Jus Corpus Law Journal
Open Access Law Journal – Copyright © 2022 – ISSN 2582-7820
Editor-in-Chief – Prof. (Dr.) Rhishikesh Dave; Publisher – Ayush Pandey

Compulsory Licensing in India Vis-À-Vis Pharmaceutical Industry in the Covid-19

Shivendra Nath Mishra[a] Shrey Shalin[b]

[a]Chanakya National Law University, Patna, India [b]Chanakya National Law University, Patna, India

Received 01 July 2022; *Accepted* 22 July 2022; *Published* 25 July 2022

Compulsory licenses are contracts between a willing buyer and an unwilling seller that are imposed or enforced by the government. A compulsory license is a legal tool intended to compel intellectual property owners to license out their statutorily granted rights to interested third parties who are capable of producing the patented product at a lower cost than the intellectual property owner. Intellectual property rights have been expanded in recent years, and businesses have been active in their patent filings, leading to the current state of affairs, in which essential and necessary goods for human use are monopolized by corporations. The award of intellectual property rights has, on the whole, fostered and aided innovation, but the grant of monopoly rights has, on the other hand, proven to be counterproductive in that it has slowed the development of competition in certain instances. A great deal of attention has been drawn to India's first compulsory licensing ruling in favor of Natco Pharma from across the world. A solution for misuse of exclusive rights protected by the intellectual property has been proposed by compulsory licensing. The paper will be discussing on how the compulsory licensing doctrine evolved and its use in the pharmaceutical industry. This paper will also talk about a few leading cases in the industry and then provide a crisp analysis of the use of compulsory licenses during the COVID time period.

Keywords: *compulsory licensing, pharma, intellectual property, patent, monopolization.*

INTRODUCTION

Intellectual property is the intangible result of a person's efforts in the intellect.“ Intellectual property refers to a big term that alludes to an organization's or an individual's assortment of intangible assets that are legitimately ensured against unapproved use or application. A non-physical resource that a business has is known as an intangible asset.”[1] There are four types of intellectual property protection recognised in developed countries, including copyright, trademark, trade secret, and patent.[2] There is no exclusivity to these methods, and given the right conditions, one may acquire several types of methods of protection for the same parcel of intellectual property. Personal property has many characteristics of intellectual property. As a result, it may be acquired, assigned, licence pledged, or transferred in the same way that other types of personal property can be transferred.[3]

The term Patent refers to a monopoly right over an invention that has been granted by a court of law. There are certain innovations that are not patentable, and it is not necessary to safeguard inventions exclusively via patent protection. Intellectual property rights in the end product that emerges from innovation may be protected by various types of intellectual property rights. In simple words, In order to safeguard the subject matter under consideration for protection, the patent office grants an inventor a legal document known as a patent. For the uninitiated, a patent is a legally protected exclusive right allowed by the government to an innovator to disallow others from utilizing the invention without his permission. A patent is essentially a grant of protection for innovation. A patent, on the other hand, will only be issued if and only if the invention meets the criteria of patentability. These criteria of patentability are ubiquitous, with only minor variations in the manner in which they are interpreted.

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[1] Will Kenton, ‘Intellectual Property’ (*Investopedia*, 13 July 2020) <https://www.investopedia.com/terms/i/intellectualproperty.asp> accessed 25 June 2022

[2] ‘Intellectual Property : Protection and Enforcement’ (*WTO*) <https://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm> accessed 25 June 2022

[3] Suchita Ambadipudi & Sheetal Srikanth, ‘India: Transfer Of Intellectual Property - A Primer’ (*Mondaq*, 6 July 2020) <https://www.mondaq.com/india/trademark/961790/transfer-of-intellectual-property--a-primer> accessed 25 June 2022

The inventor is needed to ensure that the invention has one or more components that are novel for the innovation to qualify for patenting; otherwise, the invention will not be eligible for patenting. In addition to being new, the innovation must be non-obvious to the public. This means that anybody with expertise in the area of innovation should not find the invention to be simple and apparent to implement. The process/embodiments of an invention must have a commercial market in order to be classified as utility models; otherwise, they would be deemed ineligible. Patentability is determined by whether the new and non-obvious invention has some industrial use. If so, the invention qualifies for patentability and therefore meets the criteria of patentability.

