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Immunization for the Novel Corona Virus: An Analysis of the Potential Patent Right Issues

Abstract

The coronavirus pandemic has proven to be a wakeup call for the majority of the institutions that have existed for the greater half of the past century. The virus, SARS-CoV2, have shown us the inadequacy of public health infrastructure and has emphasized the exigent necessity to improve the same. With nations rushing toward a potential vaccine for the novel coronavirus — the issues pertaining to intellectual property are sure to rise. The current article shall shed light on the issues of intellectual property rights associated with a possible vaccine of Covid-19 in conjunction with international treaties and Indian national law. The article focuses on areas of IPR such as Patent Pools, Parallel importation and the Bolar Exemption. It shall encompass possible solutions to the issues raised in adherence with current international treaties and Indian national law, suggestions to the aforementioned treaties and past instances of similar nature.

Keywords

Patent, Patent Pool, Royalty, Royalty Stacking, Standard Essential Patents (SEPs), Parallel Importation, Vaccine, Bolar Exemption, Compulsory Licensing, Doha Declaration, TRIPS.

LEGAL VIEWPOINT

❖ The TRIPS Agreement

In accordance with Article 27 of TRIPS, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are novel, involve an inventive step and are capable of industrial application (have utility). A vaccine for the novel coronavirus fulfils the aforementioned requirements and, thus, can be patented.

Patent-owners are awarded exclusive rights over their product/process for a stipulated amount of time and can charge royalties from individuals/organisations who seek to manufacture/use this product/process. In the case of a vaccine, a royalty imposed on the cost price shall raise the final selling price — making the same out of reach for a large segment of the human population who live in abject poverty.[1]

Additionally, approval of the exportation of inventions pertaining to public health without the consent of the patent holder is not reliant on Article 31(f). Article 30 of the TRIPS Agreement expressly authorizes Members to provide limited exceptions to patent rights under certain conditions. Members are empowered to sanction exports of patented products as an exception patent holders' rights when such products are required by importing Members. The use of the Article 30 exception for exports is consistent with executing the TRIPS Agreement in a manner auxiliary to public health concerns and supporting access to medicines to all.[2]

❖ Doha Declaration

The Doha Declaration was, in essence, a product of the suggestions by developing nations to uphold the concept of basic international customary law in international treaty interpretation.[3] The Doha declaration opens the door to broader compulsory licensing and parallel importation of patented pharmaceuticals by developing countries.[4] Article 4 of the Doha Declaration states that *"Agreement can and should be interpreted and implemented in a manner supportive of*

[1] IMS, 1999, the top ten national markets had 79 percent of the global market for drugs
[2] ABBOTT & FREDERICK M., *WTO TRIPS Agreement and its Implications for Access to Medicines in Developing Countries,* United Kingdom Commission on Intellectual Property Rights (2002
[Available at SSRN: https://ssrn.com/abstract=1924420]
[3] SHANKER & DAYA, *Access to Medicines, Article 30 of Trips in the Doha Declaration and an Anthropological Critique of International Treaty Negotiations*, SSRN Electronic Journal (2003)
[Available at SSRN: https://ssrn.com/abstract=391540 or http://dx.doi.org/10.2139/ssrn.391540]
[4] SYKES & ALAN, *Trips, Pharmaceuticals, Developing Countries, and the Doha 'Solution',* U Chicago Law & Economics, Olin Working Paper No. 140. (2002)

WTO Members' right to protect public health and, in particular, to promote access to medicines for all."

Article 5 of the Declaration further states that, *"Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted." And "Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency";* while specifically stating that an epidemic shall qualify as a national emergency.

With the juxtaposition of Article 4 and 5 of the Doha declaration, one can interpret that there exists a provision under the declaration wherein countries can circumvent the conventional IP regime and instantaneously begin the manufacturing of a potential vaccine. Congruently, reading the aforementioned provisions in conjunction with Article 30 of Trips allows Member nations to begin the importation of vaccines; provided a national emergency is declared.

- **Compulsory Licensing**

Compulsory licensing is a situation wherein a government allows an individual/organisation to produce a patented product or process without the consent of the patent owner[5] or plans to use the patent-protected invention itself. Therefore, in a pandemic situation, such as the one we face today, the government shall be able to circumvent such a patent and initiate the production of vaccines without accruing royalties to the cost of the potential vaccine.

A vaccine is not one patent by itself — it is generally a stack of patents piled upon one another to create a new product. A government of a country, in order to create a potential vaccine, has to circumvent all the patents that are utilised in its manufacturing process.

