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Megha Middha, Assistant Professor of Law in Mody University of Science and Technology, Lakshmangarh, Sikar

Megha Middha, is working as an Assistant Professor of Law in Mody University of Science and Technology, Lakshmangarh, Sikar (Rajasthan). She has an experience in the teaching of almost 3 years. She has completed her graduation in BBA LL.B (H) from Amity University, Rajasthan (Gold Medalist) and did her post-graduation (LL.M in Business Laws) from NLSIU, Bengaluru. Currently, she is enrolled in a Ph.D. course in the Department of Law at Mohanlal Sukhadia University, Udaipur (Rajasthan). She wishes to excel in academics and research and contribute as much as she can to society. Through her interactions with the students, she tries to inculcate a sense of deep thinking power in her students and enlighten and guide them to the fact how they can bring a change to the society

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ISSN: 2582-6433

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Assistant professor of Law

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Avinash Kumar

Avinash Kumar has completed his Ph.D. in International Investment Law from the Dept. of Law & Governance, Central University of South Bihar. His research work is on "International Investment Agreement and State's right to regulate Foreign Investment." He qualified UGC-NET and has been selected for the prestigious ICSSR Doctoral Fellowship.He is an alumnus of the Faculty of Law, University of Delhi. Formerly he has been elected as Students Union President of Law Centre-1, University of Delhi.Moreover, he completed his LL.M. from the University of Delhi (2014-16), dissertation on "Cross-border Merger & Acquisition"; LL.B. from the University of Delhi (2011-14), and B.A. (Hons.) from Maharaja Agrasen College, University of Delhi. He has also obtained P.G. Diploma in IPR from the Indian Society of International Law, New Delhi.He has qualified UGC – NET examination and has been awarded ICSSR – Doctoral Fellowship. He has published six-plus articles and presented 9 plus papers in national and international seminars/conferences. He participated in several workshops on research methodology and teaching and learning.

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PHARMACEUTICAL PATENTING: COVID-19 LESSONS OF TRIPS WAIVER

Authored By-Ashish Jain
5th Year Law Student
School of Law, AURO University
BBA LLB 2018

Introduction

The humanitarian history of the world has noted the non-selfish demands of India and South Africa, that had piloted the proposal to waive key provisions of the TRIPS agreement on Covid 19 vaccines, drugs, therapeutics, and related technologies, This proposal was initially opposed by the world, as they were eyeing over it as disturbance to the IPR Laws and damage to the objective of TRIPS agreement in the long run future. However, US had to back this proposal, when they realized the gravity of Covid 19 situation worldwide, which was seen especially in poor, under developed and even developing nations. However, the pharmacy companies in Europe, specially Germany and UK, were opposing this proposal, on the grounds of economic interests.

Patents are monopoly rights granted under a statue normally for a period of 20 years, after which it comes into public domain existence. Patents have an important role to play in stimulating innovation in healthcare products in countries where financial and technological capabilities exists. The rights of the patentee are normally subject to national legislations, however there are a few exceptions, such as Bolar Exemption.

So the core idea behind the proposal of TRIPS waiver, was that the IPR should not become barrier in scaling up the production of medical products essential to combat covid 19. However, the Government of India was beaten over this unethical business activity, as they were asking for international support to waive off trips agreement, however, domestically, not implementing compulsory licensing as to enable vaccine manufacturers to expand production and reduce inefficiencies in procurement and distribution.

ISSN: 2582-6433

This introduction is to conclude that my research problem is established on the pillars that whether it is relevant to waive of patent rights in critical upcoming situations, or rather the authorities should wait and watch, as to provide a fulfillment of objective of patent rights granted, until the situation become worrisome.

Patent Law In India

The first legislation in India relating to patents was the **Act VI of 1856**. The objective of this legislation was to encourage inventions of new and useful manufactures and to induce inventors to disclose secret of their inventions. In modern terms, the patent is usually referred to as the right granted to an inventor for his Invention of any new, useful, non-obvious process, machine, article of manufacture, or composition of matter. [1]

In India, the Patents Act, 1970, more broadly exempts acts relating to the development and submission of information required by law in India or abroad. The Patents (Amendment) Act, 2002, inserted a new provision, i.e. Section 107-A in the Patents Act, 1970, which provides for certain acts not to be considered as infringement. This provision is interpreted in liberal construction and exempts certain acts for the purpose of development and submission of information required under any law in India or abroad. This provision is very useful for the generic drug producers in India.