An invention is deemed new in case it isn't known to general society in any structure, for example oral, written, or some other structure, till the time of submitting the application. Anything that has been previously acknowledged in the public domain is not considered innovative. The patent has a duration of 20 years, which begins on the day the patent application is filed. It can be utilized in the country where it has been conceded only. As a result, any legal activity for encroachment or infringement of patent rights may just be acquired in that country. Each nation must file for a patent in order to receive patent protection in other countries. The Patent Cooperation Treaty (PCT) offers a strategy for filing a global patent application wherein a patent may be submitted in a large number of nations using a single patent application. The PCT of a patent, on the other hand, is at the discretion of the specific patent office solely after the application is submitted.

Indian Patent Act, 1970 governs the patent regime in India. A patent may be acquired under Indian patent law only for a novel and beneficial invention.[4] The innovation must be related to a manufacturer's machine, item, substance, or method of manufacturing an article. A person may even get a patent for the invention of any item or any manufacturing method. During the production of medicine or drugs, as well as certain types of chemicals, any patent is not given for the substance itself, regardless of whether it is novel, yet the production method, as well as the substance, can have the patent. The application for a patent should be genuine, and the

[4] Indian Patent Act, 1970

right to apply for a patent should be assignable to the first creator or the individual who has gained the title from him.

Some innovations are not patentable, which include techniques of medical treatment or diagnosis, as well as novel plant or animal types. Patents are not conceded for inventions whose utilization would be in opposition to public order or profound quality (clear models incorporate explosive traps or letter bombs). Coming up next are not viewed as inventions: discoveries, innovations, scientific hypotheses, and numerical strategies, aesthetic manifestations, for example, art or writing works or craft of writing, schemes, rules, and techniques for doing mental arithmetic. The most essential factor to evaluate is whether the invention relates to the patentable topic. The non-patentable topic is included in *Sections 3 and 4*[5] *of the Indian Patents Act, 1970*. Unless the Invention falls under any of the provisions of the above sections, it is a patentable subject. 'Innovation' is an essential factor in assessing an invention's patentability. An oddity or innovation is characterized in Section 2(l)[6] of the Indian Patents Act,1970 as "*no innovation or technique published in any document before the date of filing of a patent application, wherever in the nation or the globe. The whole specification, that is, the subject matter has not entered the public domain or is not state of the art*."

A step that is inventive is characterized as "*the characteristic of an invention that involves technological advancement or is of economic importance or both, as compared to existing knowledge, and invention not obvious to a person skilled in the art*" under Section 2(ja)[7] of Indian Patents Act,1970. This implies that the invention ought not to be evident to an individual qualified in the same field where the creation is concerned. It ought not to be creative or apparent to someone with experience in the same area.

Section 2 (ac)[8] *Indian Patents Act, 1970* of the Patents Act defines industrial application as "the invention is capable of being produced or utilised in an industry." This infers that Invention can't exist in the theoretical. It should be applied in any industry, which infers it should have pragmatic worth as far as the patent.

[5] Indian Patent Act, 1970, ss 3 and 4
[6] Indian Patent Act, 1970, s 2(1)
[7] Indian Patent Act, 1970, s 2(ja)
[8] Indian Patent Act, 1970, s 2(ac)

These are a portion of the legal prerequisites for getting a patent for any invention in India. Besides, the publication of an able patent is an essential basis for getting a patent. A skilled patent exposure infers that a patent draught specification appropriately unveils the Invention to such an extent that an individual educated in the same region as the Invention might do the Invention without excessive exertion.

There are many benefits of getting patents like Patents conferring "exclusive right" on the inventor, allowing him/her to prevent others from making or utilising the innovation. This is especially true for the first 20 years after the date of submitting the patent application. Having acquired the exclusive right to the innovation, the inventor may use this right by prohibiting others from commercially exploiting the patented invention, thereby limiting competition and allowing the inventor to establish a position in the commercial market. After devoting a significant amount of time and money to the development of the idea, the inventor may be able to bring the innovation to market under the protection of exclusive rights, resulting in greater returns on his or her investment. Of course, the economic usefulness of the invention will determine whether or not this is the case. As a result, before investing in a patent, the inventor must determine whether or not the invention will be commercially successful. Also, Business partners, investors, and shareholders may consider the patent portfolios to be proof of their capabilities.[9]

COMPULSORY LICENCES

Compulsory licensing is an exception to the ordinary rule of a patent owner enjoying the exclusive right over the patented product.[10] It is a process through which a government issues a licence or authorises a third party to use the rights of the patent without requiring permission from the patent owner. The object of compulsory licensing is to help industrial progress and to exploit the resources to the fullest.