Patents provide incentives to inventors for economically viable R&D by authorizing a monopoly on the patented invention. This encourages businesses to invest significant economic resources into R&D which eventually benefits the society[6] en bloc. Such is the justification behind granting patents and a governmental act to bypass patents can affect the bottom line of pharmaceutical companies which undertook R&D efforts; distressing post-pandemic relations between governments and pharmaceuticals.

[5] *Compulsory licensing of pharmaceuticals and TRIPS*, WTO (May 02 2020, 22:40) https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm
[6] *Why Do Patents Exist?*, Freelance UK (May 05, 2020, 22:42) https://www.freelanceuk.com/legal/Why_do_Patents_exist.shtml

"If people felt we were facing a pandemic situation, we would waive intellectual property rights," says Jamie Lacey of Medimmune[7], but then again Mrs Lacey also states that 'it is not clear whether the other patent holders would do the same.' (Pertaining to the Anthrax scares in the US and Canada in 2001) The aforementioned statement boils down to the inexorable: governments will be required to initiate vaccine production via compulsory licensing.[8]

Technology Transfer is the movement of scientific methods of production or distribution from one enterprise, institution or country to another.[9] The absence of technology transfer mandates in international treaties implies that Least Developed Countries (LDCs) would not be able to initiate vaccine production via compulsory licensing as they do not possess the requisite technology to do so.[10]

Furthermore, governments are incapable of pressurising pharmaceutical companies to undertake technology transfers; and most companies are disinclined to do so as they risk exposing trade secrets and aren't able to recoup R&D efforts. As a result of this legal lacunae the suggestion of developed nations helping out LDCs and developing countries by supplying vaccines as aid or by selling the same at cost gains traction. But then again, how much aid can the developed countries arrange for? Prima facie: not sufficient to supply vaccines to the rest of the world while grappling with the pandemics within their nations too.

- **The Indian Patents Act, 1970**

Section 84[11] of the Patents Act, 1970 provides for Compulsory Licensing within the territory of India. Section 84 provides a route for individuals/organisations to apply for compulsory license on any one of the three grounds:-

1. Unmet demands due to unreasonable pricing
2. Dissatisfaction of reasonable requirements of the public pertaining to the patent
3. Lack of effective utilisation of patent in India

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[7] DEBORA MACKENZIE, *Vietnam last on flu vaccine list*, NewScientist (June 06, 2020, 22:42) https://www.newscientist.com/article/dn4585-vietnam-last-on-flu-vaccine-list/

[8] CHRISTOPHER GARRISON, *Intellectual Property Rights and Vaccines in Developing countries (Background paper for WHO workshop on IP and Vaccines*, Geneva 19th-20th April (2004)

[9] *Dictionary of International Trade*, Global Negotiator (May 15, 2020, 22:44) https://www.globalnegotiator.com/international-trade/dictionary/technology-transfer/

[10] *Available Information on Manufacturing Capacity for Medicines*, Council for TRIPS, IP/C/W/345 (2002)

[11] At any time after the expiration of three years from the date of the 170 [grant] of a patent, any person interested may make an application to the Controller for grant of compulsory licence on patent…
§ 84, Patents Act [1970]

Nevertheless, such an application can only be made after three years from date of grant of the patent, provided the interested party had taken reasonable efforts to obtain a voluntary license.[12] The Patent Act further make four alternate routes available for the Government to address intellectual property concerns pertaining to a Covid-19 vaccine; they are:-

a. Section 157A empowers the Government to take any action necessary in the interest of security of India. The Government, under this section, can revoke any patent which it deems necessary in the interest of the security of India by issuing a notification in the Official Gazette of India.[13]
b. Under Section 102, the Government may acquire any relevant patents for public purpose(s). A reasonable price for the acquired patent(s) is to be negotiated between the government and patentee. Conversely, if they fail to agree on an amount, the concerned High Court is empowered to determine the price for the patent(s) u/s 103.
c. Section 100 of the Act enables the Government to permit the use of any patent (or patent applications) for "purpose of government" by particular companies. The advantage of this section is that the production of the vaccine can be initiated without a successful negotiation with patent holders. The same can be subsequently done u/s 103.
d. Section 92 incorporates the Doha Declaration within the Patent Act. The section empowers the Government to declare a national emergency; in instances such as the outbreak of Covid-19. The section acts as a special provision for compulsory licences without going through the regular licensing procedure. Under this provision, an equitable rate of royalty will be fixed by the Controller of Patents.

