PATENTS AND PANDEMIC: A BALANCE BETWEEN PUBLIC AND COMMERCIAL RIGHTS

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Abstract

The pandemic forced the entire civilization to adapt to the new normal. Covid-19 made people reimagine and recalibrate their ways of working. The field of IPR was no different. The pandemic forced dramatic changes in the IPR regime, especially, Patents, as at the helm of battling the pandemic were the drugs and vaccines which were being researched and developed with extensive resources, both monetary and intellectual. This also re-sparked the long standing debate over patent protection to medicinal and pharmaceutical products and processes. While, the TRIPS waiver and other domestic changes in law and policy allowed for relaxed patent protection and mass exploitation, allowing for mass manufacturing and disseminating of drugs and vaccines, this also caused critiques to question rigidity of the IPR regime and most importantly the certainty of protection for capital intensive research. This paper aims at giving an overview of incentive offered by IPR, especially Patents and the change in dynamics during exigencies like the Covid-19 pandemic.

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Introduction

A patent is a legal protection granting monopoly rights on invention of product or process. It deters any other individual or entity, other than the patent holder from making, using, selling, importing the patented product or process without their consent for a particular period of time, which is generally 20 years. Patents are granted in return of full disclosure regarding the invented process or product. The formal idea of patenting can be traced back to 15th Century England where letters patent was granted by the king to certain manufacturers and traders. The concept has now been envisaged and codified by domestic statutes as well as international treaties and conventions.

John Locke justified the grants of patents as a tool to grant property rights to an individual to the exclusion of others by his Labor Theory. This theory states that when an individual uses their labor to create something from naturally available resources, then such individual should get property rights for such creation to the exclusion of others[2]. However, Locke in his *Second Treatise of Government*[3] also provided a condition for granting property rights. He asserted that property rights can only be allowed on resources which are available in abundance and other people have access to it. However, if an individual exercises his labor upon scarcely available resources, then such property rights cannot be granted. Therefore, because of this condition, monopoly rights cannot be granted over resources like genes, even if an individual has exerted significant labor for their discovery, creation, or identification[4]. Furthermore, another important theory for the purposes of this research paper is the utilitarian theory which aims to strike a balance between public and private rights. John Stuart Mill's utilitarian theory suggests weighing the outcome of granting

[2] Ranbir Singh, *Intellectual Property Theoretical Justifications for Intellectual Property*, MINISTRY OF HUMAN RESOURCES AND DEVELOPMENT, https://epgp.inflibnet.ac.in/epgpdata/uploads/epgp_content/law/08._intellectual_property_law/03._theoretical_justifications_for_intellectual_property/et/5793_et_03_et.pdf
[3] John Locke, *Second Treatise of Government*, HACKETT PUBLISHING (1980)
[4] *Id.* at 7

exclusivity rights, in a way that whether such grant of protection would cause happiness which would outweigh the harm or pain caused[5]. If the aggregate happiness is less than the aggregate harm cased to the society, then such protection should not be granted[6]. This theory is useful for studying and analyzing the grant of patent protection to pharmaceutical industry as in almost all cases, especially when there is a global health crises, the welfare, survival, and wellbeing of the society is large is pitched against the grant of commercial protection. Such analysis is the foundation of this paper and has been dealt with in the forthcoming sections.

Patents play a very crucial role in the Pharmaceutical Industry as this industry is a research capital intensive. That is to say that the products and processes developed in the pharmaceutical industry require significant capital and investment for research and development. Such costs incurred on infrastructure, human resources, etc. come along with high risk as research in this industry is prone to failure. Drug research and development is a long, costly, and high-risk process wherein an average cost of $1-2 billion, spread over a period of 10-15 years is required for every new drug that is approved for clinical use[7]. In such a case, the need for statutory protection and monopoly rights becomes even more essential for the few research products that do clear the clinical trial stage and become available for commercial use. Patents and the complimentary rights act as an incentive in this industry that foster further research and development as such protection allows the industry to function on a high risk- high reward strategy. The importance of patents in this industry is highlighted by statistics as approximately 80% of overall revenue of pharmaceutical companies is derived from patents[8].