Imagine a case where a patent has been obtained by company A over a product for 20 years and it has restricted its usage to only a few members of the society possibly due to superficial

[9] *Ibid*

[10] 'Compulsory Licensing of Pharmaceuticals and TRIPS' (*WTO*) <https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm> accessed 25 June 2022

pricing or let's say its research is not apt to reach the maximum potential it could have and the company is also not eager to do anything further. The basics of Patent Law say that companies B, C, and others cannot make use of or exploit the said patented product and research. This could hamper the scientific, industrial, research, and technical progress of the society, and therefore the role of the Bolar exception and compulsory licensing becomes a must to have. It is helpful in preventing the abuse of patents by the patent holder.

These rules have elaborately been laid down in the Indian Patents Act, 1970 in Chapter XVI wherein pre-requisite conditions from Section 82 to 92[11] need to be fulfilled. Compulsory Licences have the purpose of ensuring that the patented invention works on a commercial scale in the Indian Territory without undue delay and to the fullest extent. It also seeks to ensure that the right of any person working or developing an invention under the safeguard of Patents Law is not prejudiced.[12] Section 84(1)[13] of the act talks about compulsory licences. It lays down that after the expiry of three years from the day on which the patent was granted. Any person interested (including non-patent holder individuals or an organization) can make an application to the controller for a grant of compulsory licence in case any of the following conditions are fulfilled.

- that the reasonable requirements of the public with respect to the patented invention have not been satisfied, or
- that the patented invention is not available to the public at a reasonably affordable price, or
- that the patented invention is not worked in the territory of India.

This provision is established to ensure that the public at large benefitted from the patented product or the new invention, it is available at affordable or reasonable prices and it works where it has been patented. This becomes very important in the case of the pharmaceutical industry. In a study by Tufts University - it was estimated that around 2.6 billion USD is spent on producing a new drug. The sample was taken for 106 randomly selected drugs taken from

[11] Indian Patent Act, 1970, ss 82-92
[12] Indian Patent Act, 1970, s 89
[13] Indian Patent Act, 1970, s 84(1)

10 pharmaceutical companies. In one way the research is to be valued and the pharmaceutical companies need to be incentivised to innovate more but on the other hand, the welfare of the public at large also needs to be taken care of. This topic is one of the most debatable ones in the compulsory license.

Imagine a case where Company X has spent let's say 2 Billion USD in creating a new Drug C to combat highly infectious diseases. This drug is available for 700$ per month. It can be argued that it is affordable to the people in the US[14] but through PCT Company X has obtained a patent in India as well and the government is not imposing any taxes. The company charges for delivery and a few expenses. The expense finally comes in India to be around 55,000 Rs a month. This by standards of a developing country is hardly affordable.[15] Now there will be a drastic change in income to expenditure ratio for this drug if the drug is made available to any of the undeveloped nations.[16]

So, going through Ethical and Moral norms one can argue compulsory license is the need of the hour to allow local manufacturers to exploit the research and make this drug available at a cheap rate for domestic market consumption. On the other hand - if the government of a state gives a free voluntary license to every applicant who steps in to file an application. Why will Company X spend such a hefty amount of resources on Research? The incentive to do research will surely vanish. The cause of Humanity and Incentive for development needs to be balanced through patent laws and it has been a major challenge for International Organisations, National legislatures as well as judicial and Quasi-Judicial bodies.

