Page 2259 - 2281 **DOI:** *https://doij.org/10.10000/IJLMH.11721*

INTERNATIONAL JOURNAL OF LAW MANAGEMENT & HUMANITIES

[ISSN 2581-5369]

Volume 4 | Issue 3

2021

Compulsory Licensing in the Pharmaceutical Industry

DEVIKA J. ASHAR [1]

ABSTRACT

Compulsory Licensing takes place when the government permits a third party to carry out the same rights as the right holder without his consent. The constant debate and opposing views between developed countries and developing countries with respect to compulsory licensing is something which needs to be taken into consideration. Developing countries are of the view that compulsory licensing would help to overcome the unaffordability of medicines and their unavailability. While on the other hand developed countries have an opposing view as they feel that it would be disadvantageous for innovation in the pharmaceutical industry. Compulsory Licensing helps in resolving the conflict of interest between two parties thereby ensuring develop and fair returns. The system of compulsory licensing in the pharmaceutical industry allows the conflict to be resolved by a third party which is a neutral party and in the end having the same aim to increase the universal access to life saving drugs globally. Thus in this situation compulsory licensing is the most important safety valve, it helps to address the modern healthcare conflict between patients versus patents.

With the help of this paper, the author intends to address the existing legal regime which exists for Compulsory Licensing in India followed by analysing the provisions present in the TRIPS agreement. The problem which arises is with monopolising right which are available to patent holders, this makes it harder to meet the demand if the supply is high. The author also intends to emphasise on the possibility of the Indian government to permit compulsory licensing to other manufactures thereby increases the supply of the vaccines and meeting the demand. Lastly, the author aims at providing a 360 degrees view point of Compulsory Licensing in India and suggestions for its improvement.

Keywords: *Compulsory Licensing, Patents, Pharmaceutical Industry, COVID-19 Vaccines, India, WTO.*

[1] Author is a student at NMIMS's Kirit P. Mehta, School of Law, India.

 [ISSN 2581-5369]

I. INTRODUCTION

A patent is defined as an exclusive right which is granted for an invention, which could be a product or a process that provides a new way of doing a thing or offers a new technical solution to a problem which is present.[2] By obtaining a patent, the patent holder is granted with a positive as well as a negative right. The positive right allows crediting the patent holder with exclusive rights to manufacture the invented or manufactured article according to the patented process for a particular time period. This gives the patent holder the exclusive right and legal monopoly to carry out the invention and protect his hard work as well as promotes the innovation. The negative right which is levied on the patent holder is the right which enables the holder to prevent any third party from replicating or using the patented innovation without the holders consent. The patented innovation is valid for a particular time period and after its expiration anybody can make use of the patent. A patent is a form of intellectual property where the patent holder is capable of selling the property or even granting licenses for the same in order to exploit the patent. It is pertinent to note that a patent is not granted for an idea or a principle but on the contrary to either an article or a process of making an article by applying the idea. Patents are protected under the provisions of The Patents Act, 1970 (**"Patents Act")** in India and are also regulated under Trade Related Aspects of Intellectual Property Rights **("TRIPS Agreement").**

In order to maintain a balance and save the patent holder from abuse of his patent rights, a remedy to the evil system of Compulsory Licensing has been introduced. This system allows the government to permit any third party to use patented product or process without the consent of the holder in conditions which are mentioned with the government. This system has been prevalent for a long period of time and adopted by several countries such as United Kingdom, United States of America, China, India etc. Patents as mentioned above, provide monopoly rights to the holder but when it comes to the Pharmaceutical Industry the patent law is highly controversial. Many people are of the opinion that by generating monopoly rights to patented products under the pharmaceutical industry will block access and availability of life saving drugs to the public at large and also the holder has the ability of increasing and decreasing the price according to his own choice. To the contrary, some people are of the opinion that by patenting pharmaceutical products, wouldn't attract investment in the sector and thereby lowering the incentive for manufacturing the lifesaving drugs and hinder research and innovation in the pharmaceutical industry.

[2] WIPO, Patents, Available at: https://www.wipo.int/patents/en/ (Accessed on: 13th April, 2021, 10:11pm)

 [ISSN 2581-5369]

The COVID-19 pandemic has displayed overwhelming inequality with respect to people's access to the medicines as well as medical services across states as well as countries. The availability and distribution of the vaccines is an apt example describing the same. India being one of the big manufacturing nations when it comes to drugs and vaccines hasn't been able to keep up with steady supply of COVID-19 vaccines. With rise in number of cases and demand for treatment spiking, India has banned the exports of *Gilead Sciences'*[3] pandemic antiviral Remdesivir drug. The TRIPS Agreement is the most important legal instruments which imposes binding obligations on member countries thus protecting their rights in their respective territories. Presently, one of the debates at the World Trade Organisation (**"WTO"**) is whether the vaccines and treatments which are needed to combat the virus, are subjected to protection against the TRIPs Agreement? Will the government move towards compulsory licensing and will the government allow and open manufacturing to outside companies, is something which can be questioned.

The aim of this paper is to explore the legal framework governing compulsory licensing in India and ascertain the rationale and impact of the judgement given by the Supreme Court in the case of ***Natco Pharma Limited v. Bayer Healthcare Llc*** [4]. With the onset of the second wave of the pandemic and the alarming situation with respect to shortage of vaccines and drugs, the initiates to mention whether it is viable for the Indian government to grant compulsory licensing to increase the supply of vaccines? The paper also aims to mention the proposition regarding the waiver of Intellectual Property Right cases for COVID-19 Vaccines and drugs.

(A) Objective of the project

i. To highlight the legal framework governing Compulsory Licensing in India.
ii. To analyse the landmark judgement of Natco Pharma Limited v. Bayer Healthcare Llc.
iii. To emphasis and create awareness regarding the joint proposal by developing countries at the WTO, regarding temporary waiver of Intellectual Property Laws with respect to COVID-19 vaccines and drugs.
iv. To trace out whether India should grant compulsory licensing to increase the supply of COVID-19 vaccines and meet the demand.
v. To draw conclusions towards grant of Compulsory Licensing in India.

