Volume 12, September 2020 ISSN 2581-5504

"Analysis of Issues Arising in Patent Law out of Covid-19: Indian and Global Perspective[1]"

Honey Verma
Amity Law School
Amity University, Rajasthan

****Vineet Verma***
Aishwarya College
Jodhpur, Rajasthan

Abstract

In the current COVID-19 climate, many researchers and pharmaceutical companies are rushing to find both treatment and vaccines. COVID-19 (SARS-CoV-2) is a new type of coronavirus related to the Severe Acute Respiratory Syndrome (SARS) coronavirus (SARS-CoV) and the Middle East Respiratory Syndrome (MERS) coronavirus (MERS-CoV). According to the BIO SmartBrief article of April 13, 2020, there are over 160 drug and vaccine candidates that are currently being pursued at various stages of development. Patent laws become the subject of discussion primarily with respect to a possible vaccine or a drug. A vaccine/drug is the one stop solution to unlock the misery of the pandemic, to save countless lives, and to benefit the humankind. However, the same is a farfetched fruit. Countries, their pharmaceutical companies, the labs, the scientists are actively working to achieve this milestone. Such a vaccine or drug will be beneficial resource for the benefit of the entire human race. The core question comes down to how the availability of the same can be ensured. Taking this research paper as a medium, the Authors will be explaining the arising issues in Patent law out of COVID-19 both the Indian and Global perspective.

Key-Words: Covid-19, Intellectual Property Right, Patent, Vaccine, Pharmaceutical Companies.

I. INTRODUCTION

We are in the midst of a pandemic that threatens humankind. The Novel Corona Virus, or Covid-19 has lead to drastic changes in the way we lived our lives. Countries are gearing up their healthcare systems, economic models and industries to survive these testing times. Covid-19 has also, in many ways, challenged our legal set up, and our laws. The Patent law is in the limelight here. Patent laws and other laws related to Intellectual Property Rights have a history of development, where these have gradually evolved. A crucial point here is that Laws related to IPR have evolved with the changes experienced at a global level. With this, various countries have also kept their own version of the IPR law. With such a nature, these laws are also at a test during this pandemic. Patent laws become the subject of discussion primarily with respect to a possible vaccine or a drug. A vaccine/drug is the one stop solution to unlock the misery of the pandemic, to save countless lives, and to benefit the humankind.

[1] Honey Verma, Amity Law School, Jaipur
Vineet Verma, Aishwarya College, Jodhpur

Volume 12, September 2020 ISSN 2581-5504

However, the same is a farfetched fruit. Countries, their pharmaceutical companies, the labs, the scientists are actively working to achieve this milestone. Such a vaccine or drug will be beneficial resource for the benefit of the entire human race. The core question comes down to how the availability of the same can be ensured. This has in fact led the way for another arms race. This race is to have the patent rights to a plausible Covid-19 vaccine.

A lot of our Patent laws were brought forth in the Uruguay Round where WTO members were urged to meet the requisites of the Trade-related Aspects of Intellectual Property Rights (TRIPS) agreement. This multilateral agreement provides that various aspects of a patent and the guidelines that were later adopted by the said member nations.

I. PROBLEMS WITH A PATENT – THE TIMES OF PANDEMIC

The patent is a right of exclusivity that is granted for an invention (a product or any process), where such invention provides a solution[2]. These exclusive rights accrue to the manufacture, selling and using of the invention by the inventor, and by those authorized by the inventor in this capacity, for the set period of the patent. In the context of drug or pharmaceutical Research and Development, patents help to drive innovation. Invention of a drug involves heavy funding and efforts, requiring the best of talent for the task. Therefore, patents help in giving credit to the inventor for the efforts that go into inventing the drug. It is also opined that with the help of patents and other intellectual property rights with respect to drugs, the general public has been able to access the best medical facilities and drugs for various life threatening issues.

The race here is created when the patent, in view of today's circumstances, becomes a restrictive instrument in the way of public health and welfare, against an unseen enemy. Covid-19, that has caused havoc, needs to be battled at a global level. This comes with the understanding that any supply by one player will fall short for the demand of the vaccine. This is where patent rights can be used as a tool to establish a Monopoly. And this is where we can observe that TRIPS isn't helping, at least in these times. This will be a huge problem in developing countries. The price hike is an obvious bane and one that can damage national interest and public health.

