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ROLE OF PATEMTABILITY IN COVID VACCINES

Yasir Pathan[1]
Deesha Goswami[2]

INTRODUCTION

In today's modern world vaccine is protected by multiple levels of IP often licensed from multiple partners. As an international medical humanitarian organization, vaccination is a key part of getting rid of the virus also known as the coronavirus. After the introduction of the first vaccine, many companies started running fast to create a more efficient vaccine and register their domain patent which eventually this competition helped society to get more effective and safe vaccine. Nonetheless, considering the persisting conditions where nations vaccination program is hustling a lot quicker than creation, the principle question that emerges is how could vaccine enterprises set increase its Coronavirus vaccine creation up to supply vaccines to the leftover millions individuals when intense deficiency is obvious in the past program of immunizing previously mentioned need gatherings? This article will endeavor to answer this inquiry by featuring the choices accessible that how licensing regulations have assisted the huge pharmaceutical enterprises with creating vaccines in Coronavirus virus pandemic as far as arrangements contained in the Licenses Act, 1970 and game plans set up in other creating and created countries across the globe.

As of now, the Focal Medications Standard Control Association (CDSCO) which is India's medication controller has endorsed two vaccines for crisis use-Covishield and Covaxin.

The previous for example Covishield, which has been created by the English Swedish

[1] 4th Year Student of BA.LLB(Hons) of Maharashtra National Law University, Aurangabad
[2] 5th Year Student of BA.LLB(Hons) of Maharashtra National Law University, Aurangabad

medication creator AstraZeneca regarding Oxford College, is being delivered locally by the Serum Foundation of India ("SII" for curtness), the world's biggest vaccine producer, for the stock of the vaccine to the Indian Government and furthermore to an enormous number of nations all over the planet. The College of Oxford holds the patent for the vaccine innovation, which is utilized in Covishield, and AstraZeneca has thus gone into a permit concurrence with SII to share the said innovation. Albeit, the creation limit of SII is promising, it will make some intense memories meeting the two its public and global commitments.

Literature Review:

Rimmer in his work "**Intellectual Property and Biotechnology Biological Inventions**" examines how a number of significant nations have dealt with the legal issues of biological innovations. "Patent law should be technology-specific, especially when dealing with the demands of certain sectors of biotechnology," and "patentability standards should be implemented rigidly in respect of new technologies," according to the author.

Firdos Khan in his book **Biotechnology Fundamentals 2** mentioned conventional and unique approaches to IPR industry. This book is single source referring every aspects of biotechnology.

WIPO Intellectual Property Handbook analyses of all fields of intellectual property, its administration, enforcement and teaching, technological and legal developments, and WIPO's work in its Member States.

Mitsuo Matsushita, Thomas J. Schoenbaum in his book **The World Trade Organization Law, Practice, and Policy** examines the effect of the WTO on national legislation and its interaction with other areas of law, such as competition law and intellectual property.

Rick Ng in his book **Drugs: From Discovery to Approval, 2nd Edition** draws the reader's attention on processes involved in bringing a drug to the market, including the performance of preclinical trials

Statement of Problem:

The significant role of patenting is disclosure of invaluable knowledge about patent innovation for public promulgation. This actually assists naïve innovators to learn from

existing patent and create advance innovation which can contribute more. Biological Innovations become extremely ambiguous in terms of eligibility or the appropriateness of imposing monopolies on them, posing patentability issues. In light of such pressing issues, it is appropriate to analyse the readiness or preparation of the Indian patent system in confronting or resolving the aforementioned issues.

Objectives

1. To comprehend the Biotechnical meaning of vaccine and IPR related to it.
2. To analyze the legal framework to Pharma-Biochemical patenting.
3. To understand Patentability criterion of Pharma-Biochemical Technology.
4. To observe the inadequate Pharma-Biochemical licensing.

Hypothesis

The provisions of Indian patent law are insufficient to address the patentability and eligibility issues that have arisen as a result of biotechnology advancements in the pharmaceutical business.

Research Methodology:

The work of researcher's is purely doctrinal. Researcher's strives to emphasis on how diverse conundrums or challenges are navigated, avoided, or dealt with elsewhere, and use it to carve out or propose a feasible answer for India.