The stand taken by the International Organization seems to be a rational one. It agreed to make an exception for the pharmaceutical industries and the relevant provisions were present in TRIPS ever since it's coming into existence in January 1995. Several countries have included the subject pertaining to compulsory license in their IPR Laws. In the Indian context, the

[14] 'GDP (per capita current US $) – United States' (*The World Bank*) <https://data.worldbank.org/indicator/NY.GDP.PCAP.CD?locations=US> accessed 17 June 2022
[15] 'GDP (per capita current US $) India' (*The World Bank*) <https://data.worldbank.org/indicator/NY.GDP.PCAP.CD?locations=IN> accessed 17 June 2022
[16] 'GDP (per capita current US $) Uganda' (*The World Bank*) <https://data.worldbank.org/indicator/NY.GDP.PCAP.CD?locations=UG> accessed 17 June 2022

controller has the ultimate discretion to grant a compulsory license to the applicant[17] in case reasonable requirements of the public with respect to the patent have not been met or it has not worked in the territory of India or it is not available at affordable price.[18] Although safeguarding procedures for the patentee are also present which requires a controller to - upon prima facie satisfaction from the application direct the applicant to serve the copies of the application upon the patentee and any other person who seems to be interested and shall publish the application in the official journal.[19] The patentee and any other party interested are given a chance to give a notice of opposition[20] along with a statement of grounds on which the application is opposed.[21] The controller is then required to notify the applicant and hear and decide the case.[22]

The controller apart from ordering a compulsory license also has the power to order an existing license to be cancelled or get the existing license to be amended.[23] The terms and conditions for granting such compulsory license could be set by the Controller whereby a third party could be asked to pay reasonable royalty and other remuneration.[24] It is to be ensured by the applicant to whom the license has been granted that the patented invention is working to the fullest extent[25] and available at a reasonable price.[26] The granted compulsory license can also be cancelled after an application has been moved by the patentee that the reason which gave rise to the grant of license does no longer exist.[27]

Section 92A talks of the grant of a compulsory license for the export of pharmaceuticals in exceptional circumstances. It authorises the central government to grant a compulsory license

[17] Patents Act, 1970, s 88(1)
[18] Patents Act, 1970, s 84(4)
[19] Patents Act, 1970, s 87(1)
[20] Patents Act, 1970, s 87(2)
[21] Patents Act, 1970, s 87(3)
[22] Patents Act, 1970, s 87(4)
[23] Patents Act, 1970, s 88(2)
[24] Patents Act, 1970, s 90(1)
[25] Patents Act, 1970, s 90(2)
[26] Patents Act, 1970, s 90(3)
[27] Patents Act, 1970, s 84(1)

to manufacture and export patented pharmaceutical products to any country which has inadequacy or is incapable to meet its demand.[28]

On the face of it, as it may seem, it shall be done for the benefit of humanity but another question arises. Is it ethical or isn't the government taking too much control and not respecting the rights of the patent holder? This dilemma to say the least has now been exciting for decades and there seems no hard and fast rule to decide. The Indian government as per the provision can help the countries which are suffering from manufacturing inadequacy It can help promote friendly relations between the states and keep the spirits of humanity alive.

LANDMARK CASES RELATING TO COMPULSORY LICENCES

Bayer Corporation v Natco Pharma Ltd.[29]

On 09th of March 2012, Natco became the first ever company in Indian history to be granted a compulsory license. Bayer is an American subsidiary of German MNC Bayer AG specialising in the chemical and pharmaceutical Industry. In 1990 it developed a drug named SorafenibTosylate which was given the brand name Nexavar in 2005. It was used to treat patients with stage 4 cancer. It was patented in India in March 2008. It then started importing and selling the drug in India and per month cost came to be around Rs 2.8 lakhs per month. Natco had approached Bayer to grant a voluntary licence which was denied by Bayer. In July 2011 - Natco applied for a compulsory license under Section 84(1) of the Patents Act which got granted in March 2012. Bayer filed an appeal to IPAB (Intellectual Property Appellate Board) in Bombay High Court which was rejected on the basis of Article 21 of the Indian Constitution taking societal and health considerations into a point. Following the trial, Natcco made available the drug at around Rs 8800 per month. 6% of the net selling price and later 7% was decided to be paid by Natco to Bayer.

The Issues were as follows with reference to Section 84(1)(a), (b), (c) of the Patents Act as to if

[28]Patents Act, 1970, s 92A(1)

[29] Bayer Corporation v Natco Pharma Ltd., Order No. 45/2013 (Intellectual Property Appellate Board, Chennai), available at http://www.ipab.tn.nic.in/045-2013.htm (Last visited Aug. 17, 2021)

1. ***Whether a reasonable requirement to the public with regards to Nexavar was provided by Bayer?***

As per the data provided by Natco - Nexavar imports in India were able to meet only 2% of the needs. Bayer had no argument as to why it did not manufacture/ import the required number of drugs in preceding years. Therefore, it was observed that Bayer had failed to meet the reasonable requirements of the public.