THE BOLAR EXEMPTION

The exemption that empowers generic manufacturers to conduct research that uses patented drugs and produce them in limited quantities is known as the Bolar exemption.[14] The exemption was contrived by virtue of the Drug Price Competition and Patent Term Restoration Act, 1984 (known as the Hatch-Waxman Act) as an exemption from the breach of the patent holder's rights, for certain acts pertaining to manufacturing/use of the patented invention exclusively for uses reasonably related to the development and submission of information to a regulatory

[12] RAVI SHANKER, *Intellectual Property Rights and Innovation in the Times of Corona Epidemic*, Research and Information System for Developing Countries No. 89, (2020)
[13] § 157A, Patents Act [1970]
http://ipindia.nic.in/writereaddata/Portal/ev/sections/ps157a.html
[14] ELLEN F. M. 'T HOEN, *Pharmaceutical Patents, Public Health and Access to Essential Medicines Seattle, Doha and Beyond,* Vol 3(1) Chicago Journal for International Law, (2002)

agency. The Hatch-Waxman Act overturned the position of the US Court of Appeals in Roche Products, Inc. vs. Bolar Pharmaceutical Co., Inc.[15]

In the Bolar case, the Bolar Pharmaceutical Company was using Roche's patented active pharmaceutical component and manufacturing generic versions of the drug in order to undertake mandatory clinical trials, which were a prerequisite to obtain regulatory approval from the Food and Drug Administration (FDA). However, the Hon'ble Court ruled against the Bolar Pharmaceutical Company, consequently, glooming the accessibility of affordable drugs to the economically backward sections of the society.

The Bolar exemption qualifies generic drug producers to use a patent holder's pharmaceutical drug before the patent terminates, which not only expedite the introduction of generic varieties of the drug while the patent holder's drug patent duration subsists, but also encourages additional R&D. Nevertheless, the provisions in the Hatch-Waxman Act confines the safe haven applicable to generic drug producers to producing, consuming, offering for sale or selling the patented creation exclusively for practices that are reasonably associated to the development and submission of information under US federal law within the territorial limits of the United States of America only. Such submission of information shall include but not be limited to conducting clinical trials for FDA approval of the drug. The same was held in the case of Merck KGaA v. Integra Lifesciences I, Ltd.[16], wherein the Hon'ble Supreme court broadly interpreted the safe harbour provisions Hatch-Waxman Act to include preclinical trials. The judgement further build upon the liberal decision in Eli Lilly & Co. v. Medtronic, Inc.[17] in which the safe harbour was extended to the medical equipment used while conducting research that are reasonably connected to the requirements laid down by the FDA.

Section 107A of the Patents Act, 1970 facilitates the usage of the Bolar exemption in India, nevertheless, the same is much broader in scope when compared to its US counterpart as the US law expressly prescribes a territorial limit for sale and the Indian statute omits the same.

- **<u>Scope of Bolar Exemption in India</u>**

The purview of the Bolar exemption within India has been the substance of a dispute between Natco Pharma Limited (NPL) and Bayer Corporation, the case arouse before the Hon'ble High

[15] Roche Products, Inc. vs. Bolar Pharmaceutical Co., Inc., 733 F.2d 858 (Fed. Cir. 1984)
[16] Merck KGaA v. Integra Lifesciences I, Ltd., 545 U.S. 193(2005)
[17] Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661 (1990)

Court of Delhi in a writ filed by Bayer Corporation in the case of Bayer Corporation vs Union of India & Ors.[18]

The 'Natco Pharma' case pertained to the drug 'Sorafenib Tosylate', the patent of which was held by the Bayer Corporation and promoted under the brand name 'Nexavar'. The Bayer Corporation's patent on the drug subsisted till the year 2020. However, due to its unreasonable price tag, the life-saving drug was not economically feasible for the majority of the nation. As a result, when the matter came before the Hon'ble High Court of Delhi, the Court granted Natco Pharma compulsory licensing — authorizing Natco Pharmaceuticals to produce a generic version of the drug albeit Bayer's patent on the same had not expired.

In the aforementioned case, the Hon'ble Court also stated that the expression 'sale' (as mentioned u/s 107A) is broad enough to encapsulate cross-border sales and, as a result, exports need not be expressly stated in Section 107A of the Patents Act, 1970.

The judgement entails that India can not only can manufacture but also export a potential vaccine for Covid-19 sans violating any statutes or treaties, provided the manufacturers are empowered by compulsory licensing under TRIPS and Doha Declaration. Technology requirements would also not be an ordeal for India, a country which has earned the sobriquet of the 'pharmacy of the world'.[19]

PATENT POOLS

A patent pool is an association of at least two patent holders assenting to cross-license patents pertaining to a specific technology[20]. Patents pools, in practicality, provide a path around patent thickets[21] without incurring extra expenditure to invent around existing patents. The first recorded formation of a patent pool, in the 1800s, was in the sewing industry. It was formed by Grover, Baker, Singer, and Wheeler & Wilson to ensure that they do not sue each other out of profits for patent infringements[22].