(B) Research question

[3] Fraiser Kansteiner, "India axes exports of Gilead Sciences'remdesivir, plotsboost to local production as COVID cases mount", Fierce Pharma, 12th April, 2021, Available at: https://www.fiercepharma.com/manufacturing/india-axes-exports-gilead-sciences-remdesivir-plots-boost-to-local-production-as (Accessed on 14th April, 2021, 7:34pm)
[4] 2013 IPAB 20

i. What is the legal regime which is guarding Compulsory Licensing in India? How has the ***Natco Pharma Limited v. Bayer Healthcare Llc*** case been an evolution in the pharmaceutical industry?

ii. What was the impact of the joint proposal initiated by India and South Africa at the World Trade Organisation (**"WTO")** regarding temporary waiver of Intellectual Property rights on COVID-19 drugs and vaccines?

iii. Is it viable for India to grant compulsory licensing to increase the vaccine supply and meet the demand?

(C) Research Problem

Compulsory Licensing is when generic copies are produced which is mainly done for the domestic use and not for export purposes. It takes place when the government allows a third party to carry out the same rights as the right holder without his consent. With the help of this paper, I intent to address the existing legal regime which exists for Compulsory Licensing in India followed by analysing the provisions present in the TRIPS agreement. The problem which arises is with monopolising right which are available to patent holders, this makes it harder to meet the demand if the supply is high. The author also intends to emphasise on the possibility of the Indian government to permit compulsory licensing to other manufactures thereby increases the supply of the vaccines and meeting the demand. Lastly, the author aims at providing a 360 degrees view point of Compulsory Licensing in India and suggestions for its improvement.

(D) Hypothesis

H1- Compulsory Licensing is a balancing system preventing the abuse of patent holders right, thereby protecting the intellectual property law.

H2- ***Natco Pharma Limited v. Bayer Healthcare Llc*** was an evolution in the history of India granting Compulsory Licensing,

H3- There is a need to allow compulsory licensing for COVID-19 vaccines and drugs thereby combatting the virus in India.

H4- Waiving of Intellectual Property rights on COVID-19 drugs and vaccines would lead to completing the vaccination drive globally quicker.

(E) Research Methodology

The researcher would use a combination of doctrinal, analytical and descriptive method. In order to fulfil the objectives of research reliance will be place on primary and secondary sources

 [ISSN 2581-5369]

of data such as Statutes, books, articles, research papers, journals etc. A number of legislations are involved in determining compulsory licensing. Doctrinal research would include library based data i.e. articles, books, research papers. A study on codified laws in India the Patents Act, 1970 as well as TRIPS Agreements were also referred to gain international perspective. The author would look into the laws governing compulsory licensing in several developing countries this would help to provide an overall practical understand of the system. This would help to formulate a basic understanding of the concept of compulsory licensing and account for the first 2 days of initial research which answered the first research question. The initial doctrinal research would thus be concluded under the following heads:

1. Indian Codified Laws regarding Compulsory Licensing
2. Indian Case Studies regarding Compulsory Licensing
3. Laws regarding Compulsory Licensing under the TRIPS Agreement

The next stage would be analytical as well as descriptive research which will be conducted in tracing the judicial journey and landmark cases on compulsory licensing in India and weighing its pros and cons. Steps will also be taken to analyse the joint proposal which was initiated by developing countries at the WTO regarding the waiver of intellectual property laws for COVID-19 vaccine and drug treatment. Assessing whether it is viable for the Indian government should take steps to provide compulsory licensing with respect the COVID-19 vaccines and drugs thereby meeting the supply needs will also be mentioned. This would be analysed after reading research papers, newspaper articles as well as views of political leaders.

The final step would also be to suggest legal reforms in the existing legislations, assessing the future scope and providing suggestions for the same.

II. REVIEW OF LITERATURE

1. P.Narayanan, "Intellectual Property Law", Third Edition published by Eastern Law House, 67-70.

This book provides for an overall look of the Intellectual Property Law in India. It explains all the concepts in a very efficient and concise manner which is easy to understand. The concept of Compulsory Licensing has been explained very well along with licenses of right as well as revocation for non-working of patents.

2. Indian Patents Act, 1970

This Bare Act has covered and laid down the provisions guarding and protecting the concept of Compulsory Licensing in India. The Sections applicable are from Section 84 to 90 and 94-

96.

3. Anna Niesporek, "Compulsory Licensing of Pharmaceutical Products and Access to Essential Medicines in Developing Countries", Available on: https://www.diva-portal.org/smash/get/diva2:21332/FULLTEXT01.pdf

This Thesis has accurately explained the rationale of patent protection, followed by the protection which is available under the TRIPS Agreement to patents. Further, the author has also explained the rationale behind compulsory licensing and the effect of its prevalence. Another aspect which the paper also discusses is the discussions which have been taking place at the Doha Declaration. Lastly, the thesis also draws attention to the method in which WTO deals with the export of generic drugs.

4. Kiran Kumari and Ajay Sharma, "*Doha Declaration: Compulsory Licensing and Access to Drugs", 3(2)*Amity Journal of Healthcare Management, 43-54, (2018) Available on: https://amity.edu/UserFiles/admaa/88a06Paper%204.pdf

As the title suggests, this research paper aims at highlighting the Doha Declaration in relation with compulsory licensing and access to Drugs. Further the paper outlined the compulsory licensing regime present in India and the rational behind the ***Natco Pharma Limited v. Bayer Healthcare Llc*** judgement. It also throws light on the opinions of the public health officials at the Doha Declaration who believed compulsory licensing was a positive approach towards providing easier access to health care across the globe.

5. Prabhash Ranjan, "The Case for Waiving Intellectual Property Protection for COVID-19 Vaccines", 456 Observer Research Foundation, (April 2021) Available on: https://www.orfonline.org/research/the-case-for-waiving-intellectual-property-protection-for-covid-19-vaccines/

This article completely focuses on the proposition imposed by India and South Africa at the WTO, to waive of the Intellectual Property Laws with respect to COVID-19 Vaccines. It further goes on to analyse the legal basis which are applicable and the inflexibility of the TRIPS Agreement to do so. Lastly, it concludes and states the need for the waiver to be initiated as it would help to provide vaccine faster and aid to public health and safety.