2. ***Whether Nexavar was available at a reasonable and affordable price to the public?***

Reasonable and Affordable prices would depend from case to case as to what was the expenses in R&D and if the patients are able to afford the drug. Bayer argued that a lot of expenditure was incurred during R&D and generic manufacturers had merely replicated the original drug. Bayer argued that it had a Patient Assistance Program (PAP) and tie-ups for Insurance with companies. Natco claimed that the price was a huge barrier for patients to afford the drug. Bayer also could not prove the accurate cost of developing the drug and presented merely general figures and the price of the product need not be decided in such a way that the entire R&D cost is recovered from the Indian Market and while providing for PAP it was observed that Bayer had itself accepted the unaffordability of the drug.

3. ***Whether Nexavar had worked in the territory of India?***

The term "worked in the territory of India" has nowhere been defined. Bayer claimed that the R&D costs were very high and global demands were low. So, it was feasible for them to manufacture the product from one unit in Germany due to Infrastructural advances and supplies in the global market. Natco claimed that the term should mean the product to be manufactured in India. IPAB held that this matter was to be decided on a case to case basis and despite[30] Section 84(1) for grant of a compulsory requires fulfillment of one condition whereas the Bayer Corporation had failed in all of the conditions provided and therefore the grant was justified.

[30] Zealsah, 'Case Analysis and Aftermath of Natco Pharma ltd. vs Bayer Corporation' (*Legal Service India*) <https://www.legalserviceindia.com/legal/article-5286-case-analysis-and-aftermath-of-natco-pharma-ltd-v-s-bayer-corporation.html> accessed 25 June 2022

The pharmaceutical industry is filled with such debates as to balance the needs of the patient and respect the rights of the patent. However, it is not always that a compulsory license is granted. In the case of ***BDR Pharmaceuticals International Pvt Ltd v Bristol-Myers Squibb Co.***[31] where an application was made to grant a patent for Bristol-Myers Squibb cancer drug (SPRYCEL). It was held that the applicant has not made efforts to procure a license from the patent holder and also had no ability to work with the patent to public advantage. Therefore, It failed to make a prima facie case for a compulsory license to be granted. Hence, Its application was rejected.

In another case ***Lee Pharma v Astra Zeneca AB***[32] - The applicant contended that the patent holder has failed to meet all the requirements present in Section (84)(1)(a), (b), (c). However, Applicant failed to establish what was a reasonable requirement of the public. It was also observed that the price of related drugs was in the same price range and therefore the claim that it was unaffordable stood to be unjustified. The applicant also failed to demonstrate how many patients were unable to procure the drug due to unavailability. Hence, the application was rejected. Conscious effort to safeguard the rights of the patent holders is duly made in every case but when case the patent holder clearly abuses the available patent right and threatens to jeopardize the national economy and its people available in the country. Grant of compulsory license stands to be justified.[33]

GLOBAL PERSPECTIVE

The United States has something similar to a compulsory license for its medicines and vaccines which is known as March-in-rights. It can be granted by the U.S. government provided that the development of the invention was funded by federal funds and the invention has not met requisite requirements like meeting practical application, reasonably satisfying health and safety needs of the country, reasonably meeting requirements for public use specified by federal norms, etc.

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[31] *Bristol-Myers Squibb Holdings Ireland Unlimited Company v BDR Pharmaceuticals International Pvt. Ltd.,* (2020) SCC OnLine Del 1700

[32] *Lee Pharma v AstraZeneca* [2015] AB C.L.A. No. 1 OF 2015

[33] PHD Rangappa, 'Dealing with compulsory licensing in India' (*IAM,* 19 December 2019) <https://www.iam-media.com/dealing-compulsory-licensing-india> accessed 25 June 2022