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[18] Bayer Corporation vs Union of India & Ors., 2014 SCC OnLine Del 2296

[19] SUSAN FINSTON, *India: A Cautionary Tale on The Critical Importance of Intellectual Property Protection*, 12 Fordham Intell. Prop. Media & Ent. L.J. 887, 889, (2002)

[20] LERNER & JOSH & JEAN TIROLE. *"Efficient Patent Pools." American Economic Review*, 94 (3): 691-711. DOI: 10.1257/0002828041464641, (2004)

[21] Patent thicket: a dense web of overlapping intellectual property rights that a company must hack its way through in order to actually commercialize new technology
ADAM MOSSOFF, *The Rise and Fall of the First American Patent Thicket: The Sewing Machine War of the 1850s*, 53 ARIZ. L. REV. 165 (2011)

[22] How Singer Won the Sewing Machine War, Smithsonian Magazine (May 31, 2020, 01:24)
https://www.smithsonianmag.com/smithsonian-institution/how-singer-won-sewing-machine-war-180955919/

A specific drug consists of a plethora of patents. It becomes a Herculean task for a pharmaceutical company to source all the licenses necessary to produce a potential vaccine. Additionally, a pharmaceutical company would encounter the issues of 'Holdout' and 'Royalty Stacking'. Patent pools can surge prospects of innovation and cost efficiency while effectively addressing these concerns.

❖ Standard Essential Patents

Standard Essential Patents (SEPs) are those patents that are "essential" or required as the invention by itself encompasses a technology that is necessary to implement a technological standard[23] that will be used by the public.[24]

Certain patented drugs and delivery mechanisms prove to be quintessential to formulate the vaccine and would necessarily have to be infringed if unable to be licensed. A pool that encompasses most of the SEPs would have a significantly higher probability of attracting pharmaceutical companies to be a part of the pool, as this proportion would finally get the Patent Pool some leverage. Patent Pools put big pharmaceuticals at a disadvantageous position as they have lesser to benefit from and mostly contribute to the R&D of generic pharmaceutical companies. A wide-ranging package of SEPs and Open Science[25] initiatives (discussed in the subsequent sections) make the Pandemic Patent Pool a much more attractive partnership for the 'Big Pharma'.

❖ Holdouts

From a legal standpoint, a patent holdout is a situation when a Standard Essential Patent (SEP) holder exploits a licensee's costs to switch away from the concomitant standard as a method of gaining royalties above the fair, reasonable, and non-discriminatory (FRAND) level[26]. In brief, the last patent holder whose patent is to be necessarily licensed in order to produce the vaccine

[23] Standards are essential for the wide adoption of new technologies in the marketplace. The potential for conflict between patents and standards arises when the implementation of the standard necessitates the use of technology protected by one or more patents.
Standards and Patents, WIPO (June 14, 2020, 18:41)
https://www.wipo.int/patent-law/en/developments/standards.html

[24] DR LUKE MCDONAGH & DR ENRICO BONADIO, *Standard Essential Patents and the Internet of Things*, The European Parliament
https://www.europarl.europa.eu/RegData/etudes/IDAN/2019/608854/IPOL_IDA(2019)608854_EN.pdf

[25] Open science is the movement to make scientific research and its dissemination accessible to all levels of an inquiring society, amateur or professional. (May 07, 2020, 01:24)
https://en.unesco.org/science-sustainable-future/open-science

[26] ANNE LAYNE-FARRAR, *Why Patent Holdout is Not Just a Fancy Name for Plain Old Patent Infringement, CPI North America Column* (2016)

is not willing to license the same. The status quo thus attained causes the vaccine so produced an infringement of the former's patent and liable to damages.[27] However, the Hon'ble US Supreme Court, in its ruling in eBay Inc. v. MercExchange, L.L.C[28] has laid down guidelines that deters patentees from holding outs through seeking injunctions.[29]

A patent pool addresses this particular concern as all the essential patents are pooled in; the disquiet of the final patent holder holding out does not arise. Even if the voluntary patent pool is unable to secure all the patents necessary for the vaccine, it shall be able to procure a majority of them. The same shall reflect in a significant reduction in cost of manufacturing,[30] aiding generic manufacturers to produce the vaccine — making the cure within the reaches of LDCs.[31]

- **Royalty Stacking**

Royalty stacking occurs when a single invention potentially infringes on or licenses numerous patents to manufacture the end-product, and thus may endure multiple royalty payments.[32]