6. Biswajit Dhar and K.M. Gopakumar, "India-South Africa proposal for a waiver from certain obligations under the TRIPS Agreement", Third World Network (2020)

The above mentioned research paper, again as the title suggests discusses the proposal for a waiver. It goes on to state its importance as it would help to provide greater assistance to

COVID-19 related drugs and medicines. Further it also talks about ways in which the provisions guarding compulsory licensing need to be strengthened and the next possible step forward.

7. Amanpreet Kaur and Rekha Chaturvedi, "Compulsory Licensing of Drugs and Pharmaceuticals: Issues and Dilemnma", 20 Journal of Intellectual Property Rights, 279-287, (2015)

This research paper, has meticulously explained the compulsory licensing laws in India and the issues which are related to the system. Further it goes ahead and analyses a couple of compulsory licenses cases in India and it also provides alternate measure to compulsory licensing provisions.

8. Hilary Wong, "The Case for Compulsory Licensing during COVID-19", 10 Viewpoints, University of California, Berkeley, School of Law (June 2020)

The author provides an international perspective to compulsory licensing across the globe along with the TRIPS provision. It further talks about the past experiences and tries with respect to compulsory licensing and HIV drug medicines. It lastly, also provides the struggles which countries are facing with respect to compulsory licensing during COVID-19 times and concludes with compulsory licensing being a powerful tool.

III. INTERNATIONAL AND NATIONAL LAWS GOVERNING COMPULSORY LICENSING

(A) International Laws Governing Compulsory Licensing

Under the international patent protection standards set in the TRIPS Agreement, Compulsory Licensing is expressly allowed.[5] Rwanda was the first country which imported antiretroviral drugs from a Canadian company Apotex with the help of compulsory licensing.[6] The aim of compulsory licensing in the TRIPS Agreement is to act as a balancing lever ensuring that the innovations are publicly morale "was *to keep a check on the use of innovation on the grounds of public morality*".[7] According to the TRIPS Agreement patents shall be available to all inventions[8] and it permits countries to formulate their own mechanisms regarding patent laws which are in conformity to the agreement, thereby ensuring protection to public health and

[5] Adi Gillat, "Compulsory Licensing to Regulated Licensenging: Effects on the Conflicts Between Innovation and Access in the Pharmaceutical Industry", 58 Food and Drug Law Journal, L.J. 711 (2003)
[6] Elie Betito,"Apotex Corp. Receives Final Tender Approval From Rwanda for Vital AIDS Drug",BioSpace, 7th May, 2008, Available at: https://www.biospace.com/article/releases/apotex-corp-receives-final-tender-approval-from-rwanda-for-vital-aids-drug-/ (Accessed on 16th April, 2021, 10:20am)
[7] Amanpreet Kaur and Rekha Chaturvedi, "Compulsory Licensing of Drugs and Pharmaceuticals: Issues and Dilemma", 20 Journal of Intellectual Property Rights, 279-287 (September 2015)
[8] Article 27, The TRIPS Agreement

prevention of patent misuse.[9]

Article 31 of the TRIPS agreement talks about compulsory licensing and imposes certain restrictions. It is pertinent that prior to obtaining a compulsory license, the person imposing has negotiated for a voluntary license and if he fails to obtain one, the government can then go ahead and issue the license. On issuing the compulsory license, the patentee is to be adequately compensated with a remuneration taking into account the economic value of the patent. However, nowhere are the terms "adequate remuneration" or "economic value" been defined thereby creating an ambiguity. Article 31(f) of the TRIPS Agreement which was initially a limiting provision to compulsory licensing was amended in the Doha Declaration which took place in November, 2001. Thereafter, allowing member countries to issue compulsory licenses to produce the drugs and export them to countries which have less or no "*manufacturing capabilities".*[10] This was implemented in August, 2003 where the Doha Declaration aimed at promoting health care and availing access to medicines without discrimination.

Post the amendment developing countries have been using it to provide medical care and access to all. Companies too are voluntarily taking steps to make their drugs accessible by either lowering their prices or by offering royalty free licensing thereby evading compulsory licensing. Brazil used this system, to negotiate and lower the prices for the supply of AIDS drugs by Roche, whereby Roche agreed to sell the drug in Brazil at discount and in return Brazil would not issue compulsory licensing for the same. "*In India Gilead signed a non-exclusive licensing agreement with seven India based generic pharmaceutical manufacturers thereby expanding its access to Hepatitis C treatments in developing countries*."[11]

(B) Legal Regime Governing Compulsory Licensing n India

The laws governing Compulsory Licensing in India is governed under chapter XVI and Sections 84 to 92 of the Patent Act, 1970. The Patents Act, was amended thrice in the years 1999, 2000 and 2005 to introduce the concept of compulsory licensing. As mentioned above the patent holder is granted with monopoly rights on attaining a patent on the respective product or process. With this monopoly right, it would impact the pharmaceutical industry as will it would block the access to life saving drugs and allow the patent holder to increase or decrease the price according to his choice.

[9] Article 8, The TRIPS Agreement
[10] Article 31(f), The TRIPS Agreement
[11] Gilead signs licenses with generic drugmakers for hepatitis C drugs", ThePharmaletter, 15th September, 2014, Available at: https://www.thepharmaletter.com/article/gilead-signs-licenses-with-generic-drugmakers-for-hepatitis-c-drugs (Accessed at 17th April, 2021, 10:35am)

Abuse of patent rights which are levied on attaining patent commonly takes place in several countries. They may occur in the various forms:

i. By refusing to the grant compulsory licenses locally in the country.

ii. Some countries meet the demand of the product, by importing from abroad and not by domestically manufacturing it. This discourages and prejudices the working of new trade or industry and even the development of the already prevalent industry.

iii. By enforcing unreasonable conditions which need to be met, thereby discouraging voluntary licensing from taking place.

iv. Post the expiry of the patent, imposing restriction on the use, sale, lease of the patented innovation or process thereby prolonging the monopoly right which was available to them.[12]

Thus the system of Compulsory Licensing and the act of revocation of the patent for non-working acts as a remedy to this evil of abuse of patent rights. Section 82 to 98 of the Patents Act, deal with circumstances and grounds under which compulsory licensing of different kinds or the patent may be revoked for non-working.[13]

Section 84(1) of the Patents Act, particularly states that a compulsory license can be granted to any third party or individual after the expiration of three years from the grant of patent, only when an application is made to the controller. The license can be given to the third party/individual on the following mentioned grounds:

a. *"That the reasonable requirements of public with respect to the patented invention have not been satisfied, or*

b. *that the patented invention is not available to the public at a reasonably affordable price, or*

c. *that the patented invention is not worked in the territory of India"*[14]

Failure to satisfy and meet the reasonable requirements of the public may arises due to the following reasons:

i. The inadequate manufacturing which is taking place in India, this could be due to the failure of granting licensing on reasonable agreeable terms thereby prejudicing the Indian industry and commercial activities.