A patent claim relating to a pharmaceutical product may relate to an active ingredient as such independently of or jointly with formulations, salts, pro-drugs, isomers, etc., or cover any of these subject matters separately. It may also solely cover a manufacturing process or include both a process and a product.[2]

Trips Agreement And Indian Laws:

The TRIPS agreement was negotiated in 1995 at the WTO, it requires all its signatory countries to enact domestic law. It guarantees minimum standards of IP protection. Such legal consistency enables innovators to monetize their intellectual property in multiple countries. In 2001, the WTO signed the Doha Declaration, which clarified that in a public

[1] History of Indian Patent System | Intellectual Property India | Government of India. [ONLINE]. Available at: https://ipindia.gov.in/history-of-indian-patent-system.htm.
[2] *Patents - An Important Tool for Pharmaceutical Industry.* | Open Access Journals. 2022. [ONLINE] Available at: https://www.rroij.com/open-access/patents--an-important-tool-for-pharmaceutical-industry-.php?aid=34351.

ISSN: 2582-6433

health emergency, governments could compel companies to license their patents to manufacturers, even if they did not think the offered price was acceptable.[3] This provision, commonly referred to as "compulsory licensing", was already built into the TRIPS Agreement and the Doha declaration only clarified its usage.

Under Section 92 of the 1970 Indian Patents Act, the central government has the power to allow compulsory licenses to be issued at any time in case of a national emergency or circumstances of extreme urgency.[4] India and South Africa's current proposal seeks greater flexibilities than those provided in the TRIPS Agreement. The vaccine manufacturing process is complex and exercising flexibilities on patents will be insufficient to enhance production. It will require relaxation on other forms of intellectual property as well just like India has proposed at the WTO.

The trips agreement which lays down the minimum standards for the Member states also allows the use of limited exemption. Article 30[5] states that "Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interest of third parties." Article 30, thus enables Member states to provide for certain exceptions in their national legislation subject to the condition that they do not unreasonably conflict with a normal exploitation of the patent or prejudice the legitimate interest of the patent owner.

What Is The Trips Waiver For Covid-19 Vaccines?

The TRIPS waiver refers to a proposal, advanced by the governments of South Africa and India, to the World Trade Organization to waive intellectual property rights protection for technologies needed to prevent, contain, or treat COVID-19 until widespread vaccination is in place globally, and the majority of the world's population has developed immunity. [6]

The stricter standards provided by the TRIPs Agreement caused a lot of hardship on most of

[3] Drishti IAS, 2022, *TRIPS Waiver or Compulsory License,* [ONLINE]. Available at: https://www.drishtiias.com/daily-news-editorials/trips-waiver-or-compulsory-license/.
[4] Shivangi Mittal. 2022. *Why the TRIPS waiver is unlikely to solve India's Covid-19 vaccine shortage.* [ONLINE] Available at: https://theprint.in/opinion/why-the-trips-waiver-unlikely-to-solve-indias-covid-19-vaccine-shortage/653979/.
[5] Article 30: Exceptions to Rights Conferred, Agreement on Trade-Related Aspects of Intellectual Property Rights.
[6] Johns Hopkins, Bloomberg School of Public Health. 2022. *WTO TRIPS Waiver for COVID-19 Vaccines* [ONLINE] Available at: https://publichealth.jhu.edu/2021/wto-trips-waiver-for-covid-19-vaccines.

ISSN: 2582-6433

the Member states, particularly the developing countries to address the public health issues. Recognizing this state of issues and gravity of the problem, Doha Declaration on TRIPs Agreement and Public Health was adopted in 2001. The declaration recognized the gravity of the public health problems afflicting world-wide, and forced the requirement for the TRIPs agreement to be particulate for wider national and international action to address public health problems.

In October 2020, India and South Africa had approached the World Trade Organization (WTO) seeking a waiver on intellectual property rights on Covid-related innovations to enhance access to tests, drugs, and vaccines.[7] Thereafter, a revised proposal was submitted in the second half of May. The revised proposal aims to increase global access to several crucial medical products to help countries tackle more effectively the contagious virus with affordable and accessible tools.[8]

India is among 62 World Trade Organization (WTO) members that are pushing this draft, which limits the waiver period to three years, with a provision to review the duration. TRIPS waiver will accelerate scaling up some COVID-19 vaccines where the untapped capacity for vaccine production still exists, and it may also encourage existing vaccine producers to step up their technology transfer efforts.

Supporters And Oppositions To This Draft

Most developing countries have supported the proposal. The US has also given its weight behind the TRIPS waiver, but only on the vaccine and not on other medical equipment and medicines.[9] European Union is also considering the proposal. However, some developed countries, including Japan and the UK, have opposed the move. Multinational pharmaceutical companies have also opposed this draft because they fear losing their market share and revenue earned on vaccines and medicines as well.

However, as the difficult time has passed away for Majority of the countries, the view over this draft has also tilted around a lot, such as example I read at that time was: Even Yusuf Hamied of Cipla Ltd, the daring knight exemplar of generic production, is no longer a challenger.