The multiple royalty payments increases the cost of the potential vaccine[33]. And the same is ultimately transferred to the customer in addition to the profit margin. The issue of multiple royalty payments causes the vaccine to not be economically sustainable in LDCs and many developing nations. Heavy subsidisation of the vaccine[34] by the concerned government emerges as an alternative in this scenario. Nevertheless, subsidisation would deplete the coffers and slow down the process of revamping the national economy. Additionally, it increases the risks of under-the-table transactions, vaccine hoarding and vaccine black-markets.[35]

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[27] LEMLEY & MARK A. & SHAPIRO, CARL, *Patent Holdup and Royalty Stacking*, 85 Texas Law Review 1991, Stanford Law and Economics Olin Working Paper No. 324, (2007)
[28] EBay Inc. v. MercExchange, L.L.C, 547 U.S. 388 (2006).
[29] , DAVID B. CONRAD, *Mining the Patent Thicket: The Supreme Court's Rejection of the Automatic Injunction Rule in eBay v. MercExchange*, 26 REV. LITIG. 119, (2007)
[30] CARL SHAPIRO, *Navigating the Patent Thicket: Cross Licenses, Patent Pools and Standard-Setting*, Innovation Policy And The Economy, 119–26, (2001)
[31] MS PASCALE BOULET & MR PIYA HANVORAVONGCHAI, *IPR, Innovation, Human Rights and Access to Drugs: An Annotated Bibliography, World Health Organisation (Ed. 2),* Health Economics and Drugs Series No. 14
[32] Definitions - Royalty stacking, IT Wiki Law (May 31, 2020, 01:32) https://itlaw.wikia.org/wiki/Royalty_stacking
[33]DAMIEN GERADIN & ANNE LAYNE-FARRAR & JORGE PADILLA, *The Complements Problem within Standard Setting: Assessing the Evidence on Royalty Stacking,* Boston University Journal of Science and Technology Law, Vol. 14, No. 2, 2008, (2008).
[34] MARTIN PAOLA & DIWAKAR GUPTA & V. KARTHIK NATARAJAN, *Vaccine Procurement Contracts for Developing Countries,* SSRN Electronic Journal (2019).
Available at SSRN: https://ssrn.com/abstract=3390755 or http://dx.doi.org/10.2139/ssrn.3390755
[35] F. M SCHERER, *"An Industrial Organization Perspective on the Influenza Vaccine Shortage.",* Managerial and Decision Economics, vol. 28, no. 4/5, 2007, pp. 393–405, (2007)

A patent pool effectively addresses this issue; the producers of this vaccine shall only be liable to pay a FRAND[36] fee to the administrator of the pool in order to license all the patents necessary instead of making multiple royalty payments.

❖ **Subsequent Innovation**

A universal argument against the creation of patent pools is that they are anti-competitive and stifle future innovation. An independent study conducted by David Balto, public interest antitrust attorney in Washington, D.C., concludes that after the formation of a patent pool the companies (part of the pool) experience a drop in innovation.[37] The drop is measured by means of subsequent patents filed and the number new patents filed showcases a visible decrease.

Nevertheless, Keyvan Vakili, a doctoral candidate at the University of Toronto, who meticulously scrutinized the MPEG-2 technology pool arrives at a different conclusion. Dr. Keyvan realised that patents are merely one indicator of innovativeness. The companies that joined the MPEG-2 pool were not filing new patents as they had focused their R&D efforts towards enhancing end-products.[38] Such end products did not amount to new patents but were noteworthy inventions nonetheless. The conception of the MPEG-2 patent pool enabled a surge in analogous products and not a dip in innovation.[39]

Patent pools, for all intents and purposes, act as a unidirectional catalyst. It enables pool members to focus on creating better end-products in addition to earning a decent profit. The process shall replicate itself in case of a vaccine. The primary vaccine would undoubtedly be costly and the delivery mode would be rather unrefined. A patent pool shall facilitate access to the necessary patents enabling manufacturers to focus on improving the delivery mechanism and reducing costs.

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[36] GERADIN DAMIEN & RATO MIGUEL P.L., *Can Standard-Setting Lead to Exploitative Abuse? A Dissonant View on Patent Hold-Up, Royalty Stacking and the Meaning of FRAND,* European Competition Journal: Vol. 3, No. 1, pp. 101-161. (2006)

[37] DAVID BALTO, *Barriers to Competition on the Innovation Superhighway: How the Lack of Antitrust Scrutiny of Patent Pools Deters Competition.*
Available at: http://dcantitrustlaw.com/patent%20pools%20-5%209%20pdf.pdf

[38] FREEK VERMEULEN, *Patent Pools: Do They Kill Innovation?*, FORBES (May 31, 2020, 01:33)
https://www.forbes.com/sites/freekvermeulen/2013/01/22/patent-pools-do-they-kill-innovation/#f5e075b58f4d

[39] MICHAËL A BIKARD & KEYVAN VAKILI & FLORENTA TEODORIDIS, *When Collaboration Bridges Institutions: The Impact of University-Industry Collaboration on Academic Productivity,* Organisation Science, Volume 30, Issue 2 (2018)

❖ **Pandemic Patent Pool**

A pandemic pool ought to be administered by a trusted international body and should be formed on the lines of Medicines Patent Pool (MPP)[40], with the exception of being much broader. Officials from organisations such as the World Health Organisation (WHO), Unitaid[41] and the United Nations (UN) should form the core body of the new patent administer.