BEACON OF HOPE

TRIPS cannot be solely criticized based on the ideology that led to its formation. Liberal treatment has been offered by the provisions for the developing countries, and essential

[2]WIPO, https://www.wipo.int/patents/en/#:~:text=A%20patent%20is%20an%20exclusive,public%20in%20a%20patent%20application

Volume 12, September 2020 ISSN 2581-5504

drugs[3]. Article 7 of TRIPS provides for a balance that is aimed at welfare, along with technological innovation.

Article 8 of the agreement further provides for autonomy that can be exercised by the States. This can help to ensure that public health is the primary goal.

- COMPULSORY LICENSING

Compulsory licensing is when a license will be granted for use, by the government, without the patent holder's consent. The same is enforceable by law, with a willing buyer, but a reluctant seller. The same is backed by TRIPS agreement; however the term does not expressly appear. The phrase "other use without the authorization of the right holder" is mentioned in Article 31 of the document. This phrase leads way for challenging the exclusivity when credible interests are presented. This is in light of keeping public interest in mind, so that benefits are distributed equitably and so that essential facilities are easily accessible.

Compulsory licensing is specifically mentioned here as this is a strategy being practiced by various countries and has led to changes in their patent laws, **owing to restrictive and exclusivity issues related to patents**.

The article discusses patent laws in India and around the globe to understand the existing law and the changes brought in due to Covid-19. Further, it discusses possible alternatives.

II. INDIA

India's patent regime before TRIPS was based on process patent only. With this, domestic players could make drugs and sell them at affordable rates. Post the agreement India was reluctant, despite a debate owing to its non-compliance with the TRIPS/ WIPO provisions and for not giving exclusive rights to market. India, therefore, changed its patent law in 2005.

As per a report by Reuters, the Indian government has been requested to revoke the patent given to Gilead Sciences[4]. This concerns the drug called Remdesivir which has been found to be beneficial to cure the infected patients. This move can further benefit the poorer countries. Remdesivir has been approved as a promising drug for the treatment of Covid-19 patients as per the article. U.S. had granted an emergency use of the same on the 2nd of May.

Gilead had signed pacts with 5 generic drug makers, providing them non-exclusive licensing. These are based in India and Pakistan, and will further help to make and sell the said drug to many poorer, non-profitable nations. This has sparked various appeals from health groups in

[3] Akshay Anurag, *Pharmaceutical Patents and Healthcare: A Legal Conundrum*, SCC ONLINE (Sep.3, 2019), https://www.scconline.com/blog/post/2019/09/03/pharmaceutical-patents-and-healthcare-a-legal-conundrum/#_ftn33.

[4] Zeba Siddiqui, *Health groups ask India to rescind Gilead's patents for Covid-19 drug remdesivir*, REUTERS (May 14, 2020, 3:04 PM), https://in.reuters.com/article/health-coronavirus-india-remdesivir/health-groups-ask-india-to-rescind-gileads-patents-for-covid-19-drug-remdesivir-idINKBN22Q1EL.

Volume 12, September 2020 ISSN 2581-5504

India who oppose the patent held by Gilead on the drug Remdesivir. This comes in light of the fact that this patent with Gilead will allow it to make and sell Remdesivir up till the year 2035. It is being debated that at times like these; companies must not focus on monopolizing on the basis of the patent held by them. Gilead however on the other hand believes that compulsory licensing is not the way out in this situation.

Another drug that seems promising, called Favipiravir[5], has a patent protection in India. It has been given based on a licensing agreement by its developer. This molecule needs further clinical testing to study its potential in formulating a cure. However the supply for the same is dependent on the patent holder. China has reportedly used this drug to treat patients who had subsequently tested negative some days later.

The Indian legislature has accepted various aspects of the TRIPS agreement, which was propounded at WIPO. However, the Indian Patent law still retains some of its own original version. The aim here is to maintain a balance between social and economic interests.