[5] *Id.* at 5
[6] *Id.* at 5
[7] Izumi Hinkson et al. *Accelerating therapeutics for opportunities in medicine: A paradigm shift in drug discovery*, 11 Frontiers in Pharmacology, (2020)
[8] Shilpi Kumari, *India: Patents in the Pharmaceutical Industry*, MONDAQ (March 9, 2020) https://www.mondaq.com/india/patent/900672/patents-in-pharmaceutical-industry

Legal Framework

In the domestic statutory framework, a major revolution in Patent laws took place after the Patent (amendment) Act 2005 which allowed for pharmaceutical patenting. This was done after significant debates over whether patent protections should be granted to pharmaceutical products or not as such grant of monopoly rights could cause drug prices to rise steeply, making affordability and accessibility of medicines a distant dream for the majority. The Amendment caused the deletion of Section 5 of the Patents Act, 1970, which restricted patent claims related to food, medicine, drugs, or chemical substances to only methods of processes of manufacturing and not product patents. Therefore, the problem was that the end product was not protected and could be produced by competitors by reverse engineering techniques or by modifying the process patented. The introduction of product patents secured the end product, and the final composition of the drug was granted exclusionary rights. Soon after the introduction of product patents in the pharmaceutical industry, there were debates where one argument was that the grant of protection to the end products and the monopoly rights granted therein would cause steep rise in prices and would have an adverse impact on accessibility to important drugs, whereas the other side of the argument was that by securing the final product, pharmaceutical companies would get a reward commensurate with the high risks and would be more inclined towards undertaking research and development and this would foster innovation in this industry, which would be fruitful in the long run as the industry would transform from a generic copycat industry to a market leader by way of innovative research and development[9]. The Indian Patent regime has somewhat struck a balance by introducing certain safeguards. One such safeguard is by denying patent protection to incremental innovation. The Patent (amendment) Act, 2005 defined what will constitute as an

[9] Shamnad Basheer, *India's Tryst With TRIPS: The Patents (Amendment) Act, 2005,* 1 IJLT 15, 19 (2005)

invention and explicitly stated that any existing thing or knowledge cannot be patented. It provided for three prerequisite for patentability, which include 'non-obviousness', 'inventive step', and 'industrial applicability'. The concept of novelty and innovation is furthered by Section 3(d) of the Act prevents 'evergreening' of patents and increases the threshold of what can be considered as an innovation or invention. The section excludes discovery from the ambit of patent. This means that if an individual or entity discovers or finds out something that already existed in nature, however, was not known or not recognized then such finding or discovery cannot be granted patent protection. Furthermore, the effect of this section on the pharmaceutical industry is gravitated as the section provides for cases where patents cannot be granted and states that "the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance"[10] cannot be patented. Therefore, when the quality, purpose and efficacy of a patented drug remains the same and only minor changes with respect to the elements are made, then such newly formed drug cannot be patented because of the exclusion created by this provision. In this manner, generic medicines were excluded from the patent regime and price control, affordability and accessibility were ensured because of competition. The concepts of the above section were tested and applied in the case of *Novartis AG v. Union of India*[11]. In this case Novartis International AG, one of the largest international pharmaceutical companies filed an application for grant of patent for an anticancer drug 'Gilvec' which was used for the treatment of Chronic Myeloid Leukemia (CML) and Gastrointestinal Stromal Tumours (GIST). The patent application was rejected on the grounds that the drug was prior anticipated by prior publication and failed to satisfy the requirements of novelty and non-obviousness. Furthermore, it also said that the drug did not exhibit any major changes in the therapeutic efficacy over its predecessor, i.e., the

[10] The Patent Act, 1970, No. 39, Acts of Parliament, 1970 (India)
[11] AIR 2013 SC 1311

Zimmermann patent. The High Court of Madras and the Supreme Court of India agreed with the denial of patent because of minor changes, without any change in therapeutic efficacy.

Apart from the above, another major safeguard which affects the pharmaceutical industry is in the form of compulsory licensing. The Patents Act, 1970 in Chapter XVI deals with the grant and revocation of compulsory licenses. Compulsory licenses basically override the patent granted by the authority. They are authorizations given by the controller general to a third party to make, use, or sell a patented product or process, without the consent of the patent holder. Such licenses can be granted upon applications made under Section 84 of the Act of 1970, under which a request to the controller general for granting compulsory license can be made after the expiry of three years of the patent period. However, the pre-requisite conditions for making such an application are:

1. "The reasonable requirements of the public with respect to the patented invention have not been satisfied
2. the patented invention is not available to the public at a reasonably affordable price
3. the patented invention is not worked in the territory of India."[12]