Organisations such as the Oxford University Innovation[42] have announced new procedures for fast-tracked non-exclusive licenses to potential partners who are interested to use Oxford's Coronavirus associated intellectual property.

Numerous world leaders, including the President of the United States, have declared their anti-corona measures as "a war on the Coronavirus"[43]. The same propagates the perception that the Pandemic Patent Pool (PPP) should be an involuntary one[44] akin to the involuntary pool created during the First World War. Nevertheless, such a drastic measure may, perhaps bring forth acute negative repercussions from the pharmaceutical industry.

Other instances of global fraternity during the 'Great Lockdown' include the Open Covid Pledge[45], the Costa Rica Proposal for Emergency Technology Intellectual Property Pool[46] and the Chief Science Advisors 'Request' to Publishers for Open Scientific Research'[47]. The Open Pledge necessitates pledger(s) who voluntary partake in the activity to make available all their Covid-19 related intellectual property to the public (non-exclusive) sans royalties in a form of a fully paid-up license. The second mention is the very concept of a patent pool. The pool was requested by the Government of Costa Rica to combat the CoViD-19 pandemic.[48] The final

[40] The Medicines Patent Pool (MPP) is a United Nations-backed public health organisation working to increase access to, and facilitate the development of, life-saving medicines for low- and middle-income countries. https://medicinespatentpool.org

[41] About us, Unitaid (June 14, 2020, 18:49) https://unitaid.org/about-us/#en

[42] Oxford University's Strategic Plan towards innovation. https://innovation.ox.ac.uk/technologies-available/technology-licensing/expedited-access-covid-19-related-ip/

[43] PHILIP WEGMANN, *A Changed Trump Declares War on Coronavirus*, RealClear Politics (May 31, 2020, 01:37) https://www.realclearpolitics.com/articles/2020/03/19/a_changed_trump_declares_war_on_coronavirus_142705.html

[44] *Involuntary Patent Pools*, SPIE (May 31, 2020, 01:28) https://www.spie.org/news/spie-professional-magazine-archive/2009-october/patent-pools?SSO=1

[45] About us, Open Covid Pledge (June 07, 2020, 19:11) https://opencovidpledge.org/about/

[46] Letter by the Government of Costa Rica to the World Health Organisation (WHO) to form a Pandemic Patent Pool (June 02, 2020, 20:48) https://www.keionline.org/wp-content/uploads/President-MoH-Costa-Rica-Dr-Tedros-WHO24March2020.pdf

[47] KLINT FINLEY, Global Officials Call for Free Access to Covid-19 Research, Wired (June 2, 2020, 14:02) https://www.wired.com/story/global-officials-call-free-access-covid-19-research/

[48] DIVIJ JOSHI, *CoViD-19 Pandemic Spurs Calls for 'Openness' in IP*, SpicyIP (June 03, 2020, 01:37)

mention is a humble plea made by the Chief Scientific Advisors of twelve nations asking publishers to open up scientific research published by them to PubMed[49]. The primary attraction of the model is that the same does not venture much into the field of intellectual property law, provided that inventions that utilise the scientific research shared via PubMed are not patented. The open letter only requests that researchers open up their research so as to ensure no overlap of research ensues.[50] This method shall speed up a potential vaccine by eliminating the need to research from scratch.[51]

The decision of Pharmaceutical companies in the present situation is critical to their survival. A decision to maximise profits through the IP regime shall attract public outrage whereas non-enforcement of a vaccine patent shall cause the losses in R&D to be in billions of dollars. This predicament increases the prospects of a Pandemic Patent Pool due to its inherent economic advantages[52]. Nonetheless, creating and administering a Patent pool is no insignificant task. The same necessitates months of negotiations and planning (royalty rates have to be fixed, license agreements drafted, territorial specification laid down and-so-forth). Such an enormous initial investment diminishes possibility of an effective patent pool.

Nonetheless, considering the scale of the pandemic and the pressing international need for rapid treatment of the novel coronavirus, it is in general public interest that the prospect of a Pandemic Patent Pool is not struck down.