It may seem to be powerful but till date, no federal agency has ever exercised March-in-rights. In the context of **Australia –** A person who wishes to exploit a patented invention may apply to the federal court to grant the application a license. This application can be made only after 3 years have elapsed since the patent was granted. Till Date, 3 such application has been made and it is noteworthy that no application has ever been granted till date. Under Section 133 of the Patents Act, The Federal Court has discretionary powers to grant a compulsory license. However reasonable prerequisites similar to India have also been provided like demand in Australia not being met on original terms, authorisation to exploit the original invention is essential to meet the demand. Thus, it can be observed that developed countries have similar provisions present with respect to Compulsory Licensing which till now has almost not been exploited but when it comes to under-developed or developing countries. The reasons to grant such a license do look obvious due to low infrastructure in those reasons coupled with less per capita income.

COMPULSORY LICENSING IN THE TIME OF COVID-19

The unprecedented time that the human race is experiencing as a result of Covid -19 has put the world's current systems to the test. One such system is the patent-based system of forced licencing for medicines. Patents are described as an exclusive right given for an invention, which may be a product or a process that introduces a novel method of performing an action or a novel technological solution to a problem. It is a monopoly privilege given to protect the patent holder's hard work and to foster innovation. Compulsory licencing, on the other hand, occurs when a government permits a third party to use a protected product or method without the permission of the patent holder under certain situations.

Numerous nations have previously discussed compulsory licencing in public as part of their COVID-19 reaction. “Israel granted a compulsory licence to import generic versions of lopinavir/ritonavir (AbbVie's Kaletra) on March 24, 2020. According to the Israeli Ministry of Health, antiretroviral medication may be a viable therapy option for COVID-19 patients. In contrast to Thailand and Brazil, Israel declined to grant the licence owing to the drug's high price. Rather than that, Israel granted the obligatory licence and relied on generic alternatives

from India due to AbbVie's inability to provide adequate lopinavir/ritonavir. In view of the present epidemic, AbbVie has stated that it would not enforce its patent."[34]To employ compulsory licencing for COVID-19-related objectives, a country's domestic laws must include processes for such government action. Numerous nations have already enacted legislation to guarantee that their governments may quickly issue compulsory licences in response to COVID-19.

Last year Canada and Chile established the legislative framework for the issue of compulsory licences to address COVID-19. The COVID-19 Emergency Response Act of Canada modified the Canadian Patent Act to facilitate the issuance of forced licences on public health grounds.[35] The amendment enables the government to grant a licence for essential inventions and then negotiate compensation. Chile's Chamber of Deputies (lower house of Congress) has approved the use of compulsory licencing to prevent and treat COVID-19. The resolution specifically states that the coronavirus pandemic is adequate grounds for granting compulsory licences for COVID-19-related technology

As a positive solution, opponents of the waiver have suggested compulsory licencing be implemented in order to address all of the issues associated with the production, procurement, and distribution of COVID-19 vaccines, medicines, and medical equipment. Rather than completely abolishing the rights of pharmaceutical companies, it is proposed that the rights be temporarily shared in order to fulfill the present worldwide needs for medicinal products. Moreover, it appears to be a win-win situation for all parties involved because Stakeholders' interests are protected through the preservation of rights that they have invested a significant amount of money and effort in, whereas public health is protected through the increased production and supply of necessary vaccines, among other things, as a result of allowing other parties to participate in the supply and production chain.

While protecting the public's health and safety is of the greatest importance at the time, it has become necessary to protect the interests of the pharmaceutical industry as well. The Covid-19 vaccines, as well as the mutations, are now being researched on a continual basis. It may be

[34] Hilary Wong, 'The case for compulsory licensing during COVID-19' (2020) 10 (1) JOGH (2020)
[35] *Ibid*

necessary to change vaccine formulations in order to improve effectiveness in the future, depending on potential future alterations. All of this necessitates significant expenditures in research and development. Taking away the advantages from the people who are doing the study has a significant impact on how they decide to continue with the ongoing research.

However, when implemented as a tool, compulsory licencing, although seeming to be the perfect notion on paper, has its own set of problems. In the absence of a generic manufacturer prepared to manufacture significant quantities of generics, issuing compulsory licences would be impractical for the government. Such a manufacturer must be technologically capable of producing cost-effective alternatives in a short period of time. If the manufacturer is unable to fulfil the criteria in a timely manner, the obligatory licence will be forfeited by the government. The majority of developing nations, as well as the least developed countries that support the waiver, lack the required expertise and technical know-how to begin producing vaccines and other medicines.