BIOLOGICAL MEANING OF VACCINES

Biologically stating "A vaccine is a preparation that improves immunity to a particular disease. It typically contains an agent that resembles a disease-causing microorganism and is often made from weakened or killed form of the microbe. The agent stimulates the body's immune system to recognize the agent as foreign, destroy it, and remember it, so that the immune system can more easily recognize and destroy any of these microorganisms that it later encounters."[3]

Therefore, technically Vaccine is defined as "a preparation of dead or weakened pathogens, or of derived antigenic determinants, used to stimulate the production of antibodies or

3 Firdos A. Khan, Biotechnology Fundamentals 2 (CRC Press, Florida, 2012) at 307.

immunity against the pathogens"[4] in technical terms. "Several forms of vaccines,"[5] according to biotechnology literature, includes:

Attenuated Vaccines: These vaccines contain “live, attenuated virus microorganisms.”[6] Here the “virulence of a pathogen” is reduced (i.e. “attenuated”)[7] Virulence means “the degree of ability of an organism to cause disease”[8]
Killed Vaccines: When “chemical and temperature treatment are normally used to kill or inactivate the pathogen”, these are made.[9]

Toxoids: These “are derived from the toxins secreted by a pathogen” [10]
Other kinds: There are so-called “Sub-unit vaccines” which contain “a fragment” of the microorganism, which can also “create an immune response.”[11] Reportedly, there are various “vaccines currently in the developmental stage or which are already in use, such as recombinant vector vaccines, DNA vaccines”[12] etc.
As above mentioned, because vaccines incorporate "live," "dead," or even "attenuated" germs, some of which are usually transgenic, monopolisation or even bio stealing issues arise.

STATUTORY FRAMEWORK OF PHARMA-BIOCHEMICAL TECHNOLOGY PATENTING.

The Patent Act, 1970

In India the statute which regulates patenting is “The Patents Act, 1970.” It states that “patent means a patent for any invention granted under this Act.”[13] Also, “invention” signifies “a new product or process involving an inventive step and capable of industrial application.”[14]Certain

4 FAO, “Glossary of Biotechnology and Genetic Engineering” 31 (1999) at 240.
5 S. Arora and Rekha Chaturvedi, “Section 3(d): Implications and Key Concerns for Pharmaceutical Sector” 21 JIPR 16-26 (Jan., 2016), 17 at 268.
6 Supra Note 4 at 97.
7 Rick NG, Drugs: From Discovery to Approval 94 (Wiley-Blackwell, New Jersey, 2nd Edn., 2009)
8 Supra Note 5 at 243.
9 Supra Note 8 at 97.
10 ibid
11 Supra Note 4 at 269
12 ibid
[13]The Patents Act, 1970 (Act 39 of 1970), section 2(1)(m) "patent" means a patent for any invention granted under this Act.
[14]Ibid section (2) (1) (j) "invention" means a new product or process involving an inventive step and capable of industrial application;] [(ja) "inventive step" means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not

subject-matter is disqualified as “not inventions within the meaning of this Act.”[15]

Also, “the Controller General of Patents, Designs and Trade Marks” (henceforth, CGPDTM) “appointed under sub-section (1) of section 3 of the Trade Marks Act, 1999 (47 of 1999), shall be the Controller of Patents.”[16]

The Paris Convention

“The countries to which this Convention applies constitute a Union for the protection of Industrial property.”[17] The "period of priority" for patents is set at "twelve months."[18] It further states that "patents applied for in Union nations" are "independent of patents for the same invention applied for in other countries." As a result, a negative decision (such as revocation) in one nation does not always lead to or prompt a similar decision in another. "The inventor should have the right to be mentioned as such in the patent," it further states. It also provides for "compulsory licensing."

Patent Cooperation Treaty

It attains “Rationalization and cooperation with regard to the filing, searching and examination of patent applications and the dissemination of the technical information contained therein.” PCT requires an "international application" to be lodged in three copies at a "Receiving Office"70 (or R.O.) that "will inspect and process it." All "Contracting state or states in which protection for the innovation is required" must be mentioned in the "international application." These are referred to as "designated states." The receiving office shall keep one copy of the international application (home copy), submit one copy (record copy) to the International

obvious to a person skilled in the art.

[15] Ibid section 3 (c) the mere discovery of a scientific principle or the formulation of an abstract theory [or discovery of any living thing or non-living substances occurring in nature];

[16] Controller and different officers. -

(1) The Controller General of Patents, Designs and Trade Marks designated under sub-area (1) of 160 [section 3 of the Trade Marks Act, 1999 (47 of 1999)], will be the Controller of Patents for the reasons for this Act.

(2) For the motivations behind this Act, the Focal Government might select as numerous analysts and different officers and with so much assignments as it might suspect fit.

(3) Dependent upon the arrangements of this Act, the officers designated under sub-area (2) will release under the administration and headings of the Controller such elements of the Controller under this Act as he may, now and again by general or exceptional request recorded as a hard copy, approve them to release.