PARALLEL IMPORTING

Parallel Importation is a status quo wherein goods that are manufactured and traded legally, are subsequently exported/imported without the manufacturer's authorisation.[53] In brief, 'Parallel imports' are genuine goods that are legally purchased from the rights holder and

https://spicyip.com/2020/03/covid-19-pandemic-spurs-calls-for-openness-in-ip.html

[49] PubMed is a US based archive of medical scholarship and scientific research operating under the aegis of National Centre for Biotechnology Information (NCBI) (May 07, 2020, 15:37) https://pubmed.ncbi.nlm.nih.gov

[50] North of 41 research groups and organisations are working independently to produce a coronavirus vaccine https://sciencebusiness.net/news/race-covid-19-vaccine

[51] THOMAS CROUZIER, *IPR, Technology Transfer & Open Science*, Publications Office of the European Union, ISBN 978-92-79-71790-1, EUR 28661 EN (2017)

[52] RUDY SANTORE, *"Patent Pools as a Solution to Efficient Licensing of Complementary Patents? Some Experimental Evidence.",* The Journal of Law & Economics, vol. 53, no. 1, pp. 167–183, (2010)

[53] HARRY RUBIN, *"Destined to Remain Grey: The Eternal Recurrence of Parallel Imports."* The International Lawyer, vol. 26, no. 3, 597–622. JSTOR, www.jstor.org/stable/40706986, (1992)

consequently sold at lower prices via unauthorised trade channels in the same/different market.[54]

Parallel Importation is regulated under both IP law and competition law. The same comes under IP regime as the rights holder seeks to maintain his Goodwill and earn commercial reputation in the market place.[55] Competition law is applicable as without parallel importation, not accounting for government intervention, the rights holders become the sole authority that decides the price of a product — in certain instances, rendering the product as not economically viable for the poorer sections of the society. The presence of parallel importation enables competition and lowers the price of goods.[56]

❖ Doctrine of Exhaustion

The Doctrine of Exhaustion refers to the extinction of the authority of an individual/organisation to prevent the further sale of a product once the product has been put on the market legally.[57] The position of this doctrine has been solidified in India through the 'Samsung Printers' case[58], wherein the Hon'ble court affirmed that India follows International exhaustion of rights.[59]

The applicability of parallel importation when it comes to life-saving vaccines is immense. If the world were to find itself with a highly priced Covid-19 vaccine, many of the developing nations could legally (in consideration to their national Intellectual Property laws[60]) import and resale these vaccines for a lower cost.[61]

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[54] SHRABANI ROUT, *India: Parallel Imports And International Exhaustion*, Mondaq (June 06, 2020, 01:37) https://www.mondaq.com/india/international-trade-investment/703104/parallel-imports-and-international-exhaustion?login=true

[55] NAMRATA SHARMA, *"Parallel Imports* Of Intellectual Property In India,(2010) 7 CLC Journal Pg. 241 (2010)

[56] SANKALP JAIN, *Doctrine of Exhaustion in Relation to Copyright Law in India and Parallel Imports, SSRN Electronic Journal* (2015).
Available at SSRN: https://ssrn.com/abstract=2780862 or http://dx.doi.org/10.2139/ssrn.2780862

[57] RAUL ITURRALDE GONZALEZ, *"Parallel Imports: A Copyright Problem with No Copyright Solution."* Graduate Department of the Faculty of Law University of Toronto 2, (2009)

[58] Kapil Wadhwa & Ors. vs Samsung Electronics Co. Ltd. & ..., (2012) 194 DLT 23 (DB) : (2012) 111 CLA (SN) 6

[59] Where a country applies the concept of international exhaustion, the IP rights are exhausted once the product has been sold by the IP owner or with his consent in any part of the world.

[60] Article 6, TRIPs states that "For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights." As TRIPS remain silent it falls upon National Legislatures to formulate IP laws pertaining to this subject matter.

[61] LAWRENCE M. FRIEDMAN, *"Business and Legal Strategies for Combating Grey-Market Imports,"* 32 Int'l Law 27, 28 (1998)

This process, however, increases the possibility of adulterated vaccines flooding the marketplace as the manufacturers are unable to guarantee the quality of the product[62]. The governments that subscribe to this methodology must be sufficiently equipped to conduct thorough and continuous quality checks to ensure the authenticity of the product that reaches the end consumer.

RECOMMENDATIONS

The present limitations in TRIPS, Doha Declaration and other treaties must not be left for judicial elucidations of national's patent statute of member nations

A new Declaration/Agreement is to be adopted by the member states of the WTO that codifies the Indian interpretation of the Bolar Exemption and also facilitates technology transfer. Nonetheless, the exemptions and transfer rights provided therein must only be exercised in a situation of national emergency; such as an epidemic.