[7] BYJUS, 2022. *TRIPS Waiver for COVID-19 Vaccine: RSTV – Big Picture Analysis for UPSC IAS exam.* [ONLINE] Available at: https://byjus.com/free-ias-prep/trips-waiver-for-covid-19-vaccine-rstv-big-picture/.
[8] Ibid.
[9] Ibid.

ISSN: 2582-6433

The man who stunned the world by producing life-saving drugs at a fraction of the original cost, today dismisses the idea of Compulsory Licensing's. Cipla is a spent warrior of the good fight against exploitative drug majors, having joined the queue for the voluntary license handouts.

Therefore, my purview over this research problem would be to consider a long run situation, and keeping up the exemptions of emergency. Be it pandemic or other virus leaks, sharing of data, and medical formula should be compulsory under some extent or review of an international board.

The Stance Of Compulsory License

The Doha Declaration recognizes the rights of the developing countries which are members of the WTO to make provisions in their national legislations for the grant of the compulsory licence to address the problem of public health. The provisions for grant of compulsory licence are under Article 31 of the TRIPS Agreement[10]. The developing countries amended their laws for compulsory licensing, based on the Doha Declaration. India, a major generic drug manufacturer, also amended its laws for the grant of compulsory licenses taking into account the flexibilities identified by the Doha Declaration.[11]

Section 92 and 92A of the Indian Patents Act, 1970 are relevant to the compulsory licensing, wherein Section 92 provides that in circumstances of national emergency or extreme urgency or in case of public non-commercial use, if the Central Government is satisfied that it is necessary that compulsory licences should be granted at any time after the sealing thereof to work the invention, it may a declaration to that effect by notification in Official Gazette.

[10] Article 31: Other Use Without Authorization of the Right Holder, Agreement on Trade-Related Aspects of Intellectual Property Rights.

[11] Report of the WHO Commission on Intellectual Property Rights, Innovation and Public Health, *PUBLIC HEALTH: INNOVATION AND INTELLECTUAL PROPERTY RIGHTS*, April 2006, p. 136.

ISSN: 2582-6433

Conclusion

Human Rights and intellectual property rights are two distinct areas of law. These have evolved separately over the years. The relationship and conflict between the two have become subject matter of increasing debate. It is the first and foremost duty of nations to promote and protect human rights. The nations are under an obligation to provide *inter alia* the right to food and health to their people.

At the junction of the medical sciences, public health, economics, political science, business and law lies a fascinating crisis facing much of the developing areas of the world. The question of providing access to essential medications for the third world is a complex one and faces many barriers to a solution. Diseases like AIDS, malaria, and tuberculosis have been ravaging the developing world for decades; despite the efforts of NGO's, governments, health professionals, lawyers and even major pharmaceutical companies, a solution to these problems is nowhere in sight.[12]

The effect of patents on the ability of nations to comply with their obligations under human rights law, most particularly, the obligation to ensure access to affordable medicines has been a subject-matter of debate. The balanced approach is highly recommended for orderly development of society.[13]

Patents are originally intended to encourage innovators and maximize the greater good and if we want to help people and make healthcare more affordable, we need an even more rapid process for approval of generics. Branded pharma companies need to obtain patent protection for their products to garner investments. Therefore, patents must be a fundamental incentive to innovative activities in the pharmaceuticals and biotechnology industry, hence they need to be safeguarded.[14]

Handling HIV-AIDS took 20 years, mainly due to complexities involved in compulsory licensing and challenging patents associated with drugs concerned with this.

[12] Junaid Subhan, *Scrutinized: The TRIPS Agreement and Public Health*; Archive of "McGill Journal of Medicine : MJM". - PMC. 2022. [ONLINE] Available at: https://www.ncbi.nlm.nih.gov/pmc/journals/602/.
[13] V.K. Ahuja, *Human Rights and Intellectual Property Rights* in Gurdip Singh and V.K. Ahuja, HUMAN RIGHTS IN 21st CENTURY: CHANGING DIMENSIONS (New Delhi, 2012) p. 677.
[14] Patentskart. 2022. Importance of Patents in the Pharmaceutical Industry - Patentskart. [ONLINE] Available at: https://patentskart.com/importance-of-patents-in-the-pharmaceutical-industry/.

ISSN: 2582-6433

This could not have been repeated in the case of the COVID pandemic, given the havoc it has wrecked on life and the economy across the world. All countries and other stakeholders should collaborate to fight the pandemic and medical emergencies at the earliest to constraint the unforeseen circumstances

However, the other side of the coin is that, Patents are originally intended to encourage innovators and maximize the greater good and if we want to help people and make healthcare more affordable, we need an even more rapid process for approval of generics. It is very important for branded pharma companies to obtain patent protection for their products in order to garner the investments. Therefore, it is important that patents are a fundamental incentive to innovative activities in the pharmaceuticals and biotechnology industry, hence it needs to be safeguarded.