by the WHO. Thus we can say that even if there are no Patent Waiver Rights in total, the Licensors have waived their royalty rights for providing access to the Medicine.

In May 2020, WHO launched another platform for Patent Pool named “WHO COVID-19 Technology Access Pool (C-TAP).”<sup>58</sup> C-TAP is another public health-driven program to provide a single global medium for developers of COVID-19 therapies, diagnostics, vaccines and other health products to share their Intellectual property knowledge by means of voluntary, non-exclusive and transparent licensing.

## VII. CONCLUSION

Thus it can be said that everyone is making their own effort to fight this battle against the COVID-19 Pandemic. The stringent nature of the national and international IP framework in addition to the stringent terms of the Free Trade Agreements has made the flexibilities of the TRIPS Agreement non-workable. In such a condition the unilateral effort of the different states in order to reach vaccine equity and equitable access to the medicine will not be enough to provide access to medicine and eliminate this pandemic. The joint effort made by the WHO and different multinational pharmaceutical companies, by pledging and pooling of their Intellectual Property, is a welcome initiative to fight against the COVID-19 pandemic. Though these initiatives are at their nascent stage, we have to wait and analyse the effectiveness of these efforts. It can be noted that only a handful of pharmaceutical companies have pledged their patented COVID-19 drugs or related technology, which is not enough. In fact, more pharmaceuticals should come up and stand in solidarity against the Pandemic. Moreover, to make these pledges and collaborative effort work, we may need more generic drug manufacturers, in the market to put more innovation to these patented technologies and bring out effective medicine and vaccines at an affordable rate. This will help to achieve the maximum potential of these patent pledges and at the same time provide equitable access to

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*Treatment Candidate to Expand Access in Low- and Middle-Income Countries*, MEDICINE PATENT POOL (Nov. 16, 2021) <https://medicinespatentpool.org/news-publications-post/pfizer-and-the-medicines-patent-pool-mpp-sign-licensing-agreement-for-covid-19-oral-antiviral-treatment-candidate-to-expand-access-in-low-and-middleincome-countries>.

<sup>57</sup> *Ibid.*

<sup>58</sup> *WHO COVID-19 Technology ACT*, WORLD HEALTH ORGANIZATION, <https://www.who.int/initiatives/covid-19-technology-access-pool>.

maximum people. Then only we shall be able to win this fight against COVID-19.

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