Once an application under this Section is made, the controller general is required to decide based on the application of mind and after considering the above conditions along with aspects like the nature of invention, the time which has elapsed since the grant of patent, the measures taken by the license holder to make full use of the patent, the ability of the applicant to use product or process for the advantage of the public, etc.[13]

Furthermore, the controller can also grant compulsory licenses Suo moto under the provisions of Section 92 of the Act, pursuant to a notification passed by the Central Government if there is a national emergency or a situation of extreme urgency or in case when the invented

[12] Section 84 of the Patent Act, 1970, No. 39, Acts of Parliament, 1970 (India)
[13] Section 84(6) of the Patent Act, 1970, No. 39, Acts of Parliament, 1970 (India)

product or process is needed for public non-commercial use. A compulsory license in India was granted for the first time by the Patent Office in the year 2012 for the generic production of Bayer Corporation's Nexavar, a life saving medicine used for the treatment of Liver and Kidney Cancer. The reason behind such grant was that the company sold the drug at unreasonably high prices, with one month's dosage costing around Rs. 2.8 Lakh. The applicant, Nacto Pharma was ready to sell the drug around Rs. 9000, making it affordable for people belonging to almost every stratum. The controller granted the applicant a compulsory license as it thought that all conditions laid down in the Act were being met and that such grant of license is necessary for the larger public good. This brings us back to the point we started, as we can see the application of Mill's Utilitarian theory being applied in the current legal framework. In this case the controller found the grant of patent protection to be of more harm than good and cited with public interest than commercial interest.

Exceptions to Patent Protection During Covid- 19

During the pandemic, India and South Africa initially proposed a 'TRIPS waiver' in October 2020. Such waiver was intended to act as an essential legal instrument to enable radical increase in manufacturing and supply of Covid-19 vaccines, drugs, and other medical equipment, and as step towards establishing equitable access to health services. Such a waiver would remove certain legal obligations upon member states under TRIPS. The waiver would apply 'in relation to prevention, containment or treatment of COVID-19', covering not only the temporary waiver of patents internationally but would also allow sharing of intellectual property under the umbrella of 'undisclosed information', which would include technical know-how, trade secrets etc.[14] which were otherwise protected under Article 39 of TRIPS.

[14] *Revised TRIPS Waiver Text*, WORLD TRADE ORGANISATION (May 2021) https://www.keionline.org/wpcontent/uploads/W669Rev1.pdf

TRIPS Waiver is different than compulsory licensing. During the pandemic, it was argued that countries could have gone ahead and issued compulsory licenses under the already existing WTO system and under their domestic laws, and that there was no special need for a TRIPS waiver.[15] Even though the existing IPR system and compulsory licensing was a possible alternative to allow third parties to use the technologies, inventions and other works protected by patents and boost production, without the consent of the patent holders, however, such an approach was not feasible given the impact of the pandemic and the because the existing system was fragmented and complex[16]. The problems related to granting compulsory licenses have been enumerated in a working paper published in LSE's Law, Society and Economy Journal.[17] It lists out certain drawbacks of compulsory licensing which are:

1. Compulsory licensing can only be applied on a product-by-product basis and also in a country-by- country manner. It does not allow for a blanket licensing of IP for a category of products, globally, making the process tenuous and uncertain.
2. Even though the WTO in the TRIPS agreement provides for a common set of requirements and procedures, individual states have the liberty to impose additional requirements for grant of compulsory licensing. Therefore, the process becomes more complicated as there is lack of uniformity. This also means that there could be regulatory obstacles and the grant of license and giving accessibility to such drugs and information would not be possible in a timely and swift manner.

[15] EFM 't Hoen, *Covid-19 and the comeback of compulsory licensing*, MEDICINES LAW AND POLICY (March 2020) https://medicineslawandpolicy.org/2020/03/covid-19-and-the-come-back-of-compulsory-licensing/
[16] M Gaviria and B Kilic, *A Network Analysis of COVID-19 mRNA Vaccine Patents'* 39 NATURE BIOTECHNOLOGY 546 (2021)
[17] Siva Thambisetty et al., *The TRIPS Intellectual Property Waiver Proposal: Creating the Right Incentives in Patent Law and Politics to end the COVID-19 Pandemic*, LSE 1, 27-28 (May 2021)

3. There is uncertainty on a global scale as some states refrain from granting such compulsory licenses owing to fear of challenge and/or trade sanctions.
4. Under the current setup, the rights holder must be provided with adequate remuneration in case a compulsory license is granted on their patented product or process. Therefore, determining what will be the 'adequate' compensation and negotiations with pharmaceutical companies would make the process even more complicated and uncertain.