(4) Without bias to the generality of the arrangements of sub-area (3), the Controller may, by request recorded as a hard copy and because of motivations to be recorded in that pull out any matter forthcoming before an officer selected under sub-segment (2) and manage such matter himself either once more or from the stage it was so removed or move something similar to one more officer named under sub-segment (2) who may, dependent upon extraordinary headings in the request for move, continue with the matter either again or from the stage it was so moved.

[17] Paris Convention, 1883, Article 1.1

[18] Id Article 4(C)(1)

Bureau, and transmit another copy (search copy) to the competent International Searching Authority." The last entity, the "International Searching Authority," merely performs an "international search" with the goal of "discovering relevant previous work." An "International Search Report" is sent by the "International Searching Authority" to the applicant and the "International Bureau" on the basis of this. "The applicant can evaluate his odds of acquiring a patent in or for the countries specified in the worldwide application," according to the paper. "The international bureau shall publish the international application," says another clause. An "International Preliminary Examination" may also be requested by the applicant. Its goal is to "formulate a preliminary and non-binding judgement on whether the claimed invention seems to be original, innovative, and industrially relevant." "This evaluation gives the applicant a better foundation for assessing his chances of getting a patent, and it gives the elected officials a better basis for deciding whether or not to grant a patent."

Trade Related Aspects of Intellectual Rights (Trips)

a. Most-Favoured-Nation Treatment clause: "Each member shall accord to the nationals of other Members treatment no less favourable than that it accords to its own nationals with regard to the protection of intellectual property, subject to the exceptions already provided in, respectively, the Paris Convention."[19]
b. Obligation of Paris Convention: The members should comply with pertinent paragraphs of the "Paris Convention" when it came to patents. TRIPS further states that "nothing" in the agreement "shall derogate from any existing responsibilities that Members may have to each other under the Paris Convention." As a result, it effectively made that convention obligatory.

c. The Exhaustion Rule: "Subject to Articles 3 and 4, nothing in this Agreement shall be utilised to address the issue of intellectual property rights exhaustion." This exhaustion rule is founded on the notion of "First Sale," which states that "after a patented object has been sold anywhere under the patent holder's authorization, the patent holder has no right to restrict subsequent sale or importation elsewhere in the globe" Simply said, the holder's IPRs are exhausted after the first sale.

[19] TRIPS, 1994, ArtArticle 3.1

Apart from, obviously, Supreme Court and High Court judgements would inevitably rely on, amongst alia, its practises and manuals/guidelines in the Indian context.

PATENTIBILITY

Indian law says that an "invention means a new product or process involving an inventive step and capable of industrial application"[20]. TRIPS, likewise, says that "patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are" inter-alia "new"[21] . In India judiciary has additionally thought that, "the essential guideline of patent regulation is that a patent is allowed uniquely for a creation which should be new and valuable. In other words it should have oddity and utility"[2223]. Albeit obviously oversimplified, checking such "curiosity" or originality requires correlation with supposed "earlier craftsmanship" or "cutting edge"

Original & Naive Innovations:

"New invention" is defined as "any invention which has not been anticipated by publication in any document or used in the country or elsewhere in the world before the date of filing of patent application with complete specification, i.e., the subject matter has not fallen in public domain or that it does not form part of the state of the art". In India, the provision lays down that, "the invention or technology must not have been previously made and used in India,"[24].

Something which already exists or is already being done can't be monopolized. Also, bringing out rationale for "novelty" as also its difference with "obviousness/inventive step", it is pointed that, "For a claim to be anticipated by prior disclosure, the prior disclosure must contain a clear description of, or clear instructions to do or make, something that would infringe the patentee's claim if carried out after the grant of the patentee's patent. If on the other hand, the prior publication contains a direction which is capable of being carried out in a manner which would infringe the patentee's claim, but would be at least likely to be carried out in a way which would not do so, the patentee's claim will not have been anticipated

20 The Patents Act, 1970 (Act 39 of 1970), s. 2(1)(j)

21 TRIPS, 1994, Art. 27.1

22 M/s Bishwanath Prasad Radhey Shyam v. Hindustan Metal Industries (1979) 2 SCC 511, 518

23 Supra 9 and 6 § 102 (a)(1). Other sub-sections lay exceptions etc. which are irrelevant given our ambit.

Indian Practice

Interestingly, IPO keeps up with that "a development is viewed as new in the event that it isn't expected by earlier distribution, earlier use or earlier open knowledge."[24] Consequently, even "earlier open information" annihilates curiosity. The distribution can be "in India or somewhere else in any document"[26]. Initial public offering additionally says that "earlier workmanship implies all that has been distributed, introduced or in any case revealed to the general population before the date of documenting of complete specification."[27] It additionally says that "to decide curiosity, an application for patent documented at the Indian Patent Office before the date of recording of complete determination of a later documented application however distributed after the equivalent is considered for the reasons for earlier claiming"[28]. Moreover "earlier craftsmanship ought to reveal the creation either in unequivocal or implied way" and "will be expectant on the off chance that every one of the highlights of the development under assessment are available in the refered to earlier art"[29]. For this evaluation, joining or "mosaicking of earlier craftsmanship reports isn't followed". Initial public offering likewise makes reference to that "nonexclusive divulgence" probably won't annihilate "curiosity of explicit exposure" however "explicit revelation" decimates "oddity of a conventional disclosure"