Additionally, in the wake of post-pandemic international stability, the exceptions given to pharmaceutical companies within a territorial jurisdiction to by-pass specified patent(s) must be gradually withdrawn; with the maximum grace period of one year. In addition, a lump-sum license fee could be credited to the organisation that undertake technology transfer to LDCs and developing nations as remuneration for their R&D efforts or to the patent pool that manages the same — with subsequent transfer to the inventor. This compensation may be borne by the government and/or a certain portion of the compensation may be raised by means of an open bid to the pharmaceutical companies manufacturing the generic versions of the vaccine within a nation — as the pharmaceutical company stand to gain from the technology transfer.[63]

Furthermore, a Reasonable Royalty approach of patent framework ought to be implemented in developing countries and LDCs to stimulate the generic pharmaceutical sector. This approach entails that generic manufacturers recompensing a percentage of gross sales to the patent holder(s). As a result, a considerable portion of the losses which the patentees sustain due to

[62] As Vaccines purchased legally could be adulterated subsequently; the adulterated vaccine shall reach the end consumer

[63] PIVA MARIACRISTINA, *The Impact of Technology Transfer on Employment and Income Distribution in Developing Countries: A Survey of Theoretical Models and Empirical Studies,* SSRN Electronic Journal (2004). Available at SSRN: https://ssrn.com/abstract=907473 or http://dx.doi.org/10.2139/ssrn.907473

the introduction of generics in the marketplace will be recuperated, whereas the benefits of reasonably priced generic vaccines[64] is enjoyed en bloc.

Nevertheless, it is imperative to ensure that the rate of reasonable royalty is not an invariable rate as instituted arbitrariness would be prejudicial to the patentee(s). An autonomous working group is to be established; encompassing members of the judiciary, technical specialists and officials of the Controller of Patents to adopt a reasonable rate on a case-to-case basis.

Moreover, the propositions that the present author puts forth to enhance a potential Patent Pool are listed below:-

1. The patent pool administration must be unbiased. To guarantee neutrality, the administrators of the patent pool should not have prior professional/personal commitments with any pharmaceutical company and must be deterred from subsequently joining a pharmaceutical company.
2. The Pandemic Patent Pool must not be a standing pool, it must only come into existence when an epidemic is declared. The patents in the pool shall be transferred to the medicine patent pool upon termination of the former at marginally higher royalty rates.
3. The voluntary patent contributions to the Pandemic Patent Pool should constitute the Corporate Social Responsibility (CSR) of the contributing firms and, as a result, qualify for tax breaks akin to those available to charitable institutions.[65]
4. The Pandemic Patent Pool ought to be more accessible to potential partners as compared to the Medicine Patent Pool. The vaccine pre-qualification measures by WHO are voluminous and cumbersome; the process takes approximately a year to complete.[66] A fast-tracked procedure may perhaps provide the desperately-needed opportunity to generic drug manufacturers.
5. The Pandemic Patent Pool must not be limited to an assortment of drug and process patents that are required to produce the Covid-19 vaccine. In addition, it should further license patents that are essential for the vaccine delivery mechanism.

[64] The Chinese government, prior to 1992, issued a flat 4% royalty on the manufacture of Generic drugs within the territorial limits of China, (May 23, 2020, 18:44) https://www.lawteacher.net/free-law-essays/constitutional-law/bayer-corp-versus-union-of-india-constitutional-law-essay.php

[65] DAVID E.POZEN, *Remapping the Charitable Deduction. Connecticut Law Review*, Vol. 39, 531-601, (2006). Available at SSRN: https://ssrn.com/abstract=900061

[66] Jitendra Badjatya, *A Review on Drug Approval Process for Us, Europe and India*. International Journal of Drug Regulatory Affairs. 2. 1-11, (2014).

CONCLUSION

The Indian nation which contributes the lion's share to the manufacturing of generic pharmaceutical is also ages behind in innovation of the same.[67] Indian pharmaceutical industry reliant on its western counterpart to innovate a product so that it may replicate the same. This symbiotic/parasitic relationship that exists forces the Indian government to pay more attention to the status quo of its intellectual property regime.

A potential vaccine may perhaps halt the novel coronavirus pandemic; but nations would be left in a shambolic aftermath. As nation-states encounter a plethora of problems, the recommendations and roadmap given in the current article intend to provide assistance with navigating through the labyrinth of intellectual property rights pertaining to a potential Covid-19 vaccine.

[67] DR. NOEL J. DE SOUZA, *Overview of the Indian Pharmaceutical Industry: Imperatives for the Next Millennium*, 5 Pharmaceutical News 6 (1998),
Available at http://www.gbhap.com/magazines/pharmanews/5-b-article.htm