Hindrance for India as a result of patents:

- We do look at the positives, where as per the Indian Patents Act, medicines protected by a patent can be used for the purposes of further Research and Development. However, another perspective that must be considered here is that if the prices are low, future marketing of these drugs becomes a volatile subject. Marketing approval is to be obtained by the regulatory authority. Therefore, lack of this guarantee leads to private sector companies to not invest in many such endeavours.

- Indian patent Act, Section 84 provides for the provision of compulsory licensing. This provision, in brief, allows a private pharmaceutical company to seek a license, without the consent of the patent holder. However, the provision can be initiated only after three years from the date of grant of the patent[6], after the said company has failed to obtain a license from the patent holder itself. This option, therefore, is not applicable to Remdesivir as the patent for the same was granted very recently, in 2020. Any application in this aspect would be void.

- In the case of the drug Favipiravir, an application for compulsory license can be obtained. However, this is possible only when the company seeking to obtain the license has failed to obtain a voluntary license from the patent holder within a reasonable time frame. This reasonable period, as per the act, should not exceed 6 months. This should be taken in the present context. Six months would be an unreasonable delay.

[5] K.M. Gopakumar, Pratibha Sivasubramanian, *Drugs that can be used to beat Covid-19 have another Barrier-Patents*, THE WIRE (May 15, 2020), https://thewire.in/law/remdesivir-favipravir-covid-19-patents-indian-patents-act-ustr.
[6] Indian Patent Act, 1970, Section 84.

- The processes to obtain such patents, without voluntary licenses have proven to be cumbersome. In a pre Covid scenario, companies may have initiated the process to obtain one. However, in the present times, where companies are facing economic slowdown and threats to survival, they are reluctant to pursue litigation. Therefore, the provision of compulsory license, though a feasible and supportive option, is not being pursued. It is not an option for many potential drug manufacturers.

- Indian Patent Act also talks about another situation – national emergency or urgency, in matters of public health crisis (much like an epidemic or a pandemic). In these circumstances, the controller of patents has been given the discretion to grant a compulsory license and he can do so without hearing the patent holder[7]. Further, as per this section of the act, an application for voluntary license is not a requisite. Under the section 92(3), only a government notification is a requisite in this aspect.

- A powerful provision is Section 100 of the Patents Act. This states the government's power to use inventions for purposes stated within its purview. The central government can therefore, use or authorize a private company to make use of the patents[8].

- The central government can acquire inventions and patents under the ambit of section 102 of the Patents Act. This can be done for a public purpose[9]. Through this, generic companies will be able to manufacture and sell the patented drugs.

The alternatives that involve the government allowing for manufacture and use of the patented drug on account of circumstances do not require the stated period of 3 years. Further, the government also has the right to revoke a patent that is subject to prejudiced use, thus harming the welfare of the public. These provisions however, have not yet been initiated as Gilead has been actively engaged in negotiations since the advent of the pandemic.

An example of Section 84 being used in India is the Natco case[10]. Nactco Pharma was granted the compulsory license to manufacture the more generic and affordable version of Bayer's drug Nexavar, a drug for kidney cancer. This helped establish a connection and congruence between TRIPS and our patent laws. This is where it was realized that TRIPS can also be used by various nations to ensure public health and welfare. This also further goes in line with India's Right to life (Article 21), which is a fundamental right.

However, compulsory licenses must not be seen as a fool proof plan. In 2013, BDR Pharmaceuticals' application for such a license to manufacture the generic version of the drug Dasatinib, an anti-cancer drug, was rejected on the grounds of insufficient efforts on their part

[7] Indian Patent Act, 1970, Section 92(3).
[8] Indian Patent Act, 1970, Section 100.
[9] Indian Patent Act, 1970, Section 102
[10] Bayer Corporation v. Union of India (2014 SCC OnLine Bom 963)

to obtain a voluntary license[11]. This brings us to the situation where till date; only one compulsory license has been in grant in the country. This comes as a result of the complexity of procedures and lack of flexibility within a flexible measure itself. Therefore, there is a need that policies are changed to make them friendlier. This will help in the best use of the provision of compulsory licensing.