[12] P. Narayan, Intellectual Property Law, 67, Third Edition, Third Impression, 2020.
[13] P. Narayan, Intellectual Property Law, 68, Third Edition, Third Impression, 2020.
[14] Section 84, The Patents Act, 1970

 [ISSN 2581-5369]

ii. The necessary patent is not working on a commercial scale in India

iii. The demand for the necessary patent is being met by the importing the goods as a result hindering the commercial working of the patent in India or

iv. Lastly, due to the restrictive conditions being imposed by the patentee, it ends up prejudicing the Indian industry and commercial activities.

These factors could be the possible failures to satisfy the reasonable requirements of the public. Section 84(7) of the Patents Act, further states what would be construed with respect to reasonable requirements of the public not being satisfied, the factors which will be deemed to not have been satisfying the reasonable requirement of the public are defined in the Patents Act, and may arise in the following situations:

i. The patent is not being working to the fullest extent which is practicable

ii. The patented product is still being imported, thereby hindering the invention in India on a commercialised scale

iii. The conditions imposed by the patent holder upon the grant of licence, manages to prejudice the trade or industry in India.

iv. The Patent holder is unable to manufacture and meet the demand of the public and supply them on reasonable grounds. The patent holder may also reject to grant license on reasonable terms thereby harming the establishment of new trade and industry in India.

The applicant before applying for compulsory licensing, must establish that he has a *bona fide* interest and also have a *prima facie case* in hand. Once the application is filed the patent holder will be called upon show why the compulsory license may not be granted and be heard. "*On receiving the application, the Controller takes into account factors such as nature of invention, the capability of the applicant to use the product for public benefit and the reasonability.*"[15] Thereafter, after interacting with the patent holder if the Controller is of the view that the above grounds have not been fulfilled and satisfied then the Controller with the power set out in Section 88 of the Patents Act, can grant the license.[16] The ultimate discretion lies in the hand of the Controller.

In addition to the aforesaid provisions, Section 92 of the Patents, Act states when the Controller can Suo motu issue a compulsory license. The said section empowers the Government of India

[15] Section 84(6), The Patents Act, 1970
[16] Section 84(4) and (5), The Patents Act, 1970

 [ISSN 2581-5369]

to notify the public the existence of an extreme circumstance whereby a compulsory license can be issued to the third party by the Controller. It could either be a situation of ""*national emergency" or "extreme urgency" or in cases of "public non-commercial use*""[17]. The Controller may then grant the license over terms and conditions he seems fit.[18] When it comes to dealing with dealing with compulsory licensing for export of patented pharmaceutical products,[19] the Patents Act states that it would be granted solely to manufacture and export those products to the countries in need, as per the requirements and terms and conditions of the Controller General. Under Section 92A the Patented Pharmaceutical products are drugs, ingredients which are necessary for their manufacturing and diagnostic kits which are required for their use.[20]

The compulsory license can be terminated according to the provisions set under Section 94 of the Patents Act. If the Licensee was unable to fulfil his duties for which the license was granted, his license can be terminated for the same. The Controller can also terminate the license if the circumstance which gave rise to the grant does not exists and are unlikely to occur again. The licensee would have the right to object to the termination.[21]

The government of India is capable of providing compulsory licenses of patents solely government use whereby in return the patent holder is compensated.[22] The patentee is capable of challenging such use and terms but however isn't permitted to do so when the government acquires the invention for public purposes.[23]

(C) Indian Cases on Compulsory Licensing

9th March, 2012 marked a revolutionary day in the history of compulsory licensing in India. It was the day when India, granted their very first compulsory licensing in the case of ***Natco Pharma Limited v. Bayer Healthcare Llc***[24] to a Hyderabad based Pharmaceutical Company called ***Natco Pharma Limited*** (**"Natco"**) for manufacturing the drug called '***Nexavar'*** (Sorafenib) for the treatment of advance staged cancer in kidney and liver. ***Bayer Corporation*** obtained the patent for this drug in United States of America (1999) and in India in the year

[17] Tanu Goyal, "Compulsory Licensing", Khurana & Khurana, Advocates and IP Attorneys, 3rd August, 2017, Available on: https://www.khuranaandkhurana.com/2017/08/03/compulsory-licensing/ (Accessed on 16th April, 2021, 6:18pm)
[18] Section 90, The Patents Act, 1970
[19] Section 92A, The Patents Act, 1970
[20] Id.
[21] Section 94, The Patents Act, 1970
[22] Section 100, The Patents Act, 1970
[23] Section 102, The Patents Act, 1970
[24] (2013) 3SCC (Civ) 227

 [ISSN 2581-5369]

2008.[25]

In 2008, Natco Pharma Limited is a generic pharmaceutical company and it approached Bayer Corporation to grant voluntary licensing for the purpose of manufacturing as well as selling of the patented drug in India, however the same was rejected. In the meantime in the year 2010, Cipla Pharmaceuticals which is an Indian drug manufacturing company started selling a generic version of the drug Nexavar. after a period of three years (2011) since Bayer attained its patent in India, Natco applied to the Controller for the grant of compulsory licensing under Section 84 of the Patents Act. The Controller held that all the three conditions were fulfilled, stating:

i. Firstly, Bayer failed to meet the reasonable requirement of the public. Over the three years of the patent being granted in India they only supplied 200 bottles of the drug, whereas the actual requirement was approximately 9000 bottles.

ii. Secondly, the patented invention was not available at reasonable affordable pricing. In the present case one month worth's dosage amounted to Rs. 2,80,000 (Rupees Two Lakhs Eighty Thousand) whereas Natco was offering to sell the drug for Rs. 9000 (Rupees Nine Thousand) thus making the drug available at a reasonable affordable price for the general public.

iii. Lastly, there were no manufacturing units present in India, there were nor were there any efforts made to set up any manufacturing unit. Therefore, it could be said that the patented innovation by Bayer was not adequately worked in the territory of India.