It is important to note that India is not the only nation requesting a waiver of this kind. The constant arguments that India can resort to the acquisition of patent rights or issuing compulsory licencing, while logical in theory, are not necessarily practical in practice, given the waiver's support by more than 120 countries, many of which lack the infrastructure to set up production units if compulsory licencing is implemented in the real world. Another disadvantage of this type of licencing is the inability to safeguard trade secrets. "*In accordance with Article 39 of the TRIPS agreements, members are obliged to protect trade secrets against unfair commercial exploitation*."[36] The proponents also claim that the procedure of forced licencing is time-consuming and complex.

Compulsory licencing is despised by the industrialised nations, which were the majority of those who originally opposed the waiver. In reality, several nations that were formerly strong opponents of compulsory licencing have now changed their positions and have turned to compulsory licencing to meet the contemporary requirements of their citizens. Other domestic

[36] Satakshee Patnaik, *Compulsory Licensing And COVID-19*' (*Mondaq,* 8 July 2021) <https://www.mondaq.com/india/trade-secrets/1089094/compulsory-licensing-and-covid-19-the-good-the-bad-and-the-ugly> accessed 25 June 2022

legislative initiatives have been implemented to achieve the same results. In the end, it comes down to the choice between voluntary/compulsory licencing and complete surrender of intellectual property rights (albeit temporarily). Those who are opposed to the waiver argue that the already-existing licencing requirements are a preferable alternative to the waiver. While supporters of the waiver have concerns about licencing, these objections seem to be well-founded at this point in the game's development. First and foremost, not all countries have the ability to ramp up production in order to satisfy demand, should licences be granted. In the meanwhile, it is still unclear how the members will come to an agreement, or even if they will get to an agreement at all.

Decisions taken by the World Trade Organization (WTO) are nearly usually unanimous. A TRIPS waiver would require a ¾ vote in order to be granted.[37] Furthermore, although the rationale behind the coalition's decision to waive off intellectual property rights is understandable and welcomed, the issue of whether such a decision will be successful still remains. A waiver of intellectual property rights would enable generic manufacturers to acquire proprietary technology and know-how in order to develop more affordable vaccines and medicines in order to satisfy the soaring demand as quickly as feasible. However, it would undoubtedly discourage large pharmaceutical companies from investing in future research and development since they would be concerned about a similar result. As an alternative, the companies may attempt to recoup such losses by adjusting the prices of other non-covid medicines and equipment. Setting aside the motion for a waiver would protect the interests of a small number of major companies, but it would have a negative impact on the general public. Any choice would be a double-edged sword, regardless of the circumstances.

CONCLUSION

The question as to if there shall be a provision for compulsory license still persists. At one point there is a huge risk involved in R&D due to the fact that nobody can be sure of developing a medicine that will work for sure. A million of dollars get wasted in failed tests and development processes and then there is competition in development. Another company

[37] Thomas J. Dillon Jr., 'The World Trade Organization: A New Legal Order for World Trade?' (1995) 16 (2) MJIL, 371,350-398

wanted to develop a product earlier and get it patented. Adding one more point to this is that even after obtaining a patent – Government can still grant compulsory licenses if it finds reasonable cause. Obtaining the investment back in such a scenario becomes a difficult task for companies. It could also not be ignored that any company shall not be allowed to play with the health sector and therefore, a reasonable check to the protection is also a must. As already highlighted in the case laws.

The Patents Office in India has been selective in granting compulsory licenses. During the COVID times, Government can incentivize the companies openly coming for voluntary licensing and the companies who have worked hard in R&D of the lifesaving drugs. Compulsory licencing may not be required in the long run. After a few years, the remedy for COVID-19 may turn out to be an already-approved medication that has lost its patent protection. Even if the found treatment is patent-protected, medication donations and discounts may be available, or the patent owners may provide cheap voluntary licencing. Compulsory licensing shall be the last resort to be taken by any country and If at all ta country finds out compulsory licensing to be the only hope. The relevant legal measure shall be taken by the country as soon as possible. A patent shall not become a reason for lives to perish and safeguarding humanity shall be the highest purpose.