An article in "The Economic Times" provides other alternatives, as proposed by the authors. They talk about a strategy wherein Indian Pharmaceuticals can take the "risk" to simply infringe the rights of Gilead over the drug for the sake of making it available at affordable rates for public use. This would result in a legal battle with Gilead[12]. The defendants (Pharma companies) would state that the same is being done since the drug is not available to the public and they are working towards common welfare. This would require to judiciary to come to a balance between Intellectual Property rights and welfare. However, the authors have also observed that defenses of public interest have mostly been a failure in past litigations and that a very strong reasoning has to be formulated to convince that court.

The other measure would be potentially a ball in Gilead's court. These would be the granting of voluntary licenses to Pharmaceutical companies in India. This system would ensure that the race is less adversarial and more collaborative. This will save time and help to provide the necessary drugs at affordable rates. Apart from the fact that such a voluntary license is hard to obtain, such a contract would require bona fide intensions from both the parties so as to achieve the end result of public welfare. Since Gilead has engaged in granting these licenses without royalty for the present times, it can be seen as a PR move. We also have to consider that Gilead can raise the royalty rates once the disease becomes less severe. In the scenario of such licenses, price control is something that will have to be achieved[13]. Voluntary licenses are being seen as the ideal and the golden beacon of hope to help us spring out of the pandemic.

A recent development in India comes from the CPAA (Cancer Patients Aid Association) which provides better healthcare access to patients suffering from cancer. The Association has made a representation to the Health Ministry, seeking the revocation of patent that was

[11] *BDR Pharmaceuticals International Pvt. Ltd. v. Bristol-Myers Squibb Company*, CLA No. 1 of 2013 before the Controller of Patents, Mumbai

[12] Anusuya Nigam, Vrinda Pathak, *Affordable access to Cocid-19 drugs: Are voluntary patent licenses here to stay?*, THE ECONOMIC TIMES (May 15, 2020, 03:36 PM IST), https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/affordable-access-to-covid-19-drugs-are-voluntary-patent-licences-here-to-stay/articleshow/75756605.cms.

[13] Anusuya Nigam, Vrinda Pathak, *Affordable access to Cocid-19 drugs: Are voluntary patent licenses here to stay?*, THE ECONOMIC TIMES (May 15, 2020, 03:36 PM IST), https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/affordable-access-to-covid-19-drugs-are-voluntary-patent-licences-here-to-stay/articleshow/75756605.cms.

Volume 12, September 2020 ISSN 2581-5504

granted to Gilead for the drug Remdesivir[14]. This, if accepted, can help get better and affordable access. This move however, awaits a more legal recourse to put things in place.

III. GLOBAL

The globe is in the grip of the virus, and as of now, there is no vaccine in place that can promise recovery or immunization. This is a world problem, meaning there is not a specific country that is affected. The people all around the world are suffering from the impact of the virus. Looking at the global perspective, there is a divide that can be seen between the developed and the developing countries.

At the global level, patent laws were advocated to have a wider scope. This was done to prevent the developing countries from copying the product or technology to catch up in the race. It was said that an uncontrolled distribution, in the absence of patents causing harm as in the competition, the adversary may most likely produce a sub optimal product, that the manufacture might be faulty. However, this can also be seen as an endeavor by developed countries, or the countries in the conventional Global North to ensure their supremacy with the help of exclusive rights.

With the provisions of the TRIPS agreement, a patent could be granted to a product as well as to a process. This is an addition to the sole process patent that was granted by most countries during that time. This complete protection, when applied to a possible vaccine to cure or prevent Covid-19, would make the entire technology, method and technique "exclusive". Accepting the provisions of this agreement were debated as these would hike the prices of patented products, especially drugs, thus making them inaccessible to the poorer sections within these countries.

A turning point here was the Doha Declaration which emphasized that the provisions cannot be restrictive and that countries should be able to legislate based on their social and economic background. This flexibility thus helps nations to implement IPR legislations that may be more suited to the ongoing national or international scenario. Such lack of flexibility can make the access to the vaccine more restrictive, thus jeopardizing public welfare.