Taking into consideration all the above points, the Controller allowed a compulsory license in favour of Natco in India. However, the same was challenged before the Intellectual Property Appellate Board (**"IPAB"**) and it upheld the order of the Controller with certain changes:

i. According to Article 21 of the Indian Constitution no one should be deprived of his right to health, and therefore when it comes to the drug in question, it can be said that the reasonable requirement of the public was not met. Bayer had only provided 200 bottles thereby not meeting the demand of 3,000 bottles. Secondly when it comes to the Cipla selling the generic version of Nexavar and thereby meeting the demand of the public. The IPAB held that the requirement needed to be met by Bayer Corporation alone and that they could not rely on the sales undertaken by Cipla since that was being contested in another litigation.

[25] Mansi Sood, "Natco Pharma Ltd. v. Bayer Corporation and the Compulsory Licensing Regime in India", Manupatra, (Accessed on 16th April, 2021, 9:08pm)

 [ISSN 2581-5369]

ii. With respect to Bayer's contention that granting of compulsory licensing would result in the patented product being sold at a lower price than the patentee (Bayer Corporation) and this would affect its market and have an adverse effect on recovery of research and development costs. This would also pressurise Bayer to reduce its own prices which would affect the primary object of their grant. However IPAB overruled the contention and stated that the interest of public at large should be adopted and taken into consideration. The main purpose of compulsory licensing would be to provide the patented product at an affordable price to the public.

iii. IPAB held that importation was not the only option which was available for this drug in India, to the contrary it held that Bayer should take efforts for establishing a manufacturing unit in India.

iv. Lastly, on the issue of reasonable efforts for negotiations not been taken place by Natco, in terms of discussing the potential license agreement as mentioned under section 84(6)(iv) it was held that there were no obligations for Natco to make any further attempts.

Thus granting Compulsory Licensing to Natco Pharmaceutical Limited and that 6% of the net selling price of the drug would be paid to Bayer Corporation as royalty.

This decision was heavily criticized by several pharmaceutical companies as it would negatively affect the sector and weaken their ability to create and innovate. This judgement has opened the doors for easier ways of obtaining compulsory licensing not only in India but leaving an international impact too. The impact would be seen drastically in the pharmaceutical industry, in terms of investments, research and development costs, trade relations as well as other related matters.

Followed by this judgement, in the case of ***BDR Pharmaceuticals Pvt. Ltd. vs. Bristol Myers Squibb***[26] (2013) where the plaintiffs request to compulsory licensing of Bristol's cancer drug Sprycel was rejected. The Controller rejected the application made by BDR, as it failed to make a prima facie case under Section 87 of the Patents, Act. It was held that BDR had failed to take steps to procure voluntary license from the patentee and also that BDR did not have the ability to work the invention for the benefit of the public. Another case where compulsory license was rejected was in the case of ***Lee Pharma v. AstraZeneca AB***[27] where their application for compulsory licensing was rejected in respect of AstraZeneca's drug Saxagliptin which deals

[26] CLA No.1 of 2013 before the Controller of Patents, Mumbai
[27] CLA No. 1 of 2015

 [ISSN 2581-5369]

with diabetes. Lee Pharma strived to show that negotiation for a voluntary license with the patentee had taken place however, they weren't rewarding as the patentee did not respond within a reasonable period. Lee pharma challenged on the three grounds of Section 84(1) which was rejected by the Controller General and the license was refused.

The main aim and purpose of this system is to, balance the conflict of interest which takes place between the patent holders exclusive right as well as making the invention available to the public at affordable pricing. The system should be used judiciously as it acts as both an exception as well as flexibility guarding patents. Taking into consideration the last two cases where the compulsory license was denied in India, it proves that the provisions cannot be abused to dwindle with the patentee's right.

IV. PROPOSITION OF TRIPS WAIVER

Currently, the major global crisis the world is grappling with be it economically or socially is COVID-19. Though there have been vaccines and drugs which have been developed to combat the said virus, sadly, we have reached a situation where the demand of the public hasn't been met and the drugs are inaccessible to the public. The patent holder who innovates the said vaccine or drug is permitted to sell and use the innovation for a period of 20 years from the date of filing this restriction. This as a result would prevent broader accessibility and prolong the pandemic from ending. There have been increasing concerns regarding "vaccine nationalism" which basically involve the process of rich/developed countries acquiring the vaccines while developing countries and least developed countries are unable to meet the demands for medical products in the their countries. As a result, this derails the process of vaccination and the process of combating the virus.

In this context a joint proposal was initiated by India and South Africa at the WTO asking for temporary waiver of Intellectual Property Rights to COVID-19 vaccines and drugs. As a result, this would speed up the process of manufacturing and distributing the vaccine and meet the demand. On this proposition being put forth the WTO's TRIPS Council recommended to the General Council "a waiver from the implementation, application and enforcement of" certain provisions of the TRIPS agreement thereby helping in the prevention, containment and treatment of COVID-19.[28]The scope of the proposed waiver is inclusive of copyrights, patents, and trade secrets. Article IX.3 of the Marrakesh Agreement states that in "*exceptional circumstances"* the Ministerial Conference may waive an obligation imposed on a WTO

[28] TRIPS Waiver Proposal, Para 12, Available on: https://www.wto.org/english/tratop_e/trips_e/trips_and_covid19_e.htm

 [ISSN 2581-5369]

member by WTO agreement or any other multilateral trade agreement.[29] The term "*exceptional circumstances"* however hasn't been defined in the WTO Agreement. In this case the TRIPS Council would have jurisdiction over the matter according to Article IX.3(b) of TRIPS Agreement. It is pertinent that when granting the waiver, the Ministerial Conference states and justifies the "*exceptional circumstances"* and the terms and conditions which shall be agreed and governing the waiver. The period should have an end date and could be subjected to being renewed at the discretion of the Ministerial Conference. If the waiver is granted it should be exercised with great deal of power and caution and not used as an escape route.