Indian Practice and Bio-Innovations

IPO, in its different Biotech guidelines[30], says that, "if there should be an occurrence of biotechnological developments, the evaluation of oddity will be completed in a similar way concerning other inventions". Consequently, up to cited rules[31] will apply thus. Rules furthermore say that, "A case to an item acquired or created by a cycle is expected by any earlier revelation of that specific item essentially, no matter what its strategy for production". Obviously, for pharma-biotech, no unmistakable or separate standards/principles exist as respects originality assurance. Additionally, its assurance shows up all around settled and unproblematic with comparable standards/practices all over the place. We, consequently, presently draw in with the second necessity.

24 Office of CGPDTM, "Manual of Patent Office Practice and Procedure" (Mumbai, March 22, 2011) (henceforth "MPOPP"), 77-78 available at

INADEQUATE LICENSING MECHANISM

Current licensing components deficient Voluntary licenses have not and won't stay up with public health interest. Since organizations decide the conditions of intentional licenses, they are regularly conceded to LMICs that can bear the cost of them, leaving out more unfortunate regions[25]. For instance, in South Asia, AstraZeneca has will fully authorized its vaccine to the Serum Institute of India, despite the fact that the locale has various skilled vaccine manufacturers[26]. Many Coronavirus vaccine designers have not made strides towards licensing their advances, essentially in light of the fact that there is restricted monetary motivator to do so[27]. To date, none have imparted IP safeguarded vaccine data to the WHO Covid-19 Technology Access Pool (C-TAP) laid out keep going year[28]. Relying on the ethical compass of organizations that solution to investors to deliberately permit their advances will have restricted impact on vaccine value. Their market is driven by overall revenues, not public health. Mandatory licensing by LMICs will likewise be lacking in quickly growing vaccine creation, as each patent permit should be haggled independently by every country and for every item founded on its own legitimacy. From 1995 to 2016, 108 necessary licenses were endeavored and just 53 were approved[2930]. The made to order approach is slow and not reasonable for a global crisis that requires quick activity. What's more, TRIPS requires necessary licenses to be utilized prevalently for homegrown stockpile, restricting commodities of the authorized goods to local low pay nations without creation capacity[31]. Although a "unique" mandatory permit framework was concurred in the Doha presentation to take into account quick exportation and importation (formalized as the article 31bis amendment to TRIPS in 2017), the arrangement is restricted by bulky calculated strategies and has been

25 Irwin A. What it will take to vaccinate the world against covid-19. Nature 2021;592:176-8

26 Vaccine patents, global equity and how to vaccinate the world. WBUR, 24 Mar 2021. https://www.wbur.org/onpoint/2021/03/24/how-to-equitably-vaccinate-the-world

27 Morten C, Herder M. We can't trust big pharma to make enough vaccines. Nation 2021 May 31. https://www.thenation.com/article/world/covid-vaccines-pharma/

28 Safi M. WHO platform for pharmaceutical firms unused since pandemic began. Guardian 2021 Jan 22. https://www.theguardian.com/world/2021/jan/22/who-platform-for-pharmaceutical-firmsunused-sincepandemic-began

29 Son KB, Lee TJ. Compulsory licensing of pharmaceuticals reconsidered: Current situation and implications for access to medicines. Glob Public Health 2018;13:1430-40. doi: 10.1080/17441692.2017.1407811 pmid:

30 Ibid. This also follows from supra 6 s. 13

31 World Trade Organization. TRIPS agreement. 1994. https://www.wto.org/english/docs_e/legal_e/27trips_02_e.htm

seldom used[32]. Governments may likewise be reluctant to seek after obligatory licenses as big league salary nations have recently harassed them for doing as such. Since India initially utilized necessary licensing for sorafenib tosylate in 2012 (lessening the disease medication's cost by 97%), the US has reliably compelled the country not to utilize further mandatory licences[33]. During this pandemic, Gilead sued the Russian government for giving an obligatory permit for remdesivir[34].Furthermore, while necessary licenses are principally for licenses, Coronavirus vaccines regularly have different sorts of IP, including proprietary advantages, that are indispensable for production[35]. The emergency TRIPS waiver eliminates all IP as a barrier to beginning creation (not simply licenses) and invalidates the delayed time, irregularity, continuous disappointment, and political strain that go with deliberate licensing and mandatory licensing endeavors. It likewise gives a quick way to new providers to import and product vaccines to nations deprived without administrative constraints. At long last, there is no unquestionable proof that the proposed TRIPS waiver would destroy the IP framework and its development motivations. The waiver is confined to Coronavirus related goods and is time restricted, assisting with safeguarding future advancement. It would, nonetheless, lessen overall revenues on current Coronavirus vaccines. With significant income in the principal quarter of 2021, many medication organizations have as of now recovered their research and improvement costs for Coronavirus vaccines[42]. However, they have not been the sole financial backers in vaccine advancement, and they ought not be the only ones to benefit. Most vaccines got a significant part of their immediate financing from governments and not-for-benefit organizations-and for some's purposes, like Moderna and Novavax, almost all[43]. Decades of

32 Garrison C. Never say never - why the major league salary nations that quit from the Workmanship. 31bis WTO TRIPS framework should desperately reexamine their choice notwithstanding the Coronavirus pandemic. Medications Regulation and Strategy 2020 Apr 8. https://medicineslawandpolicy.org/2020/04/never-sayneverwhy-the-big time salary nations that-quit from-the-craftsmanship 31bis-wto-trips-framework musturgentlyrethink their-choice despite the-Coronavirus pandemic/

33 Médecins Sans Frontières. A timeline of US attacks on India's patent law and generic competition.2015. https://msfaccess.org/sites/default/files/201810/IP_Timeline_US%20pressure%20on%20India_Sep%202014_0.pdf

34 Gilead sues Russia: private company challenges a country 's right to protect public health. Make Medicines Affordable, 2021. https://makemedicinesaffordable.org/gilead-sues-russia-privatecompany-challenges-acountrys-right-to-protect-public-health/

35 Contreras J. US Support for a WTO waiver of covid-19 intellectual property – what does it mean? Bill of Health, 2021. https://blog.petrieflom.law.harvard.edu/2021/05/07/wto-waiver-intellectualproperty-covid/ [42] Buchholz K. Covid-19 vaccines lift pharma company profits. Statista 2021. https://www.statista.com/chart/24829/net-income-profit-pharma-companies/ [43] Covid vaccines: Will drug companies make bumper profits? BBC News 2020 Apr 22. https://www.bbc.com/news/business-55170756

publicly supported research have laid the basis for ebb and flow developments behind the scenes innovations utilized for vaccines [36]. Given that organizations were allowed forthright gamble assurance for Coronavirus vaccine research and improvement, a waiver that propels global public health however diminishes vaccine profits in a global crisis is reasonable.

CONCLUSION

In today's world where vaccine which has been protected the entire world is being protected by multiple of IP which is being licensed from multiple developers and partners. Many Coronavirus vaccine designers have not made strides towards licensing their advances, essentially in light of the fact that there is a restricted monetary motivator to do so. while necessary licenses are principally for licenses, Coronavirus vaccines regularly have different sorts of IP, including proprietary advantages, that are indispensable for production. To date, none have imparted IP safeguarded vaccine data to the WHO Covid-19 Technology Access Pool (C-TAP) laid out to keep going year. Relying on the ethical compass of organizations that solution to investors to deliberately permit their advances will have a restricted impact on vaccine value. Their market is driven by overall revenues, not public health. Mandatory licensing by LMICs will likewise be lacking in quickly growing vaccine creation, as each patent permit should be haggled independently by every country and for every item found on its own legitimacy. Otherwise, if countries follow this type of approach, then production and innovation regarding vaccines would be slow and not reasonable for a global crisis where the globe wants quick activity. We are in the middle of one of the largest vaccination efforts in human history. We cannot rely on companies to thread the needle of corporate social and moral responsibility with shareholder and stock value returns nor expect impacted governments to endure lengthy bureaucratic licensing processes in this time of crisis. It will be a legacy of apathy and unnecessary death. Instead, there should be strong competition among the country where every individual country is competing to save the world.

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36 Cross S, Rho Y, Reddy H, etal. Who funded the research behind the Oxford-AstraZeneca COVID-19 vaccine? Approximating the funding to the University of Oxford for the research and development of the ChAdOx vaccine technology. [Preprint.] medRxiv 2021 ;2021.04.08.21255103. doi: 10.1101/2021.04.08.21255103