An important factor to keep in mind here is that many developing member nations have resorted to only legislate Intellectual Property Rights along the lines of TRIPS provisions. This deliberation is based on an attempt to boost foreign investment and maintain better trade relations. However, public welfare, to access affordable drugs becomes a concern.

With the global perspective in mind, it is important to note that many countries, at least prior to the pandemic, did not have such flexible patenting norms in place. Many of these legislations have only recently been brought forth.

[14] *Coronavirus- Government urged to revoke patent cancer drug*, The HINDU, (Apr 13, 2020, 23;08 IST), https://www.thehindu.com/sci-tech/health/coronavirus-government-urged-to-revoke-patent-on-cancer-drug/article31333796.ece.

Volume 12, September 2020 ISSN 2581-5504

Another global issue is the battle against counterfeit drug makers. We must keep in mind that with a pandemic in place, the vaccine/drug would be an elixir of life and normalcy. This comes in the wake of not just commercial interests, but primarily public health interests[15].

European pharmaceutical companies have given assurances that in the event that they are the first ones to invent the vaccine, they will ensure that it is widely and appropriately available to the people[16].

The UK has brought forth the "Crown use" for patents in the wake of the pandemic. Hence, authorization is given to make use of patents without an agreement made prior to use with the patent holder. The scope here is when the use is for serving the interests of the crown.

Germany has made a legislative move so that third parties may be able to work with patented drugs. The country will further identify patented drugs that in its view should be made more globally available. Licenses for face masks and PPE kits have been loosened so that manufacturers can produce these essentials for patients and health care workers during this health crisis. The holders of all these patents will subsequently be given compensation from the government.

Ireland is one of the biggest manufacturers of medical products, especially ventilators. The country has brought in measures to deal with this emergency – the Public Interest (Covid-19) Bill, 2020. This legislation provides for alternatives to restrict patenting rights in the public welfare sphere. Further, there has been ease in manufacturing, importing and selling of the required medical products, with patent infringement that does not involve the patent holder's consent.

Various provisions have been added to France's health code. These permit the use of patent protected drugs, along with the introduction of generic products in times of need, before the stipulated expiry of the patent.

The two important parties that we must consider here are the USA and China. It is believed that in the event that any one of them is to come up with a vaccine first, access to the same would be a political tussle. Such political standpoint and the power play with laws will not help in winning against the pandemic.

Some of the most recent developments in China include the filing for patent by the Wuhan Institue of Virology, China. The technical aspect revolves around a different "method of use" as claimed by the institute, where the drug Remdesivir was used along with chloroquine, a malaria drug. This attempt to claim an IP right however, will most likely not be granted. The matter still stays. The institute will have to pay compensation for the use of Remesdivir to

[15] Dhruv Nayar, *Compulsory Licensing during a Pandemic: Patent law and Covid-19*, BAR AND BENCH, (April 13, 2020, 1:42 IST), https://www.barandbench.com/columns/policy-columns/compulsory-licensing-at-the-time-of-pandemic-patent-law-and-covid-19.

[16] Rebecca Harasimowicz, *The Global Patent race for a Covid-19 Vaccine*, THE NATIONAL LAW REVIEW, (Mar. 24, 2020), https://www.natlawreview.com/article/global-patent-race-covid-19-vaccine.

Volume 12, September 2020 ISSN 2581-5504

Gilead. The institute has further claimed this in the name of national interest and collaboration[17]. This can be seen as a strategy to get access to the much needed drug for the purpose of research and treatment.

A contention that comes into the picture here is the lack of trust among American investors owing to the weak implementation of Intellectual Property Laws in China. This can lead to a growing tussle, not just for them, but also for other countries. This distrust can also lead to foreign Pharmaceutical companies not willing to collaborate with China to develop a vaccine. China therefore, needs a more promising IPR structure for more investment and patent pooling.