If this waiver is granted to the members of WTO in the present case, it would undoubtedly fall under the "*exceptional circumstance" and* would result in members granting or enforcing patents and other intellectual property related rights to COVID-19 drugs, vaccines and other necessary treatments without any obligation for a temporary period of time. In other words, accelerating the medical supplies and making them more accessible at affordable prices to the public. It would also give legal clarity to the members state against any political pressure which they are facing which are refraining them from taking such measures.

As emphasised by India and South Africa, this would enable countries to work together and ensure that IP rights and undisclosed trade secrets do not cause barriers and hinder the process of providing timely access to medical products. The proposition of this waiver can be resultant of the following three apprehensions:

i. The presence of Intellectual Property Law and monopolistic rights which are available to the right holder thereby controlling the availability of these medical drugs, vaccines and other related items and providing them at affordable prices.

ii. Secondly, Inhibition faced by innovator in terms of developing new products.

iii. Lastly, the whole process of implementing the mechanisms under WTO, which permits the access to medicines and other medical products to other countries who are unable to manufacture domestically is a hard process. This implementation having its own hardships and demotivates the member states from research and development.[30]

A similar waiver was granted to the other developing countries and least developed countries which did not have manufacturing ability to produce medicines and drugs, thereby having low accessibility of medicines. In 2003 the general council waived the obligation mentioned under

[29] Prabhash Ranjan, "*The Case for Waiving Intellectual Property Protection for COVID-19 Vaccines",456* Observer Research Foundation, April,2021.
[30] Biswajit Dhar and K.M. Gopakumar, *"India-South Africa proposal for a waiver from certain obligations under the TRIPS Agreement",* Third World Network, December 2020, (Accessed on 14th April, 2021)

 [ISSN 2581-5369]

Article 31(f)[31] and 31(h)[32] of the TRIPS Agreement.

People who are opposing the complete waiver of the TRIPS rights, are of the belief that other flexibilities like Compulsory Licensing[33] and voluntary licensing can be used. However, sadly using these flexibilities in dealing with the global pandemic would not be the best possible decision in all nations. For example the utility of Compulsory Licensing would necessarily not be the same in all countries, developing countries, least developed countries and developed countries each will have different manufacturing abilities. It is not necessary that all countries would have the complete manpower, resources and recourse to issue compulsory licensing and manufacture the products. Secondly, it has been seen that several developing countries have pressure from developed countries not to issue such compulsory licenses. Thus in the proposal India and South Africa have contended the unfeasible practicality of Article 31 to address the present challenged of the pandemic. Since several countries lack the manufacturing ability in the pharma sector, the lengthy process of Article 31 would be tedious to follow and prevent universal inoculation of the vaccine. If several countries at the same time follow the procedure set out under the article, it would slow down the export of vaccine in countries which urgently need it. This is as a result would make the provision under TRIPS to be unfeasible in the pandemic.

In my opinion, granting a complete waiver would not end the pandemic, but would surely increase the production of vaccines systematically thus distributing them equitably. In order for this to take place several countries would have to reform their necessary provisions and laws and amend the administrative machinery. Different countries can take up different flexibilities which are available under the TRIPS agreement, in terms of compulsory licensing and voluntary licensing. If the waiver is granted, it could be granted for a period of one year and depending on the distribution as well as recovery it could be renewed if needed or maybe not.

V. WHETHER INDIA SHOULD GRANT COMPULSORY LICENSING TO MANUFACTURE MORE VACCINES AND INCREASE THE SUPPLY TO MEET THE DEMAND?

"*The Centre will not allow any state to face vaccine scarcity*" [34] - **Dr. Harsh Vardhan (Union**

[31] Issuance of Compulsory Licensing for domestic use by supplying the patented good
[32] Payment of remuneration to the patentee.
[33] Article 31 of the TRIPS Agreement.
[34] Outlook Web Bureau, "*Odisha to Maharashtra: Six States Complain of Vaccine Shortage, Centra Says 'No Scarcity Anywhere",* Outlook, 8th April, 2021, Available on: https://www.outlookindia.com/website/story/india-news-odisha-to-maharashtra-six-states-complain-of-vaccine-shortages-centre-says-no-scarcity-anywhere/379615 (Accessed on: 18th April, 2021, 12:41am)

 [ISSN 2581-5369]

Health Minister)

With the onset of the second wave of the pandemic approaching India and India entering into the third stage of vaccination drive, contrary to the statement made by the Union Health Minister, several states are facing shortage of COVID-19 vaccines. The second wave has caught us of guard and with greater inhumanity and aggressiveness. Several states have also been facing shortage of drugs such as Remdesivir, oxygen tanks as well as timely medical assistance. The *Central Drug Standards Control Organisation* has approved two vaccine candidates for use namely Covishield and Covaxin. Covishield is the vaccine which has been developed by AstraZeneca and have signed a voluntary licence with India's Serum Institute. While on the other hand Covaxin is the vaccine developed by Bharat Biotech, The Indian Council of Medical Research(Delhi) ("**ICMR**") and the National Institute of Virology (Pune) collectively. However, between the two vaccine candidates, Covaxin has concerns regarding their safety and efficacy since it was approved prior to the completion of the phase 3 clinical trial. Indian has already supplied several doses of Covishield as either gifts or grants to several countries like Sri Lanka, Seychelles, Morocco, Nepal, Maldives etc.

However looking into the present situation several states in India are complaining of shortage of vaccine doses. At least six states namely, Andhra Pradesh, Chhattisgarh, Haryana, Odisha, Telangana and Maharashtra are complaining about the shortage of vaccine amidst the second wave of the pandemic. Several citizens have been asked to go back due to the shortage of vaccines in states. In Odisha over 700 vaccination centres have to closed due to shortage of vaccines.[35]Besides shortage of vaccines, Indore has been facing shortage in supply of Remdesivir injection which has been helpful in treating patients. Haryana has been vaccinating around a lakh of people every day and has now seen a shortage in supply. Despite the mentioned states complaining of the necessary shortages, the Centre reiterates that there is no scarcity of vaccine in the country and that the Centre would not allow them to face the same.[36]

In order to fill the gap and provide ready medical access to all, compulsory licensing plays an important health tool which would help to work around concerns of insufficient supply of pharmaceutical products. The Union Government by allowing compulsory licensing would allow other pharmaceutical companies to manufacture the vaccines and use them in the country. Pharmaceutical company, Bharat Biotech can with the help of compulsory licensing, by transferring technologies to other pharmaceutical companies as well as public sector undertakings and increase the production of the vaccines. With the government investing in

[35] Id.
[36] See supra 33.