Therefore, the TRIPS waiver proposal which aims at granting a blanket waiver over obligatory provisions under the TRIPS Agreement, which would allow countries to swiftly tackle the challenges posed by the pandemic.

Furthermore, another challenge apart from those already mentioned is that pharmaceutical industries, while patenting the product, do not necessarily reveal crucial information regarding who the product came into being[18]. Therefore, even though compulsory licensing would allow third parties access to the composition of the drug and vaccine and would allow them to manufacture the same, they would not necessarily have the requisite information, know-how or the expertise to determine the process behind manufacturing the same. Therefore, the waiver would also aid disclosure of trade secrets and technical expertise which would facilitate a boost in global output of drugs and vaccines.

Problems

Certain issues associated with denying patent protection and monopoly rights to pharmaceutical companies on Covid-19 related products and processes are that such waiver is

[18] The Petrie-Flom Center, *The COVID-19 Vaccine Patent Waiver: The Wrong Tool for the Right Goal*, Bill of Health Harvard Law (May 5, 2021) https://blog.petrieflom.law.harvard.edu/2021/05/05/covid-vaccine-patent-waiver/

against the foundation of IPR law and would deter further innovation and investment in research and development. However, if we again trace back to the utilitarian theory propounded by John Stuart Mill, the grant of patent protection can be denied with such grant would cause more aggregate harm than good. In this case, in pursuit of protecting commercial rights, a grant of patent protection on Covid-19 drugs and vaccines would have aggravated the global health crises, causing low-income countries and developing countries to suffer the most. The rhetoric of intellectual property rights acting as incentives promoting further innovation cannot hold true during the extraordinary circumstances posed by Covid-19[19]. Furthermore, with respect to incentives, the proposal only waives protection for a limited period of time, i.e., three years[20]. Also, the protection is waived only for low income and developing countries and not the developed countries, where such pharmaceutical companies reap maximum profit[21]. Additionally, such pharmaceutical firms and research organizations are also being incentivized in form of grants received from governments for research and development and infrastructure[22].

Conclusion

While some critiques may argue that the waiver of IPR protection would dissuade the pharmaceutical industry from making significant capital investments in research and development and that the waiver puts them in a difficult position, where they cannot contest the same because

[19] Also see S Thambisetty, *Why Patent Law Doesn't Do Innovation Policy*, 20 LSE (2013) https://ssrn.com/abstract=2328173
[20] Ibid
[21] Michele Goodwin & Gregory Shaffer, *Op-Ed: Changing the incentives for global vaccine production*, Los Angeles Times (May 21, 2021) https://www.latimes.com/opinion/story/2021-05-21/covid-vaccine-intellectual-property-protections-waiver
[22] *PM CARES Fund: The Mystery of Rs100 Crore Allocated for Vaccine Development Continues*, MONEY LIFE (January 18, 2022) https://www.moneylife.in/article/pm-cares-fund-the-mystery-of-rs100-crore-allocated-for-vaccine-development-continues/66154.html#:~:text=20%20crore%20and%20Rs78.,development%20of%20COVID%2D19%20vaccines.; Richard G. Frank et al. *It Was The Government That Produced COVID-19 Vaccine Success*, HEALTH AFFAIRS (May 14, 2021) https://www.healthaffairs.org/do/10.1377/forefront.20210512.191448/

that would cause significant damage to their goodwill, the reality holds different. During the pandemic, multiple vaccine manufacturers and researchers voluntarily licensed their research and products and established global partnerships in response to the global health crises[23]. The same was because of the fact that any commercial, private interests, when pitted against the global health and security are bound to be outweighed.

[23] For example, there is an agreement between Johnson & Johnson (J&J) and Merck to boost US production of the J&J vaccine, AstraZeneca has a deal with Serum Institute of India (SII) and Fiocruz in Brazil, BioNTech has a joint venture with Fosun Pharmaceuticals in China. See Siva Thambisetty et al., *The TRIPS Intellectual Property Waiver Proposal: Creating the Right Incentives in Patent Law and Politics to end the COVID-19 Pandemic*, LSE 1, 8 (May 2021)