Israel is one of the biggest drug makers in the world. It was one of the first countries to make the move, to ensure that human welfare is without legal hindrances. On March 18, 2020, Israel issued a permit in this capacity. As per Israel's patent law, the minister can permit that the government may proceed to exploit an invention, irrespective of whether a patent for the same has been granted or not, if he is of the opinion that it is necessary in view of National security or for the maintenance of essentials[18]. With this, Israel looks forward to obtain Kaletra directly from its authorized importer. The application of this provision comes in response to Covid-19. Further treatments have also been put on way for approval by Israel's health Ministry. This was also done to solve the problem of the lack of inventory of the patented drug. With these developments, AbbVie, the manufacturer of the Kaletra drug has in fact emphasized that it will not seek to enforce its patents in the midst of the Coronavirus pandemic.

In March of this year, Canada stepped up and the Emergency Response Act was put in place to battle Coivd-19. This act provides for provisions to pave way for compulsory licensing. These licenses are restricted to the use of emergency and these will expire by the month of September this year.

A recent development in the United States has been the removal of licensing barriers to the practice of medical professionals in different states within the country. The same was not transferrable previously, with procedures being state specific. This has come as a result of the higher number of cases in the country. **INCENTIVISATION** is a crucial factor here. Drug makers and inventors need an incentive system in place to fuel innovation and get good returns for their work. Here, a better way proposed is the giving of financial prizes. With the

[17] Rebecca Harasimowicz, *The Global Patent race for a Covid-19 Vaccine*, THE NATIONAL LAW REVIEW, (Mar. 24, 2020), https://www.natlawreview.com/article/global-patent-race-covid-19-vaccine.

[18] Patents Law 5727-1967, prepared by WIPO (from the Hebrew version), Israeli Patents Law, 1967, Article 3: Use of Inventions in the Interest of the State, Section 104, https://www.wipo.int/edocs/lexdocs/laws/en/il/il040en.pdf.

right incentive in place, the market will be open for more drug makers to distribute the vaccine faster[19].

IV. ANOTHER STRATEGY – LET'S COLLABORATE – PATENT POOL

A global development that can fuel the making and distribution of a possible vaccine will be collaborative research. This is the development of patent pools, which involves the pooling of voluntary patent grants by patent holders, where drug makers come together and gear the invention. The World Health Organization and the EU are in constant support of such collaboration. With this initiative, The Medicines Patent Pool has long worked to provide essential drugs to the poorer sections. This is UN-backed organization that can turn the tables with its strategy. The pool combines its patents, useful intellectual property and technology and that can help fast track the development of a cure. With contribution in the pool, the patent holder exchanges the invention with the other voluntarily. This speeds up innovativeness.

This strategy is being advocated by governments in place of compulsory licensing. The latter, though seen as one of the most optimum alternatives to solve the patent problem, is characteristic of cumbersome procedures. The legal work involved is heavy and further approval is not an assured outcome. This norm goes for many countries, despite many of them having introduced this very recently. Costa Rica has played a role in this aspect and had first proposed to create such a pool to battle the pandemic. The aim here is to work for a more affordable cure, with flexible licensing. The leaders of Costa Rica have in fact submitted a letter to WHO in order to drive the negotiations forward.

The strategy of patent pooling, if put in place will help create a cure that can be termed and used as a global public good by the world.[20] This brings the focus to advancement of the globe to win against this disease. Countries like Israel, Chile, Canada and the nations of EU have collaborated in this respect to make their licensing flexible and to create a voluntary patent pool.

V. CONCLUSION

These testing times call for an innovative solution to a tough problem. Human minds must be put together to fight against this. The cure will be an Intellectual Property that would be celebrated by the society for the years to come. It is urged that this problem is dealt in the absence of a political power play, within the countries and amongst countries as well. Patent laws can help in identifying and rewarding innovators and inventors. They must not be used in an adversarial manner in the midst of the pandemic. The world needs to find solutions to these legal issues for public welfare.

[19] Simon Lester and Bryan Mercurio, *We Need a Coronavirus Vaccine. Patents Might Slow the Process*, CATO INSTITUTE, (Apr 8, 2020), https://www.cato.org/publications/commentary/we-need-coronavirus-vaccine-patents-might-slow-process

[20] PA Media, *EUROPEAN LEADERS JOIN FORCES TO COMBAT COVID-19*, THE GUARDIAN, (May 3, 2020, 00:28 IST), https://www.theguardian.com/world/2020/may/03/european-leaders-join-forces-to-combat-covid-19