 [ISSN 2581-5369]

public sector undertakings could increase the production capacity of the vaccines. On request of the Maharashtra Chief Minister, the Central government has agreed to permit Mumbai's Haffkine Institute to manufacture Bharat Biotech's vaccine combating COVID-19 for a period of one year.[37] The Union Government can grant compulsory licensing of these vaccines in India to other manufacturers on the basis of Section 84 and 92 of the Patents Act.

One of the questions which is most frequently asked is whether the COVID-19 vaccines are patented? It has been observed that presently, there is no patent which is granted to the vaccines, however many vaccines are protected due to the underlying technology used to manufacture them. For example the underlying technology which is used behind the production of Moderna's mRNA vaccine is protected by patents and also has a specific Betaccoronavirus mRNA vaccine which is protected as well.[38] The same applies to Pfizer-Biotech's vaccine which uses lipid nanoparticle (NP) technology to give the mRNA cells.[39] Thus even though the vaccines, aren't protected by patents, the underlying technology which is used to manufacture them is protected.

The use of the system would dramatically change the political economy of COVID vaccines in India, by providing them at lower prices and in larger quantities thereby meeting the demand in India. Once the production is sufficient, each state can have their control of their set of vaccine and have specific resources accounted for its funding.[40] Pharmaceutical Industries could also take into consideration the flexibility of patent law and provide voluntary licensing to pharmaceutical companies to increase the supply of vaccines.

VI. CONCLUSION AND SUGGESTIONS

"There is a possibility that if governments don't act and take steps now, that access to medicines may be limited for the wealth few."

- **Zain Rizvi (Law and Policy Researcher)**

Compulsory Licensing as already observed and mentioned above, is a powerful tool which helps providing sufficient medical supply in the pharmaceutical industry. It also helps in

[37] Mirror Online, *"COVID-19: Centre allows Mumbai's Haffkine Institute to produce Covaxin",* Mumbai Mirror, 16th April, 2021, Available on: https://mumbaimirror.indiatimes.com/coronavirus/news/covid-19-centre-allows-mumbais-haffkine-institute-to-produce-covaxin/articleshow/82094545.cms (Accessed on: 18th April, 2021, 1:11am)

[38] Praharsh Gour, "Compulsion for Compulsory Licenses for Covid Vaccines Climbs: But Are They the cure?", Feedspot, 14th May, 2021, (Accessed on 14th May, 2021 8:18pm) available on: https://www.feedspot.com/fo/1459244/fe/4659502?hash=feed/fof_fo_1459244__f_4659502/article/7064206144?dd=7644856861217571

[39] Id.

[40] Ravi Duggal,"Political Economy of COVID-19 Vaccine shortages in India", The Leaflet, 10th April, 2021, Available at: https://www.theleaflet.in/political-economy-of-covid-19-vaccine-shortages-in-india/# (Accessed on 18th April, 1:25am)

 [ISSN 2581-5369]

providing these essential drugs at affordable reasonable prices to the public at large thereby making it easily accessible. With the rise of the on-going pandemic, compulsory licensing can be a saving grace by helping with increasing the supply of the vaccines across the nation. It is pertinent that Governments take the necessary steps to fight the pandemic and ensure their citizens are safe. The aim of this system is to balance the rights for the public good as well as protect the rights of the patentee in question. Several countries have started to publicly consider and introduce legal frameworks for compulsory licensing in present times. Israel has issued compulsory licensing with India to procure imports of the generic drug, "*lopinavir*" which they claim to be a possible treatment for the virus.

It would be helpful if governments of all nations take necessary steps in terms of amending their legal frameworks and including provisions regarding compulsory licensing and authorising the same. It has been seen that since the onset of the pandemic, several countries like France, Canada and Germany have laid down the legal regime governing compulsory licensing and countries like Chile and Ecudor have initiated proceedings. Canada has amended the laws and ensured speedier process for obtaining compulsory licensing on public health grounds and also allowed negotiations with respect to the remuneration payable to the patentee. Chile has specifically permitted grant of compulsory licence for COVID-19 related technology or drugs. Ecudor has also passed a resolution thereby permitting easily accessible drugs, vaccines, diagnostic as well as treatment technology at affordable reasonable prices to its citizens.

Several times it has been seen that the issuance of compulsory vaccine have led to patentee's being dismayed and this may restrict the innovation. The proposed waiver which was introduced at the WTO by India and South Africa may be broader than necessary. A better solution could be compulsory licensing however, if countries aren't willing to introduce new legislation for the same, to counter the system of compulsory licensing other *alternatives* can be considered for the pharmaceutical industry.

i. The government can either formulate an international collective rights organization or an international panel of neutral individuals. This body will review national decisions and ensure that the needs of pharmaceutical sector are met and so are necessary medical assistance provided to individuals at affordable reasonable prices. The body being constituted by neutral individuals will permit members to determine the situation judiciously and come up with an appropriate answer.

 [ISSN 2581-5369]

ii. Government can increase the funding and invest more money in the research and development of healthcare. This could be done by funding research laboratories and making countries self-sufficient. By increasing expenditure in the healthcare sector, the government can provide insurance to a larger number of people thereby providing them with more access to medical products at reasonable affordable prices.

iii. Countries should encourage negotiation in terms of pricing of patented drugs according to the economy of the country, this thus helps patent holder to earn profits irrespective of developed or developing country they deal with.

iv. Providing patent holders with incentives like tax benefits would encourage them to do more business. Patent holders could be encouraged to voluntarily donate medicine to developing and least developed countries thus providing medical access to all.

v. There is a possibility when the government can purchase a necessary lifesaving drugs from the pharmaceutical company or patent holder and thereafter license it at lower prices to their domestic local drug company thereby making it easily accessible to the public at reasonable affordable prices.

The following steps can also be taken to amend and support the provisions referring to compulsory licensing in India under the Patents Act, 1970:

i. To introduce the concept of Corporate Social Responsibility ("**CSR"**) for pharmaceutical companies. The combined efforts of the government as well as pharma companies would help in building a healthcare fund which can be used to provide medicines as well as reduce chance of patent infringement.

ii. The Indian Government should encourage process patent rather than product patent. Product patent ends up creating monopolies in the market leading to drugs being sold at unaffordable high prices. Product patent has often seen to be violating various human rights, since the patented products aren't being accessible for the benefit of public health.

iii. Bayhe-Dole Act, which provides protection to patents through government funding should be introduced in India. This would ease the process of the government granting compulsory licenses on inventions.

iv. Research and development is the backbone of compulsory licensing. It is important that the Government should firstly invest huge funds in research and development and also rightly compensate patent holders. This would encourage patentee's to come up with new innovations at reasonable affordable prices.

 [ISSN 2581-5369]

v. The government can initiate price control or negotiation mechanisms with pharmaceutical companies and allow easy availability of innovations.

vi. In order to reduce the ambiguity and common concerns of pharmaceutical companies, the Government of India can introduce a set of guidelines addressing the interpretation and practical application of compulsory licensing.

vii. The government can issue guidelines, whereby depending on the circumstances and urgency of the necessary pharmaceutical product, different method of royalty can be used. Be it low royalty or royalty free arrangements.

In order to overcome the shortage of vaccines and drugs the following suggestions can be implemented to fasten the process:

i. The government can issue a notification under Section 92(1) of the Patents Act, permitting interested parties to apply to the controller for such licensing of the vaccines. If the government is not permitted to grant patents on the basis of no patent being registered for the vaccines, then they could petition Section 100 of the Patents Act, to authorize any person to manufacture these vaccines for the benefit of the government. With the help of this the government could permit the use of the technology to manufacture the vaccines and the vaccine not being registered wouldn't be a problem.

ii. The government could formulate a scientific formula which helps in the disbursement of vaccine thereby using the monopoly control present over vaccine in an advantageous manner. The formula would aim to have monopoly control over vaccine purchase and supply and weighing in the prevalence of cases and population thereby ensuring the amount each state would be allotted reasonable number vaccines.

iii. The government can set up bilateral agreement with those countries which have the production capacity and ability to produce mass production of the vaccines.

iv. Countries can formulate vaccine blocks, which would negotiate the pricing of the vaccines and supply them to other countries as well.

v. Encourage the possibility having voluntary licensing which could increase the supply of vaccines.

 [ISSN 2581-5369]

VII. BIBLIOGRAPHY

Books

1. P. Narayanan, "Intellectual Property Law", Third Edition published by Eastern Law House, 67-70.

Bare Acts:

1. Indian Patents Act, 1970

Research Papers:

2. Anna Niesporek, "Compulsory Licensing of Pharmaceutical Products and Access to Essential Medicines in Developing Countries", Available on: https://www.diva-portal.org/smash/get/diva2:21332/FULLTEXT01.pdf
3. Kiran Kumari and Ajay Sharma, "*Doha Declaration: Compulsory Licensing and Access to Drugs", 3(2)*Amity Journal of Healthcare Management, 43-54, (2018) Available on: https://amity.edu/UserFiles/admaa/88a06Paper%204.pdf
4. Prabhash Ranjan, "The Case for Waiving Intellectual Property Protection for COVID-19 Vaccines", 456 Observer Research Foundation, (April 2021) Available on: https://www.orfonline.org/research/the-case-for-waiving-intellectual-property-protection-for-covid-19-vaccines/
5. Biswajit Dhar and K.M. Gopakumar, "India-South Africa proposal for a waiver from certain obligations under the TRIPS Agreement", Third World Network (2020)
6. Amanpreet Kaur and Rekha Chaturvedi, "Compulsory Licensing of Drugs and Pharmaceuticals: Issues and Dilemnma", 20 Journal of Intellectual Property Rights, 279-287, (2015)
7. Hilary Wong, "The Case for Compulsory Licensing during COVID-19", 10 Viewpoints, University of California, Berkeley, School of Law (June 2020)

Online links:

1. https://thewire.in/health/india-fast-tracks-emergency-approvals-for-foreign-produced-covid-19-vaccines
2. https://www.downtoearth.org.in/news/health/covid-19-vaccines-waiting-for-advantage-india-76543
3. https://www.downtoearth.org.in/blog/health/the-global-approach-to-vaccine-equity-is-failing-additional-steps-that-would-help-76509

 [ISSN 2581-5369]

4. https://www.news18.com/news/opinion/right-to-equitable-access-to-covid-19-vaccination-if-not-now-then-when-3636485.html
5. https://www.theleaflet.in/political-economy-of-covid-19-vaccine-shortages-in-india/#
6. https://thewire.in/health/india-patent-law-compulsory-licenses-covid-19-vaccines
7. https://www.arabnews.com/node/1840896/world
8. https://www.livemint.com/Companies/fWcUdihmEP66hZZoXgxctO/Big-pharma-firms-may-learn-to-live-with-compulsory-licensing.html
9. https://www.devex.com/news/covid-19-countries-race-to-strengthen-compulsory-licensing-legislation-97595
10. https://www.arabnews.com/node/1840896/world
11. https://thewire.in/health/india-patent-law-compulsory-licenses-covid-19-vaccines
12. https://www.theleaflet.in/political-economy-of-covid-19-vaccine-shortages-in-india/#
13. https://www.fiercepharma.com/manufacturing/india-axes-exports-gilead-sciences-remdesivir-plots-boost-to-local-production-as
14. https://www.news18.com/news/opinion/right-to-equitable-access-to-covid-19-vaccination-if-not-now-then-when-3636485.html
15. https://blog.ipleaders.in/compulsory-licensing-pharmaceutical-industry-threat-necessity/
16. https://www.lexology.com/library/detail.aspx?g=c74e553c-4659-49cf-b133-f6da0543a002
17. https://www.mondaq.com/india/patent/772644/compulsory-licensing-in-india

*****

 [ISSN 2581-5369]