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HOW COVID-19 CAN IMPACT THE PATENT LAWS OF ESSENTIAL MEDICINES IN INDIA

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ABSTRACT

In this research paper discusses how COVID–19 can impact the patent laws of essential medicines in India. Patent on drugs do act as a barrier to make the vaccine available to the public at large but still many shortcomings in the legal system are being used to make sure that the public does not suffer as a result of the pertaining patent issues.

Keyword: *Covid, Women, Maintenance, Criminal Procedure Code, Uniform Civil Code*

1. INTRODUCTION

The extremely aggressive COVID–19 has taken the world by storm and many scientists and drug makers are focusing on increasing the production or repurposing the existing medicines namely Remdesivir, Hydroxychloroquine, Leronlimab, EIDD–2801, Ivermectin for treatment of patients so as to contain the fatality caused by the disease. Though the drugs being tested will become the life-saving solution for the distressed mankind, it also encompasses the issue of Patents Act.

The Patents Act, 1970 along with the Patents Rules 1972, came into force on 20th April 1972, replacing the Indian Patents and Designs Act, 1911. The Patents Act was based on the recommendations of the Ayyangar Committee Report headed by Justice N. Rajagopala Ayyangar. The patent can be useful to the patent holder in the following ways:

- It provides an exclusive right for the invention which can be exploited for 20 years.
- Through these rights patentee can prevent others from making commercial use of the invention, thus providing a stronghold in the market.
- Patents are acquired to gain maximum return from the invention.
- Patentee can license the rights to commercialize the invention to another enterprise which can become its additional source of income.

India became a member of Trade–Related Intellectual Property Rights (TRIPs) system with an objective of strengthening its patent laws and competing with the modern world. India also became a signatory of the Paris Convention and the Patent Cooperation Treaty on 7th December, 1998 and thereafter signed the Budapest Treaty on 17th December, 2001.

Patent Laws in Medicine Industry

Talking about patent laws in the medical field, it is heartening to know that India is the largest producer of generic medicines. We have observed in the recent months of COVID–19 that nations looked towards India for the supply of generic medicines like Hydroxychloroquine, Paracetamol and Amoxycillin for treatment of SARS–CoV2 symptoms as these drugs were identified to render encouraging results.

The developed nation like the United States of America gave an appeal for supply for drugs based on its bilateral relations with India, to which India conceded. Under the present circumstances, it becomes the moral responsibility of each country to provide medical aid to the other along with taking care of its own interests.

Under the volume of the existing pandemic, the exigency of production of cost–effective medicine is of paramount concern. The cost of generic medicines is manifold less than that of patented ones. The protection period of 20 years conferred to the Company with the patented drugs under Section 48 of the Indian Patents Act, 1970 gives it the sole right to make, use, sell or distribute that drug within the protected period.

Polar exemption comes to the rescue of third–party manufacturers as it gives them the privilege of conducting research and development on the product while the patent is still within the lifetime of the patent. It is in fact used as a defence against patent infringement. This helps both the inventor and the interested party, as, after the patent of invention, it becomes available to the third party

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that seeks to boost its business without delay after the expiry from the patent protection period.

In this way, the generic drug manufacturers can launch their product of the generic version of the drug by strengthening its application which runs in parallel with the patent period.

2. CHALLENGES FACED BY PATENT

The patent can be contested on the following justifications:

- Granted patents are frequently challenged on the ground that they are orthodox and do not meet the requirements of grant of a patent.
- The exclusivity of the patent can be subject to Section 84 of the Patent Act which states that an interested party can apply for a compulsory licence at any time after three years from the date of grant of the patent based on—
  - failure to meet reasonable public requirements;
  - the inaccessibility of the patented invention at a reasonably affordable price to the public; or
  - the non–working of the patented invention in India.

Point (a) can be invoked since an increase in the number of the patients is anticipated and holding a patent will make it difficult to meet the demands of the public. A loophole to Section 84 of the Patent Act can be sought in Section 92 of the Patent Act which states that the government can provide for the grant of permission in case of emergency removes the mandatory 3–year protection for it.

The government has the power to sell this drug for its purpose without the intent of earning any profit out of it. Under this provision, the Government can pay the decided remuneration to the patent holder. The important point to note over here is that the Government can start to make use of the drug even before reaching an agreement with the patentee. In case Government is unable to reach an agreement the High Court will come in force and it will decide as to what remuneration has to be paid to the patentee.

The Government has the powers to rescind a patent in the public interest under Section 66 of the Act. The Central Government can rescind a patent if the patent itself or the mode in which it is exercised is stopping the State from acting in the interest of the public.

The Court can modify its provisions pertaining to patent law in order to serve the public interest. It has to be kept in mind that injunctions are issued in order to stop a company from making unauthorized use of the drug which is patented. However, courts can refuse to grant an injunction if the case is of public interest.

The case of COVID–19 drug trials in association with the drug manufacturer is a striking example of this provision. The drug under trial is, Remdesivir [IN 332280], the patent for which was recently granted on 18th February, 2020 and is valid till 2035.

If research on the repurposing of the drug for the treatment of COVID–19 proves to be a silver bullet, the alternative strategy for coming out of the paradoxical situation lies in compulsory license or government use license wherein the government can facilitate the generic production of the drug.

Certain countries like Israel and Chile have issued compulsory licenses to allow producing or using the patented medicine/invention without the permission of the patent holder. In order to tackle this situation of patent protection Germany amended its patent law to facilitate the quick issuance of compulsory licenses.

Gilead Sciences, USA has already filed patents for the Coronavirus control by the drug Remdesivir in several countries, like the United States, China, Europe, Japan, and Korea. Reacting to the patent issue the CEO of the Gilead Sciences, Daniel O'Day, has claimed that they are in no way interested in getting involved in a patent dispute at this stage.

At present they care about is the patients well–being but the protection of the Intellectual Property will not be neglected at the same time. This statement clarifies that the company is concerned about the betterment of the public health and it will do whatever it can to find a cure for the COVID–19 pandemic.

Infact, other than Gilead Sciences, Indian immunobiological and vaccine company, SERUM Institute of India is working at the front foot to find a vaccine to the COVID–19 pandemic. In fact, many clinical trials are going on in Tamil Nadu and have also shown encouraging results for the same.

Regarding the issue of Patent, Adar Poonawala, the CEO of the SERUM Institute of India, said that it will not patent the vaccine which is expected by 2021 because it has decided to work with multiple firms to manufacture it so

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that it is the available world over and the company doesn't want the Patent to act as a firewall in the process of achieving this feat. This company was founded in the year 1966 with aim of providing life–saving drugs at affordable rates which were available at imported rates at that time. It came to prominence the moment it found a vaccine for the deadly H–1, N–1 flu and manufactured it on a large scale.

Another drug some researchers are eyeing for is Favipiravir, which was developed by the Fujifilm Toyama Chemical Corporation, and is based on a licensing agreement, the antiviral drug is being manufactured by Zhejiang Hisun Pharmaceuticals for treating influenza viruses. Favipiravir is very much capable of treating RNA viruses, like SARS–CoV–2. China is using this drug for treating patients in Shenzhen who had tested positive for COVID–19 and found that patients given this drug tested negative four days later. Favipiravir is a part of five patents in India, although one of these patents has already expired.

3. DOHA DECLARATION–PUBLIC HEALTH

Despite the right to medicines being of the most essential human rights, around 2 billion people still have little or no access to essential medicines with the issue being more prevalent in underdeveloped and developing countries. Since most of the new medicines are backed by patents in these countries by various pharmaceutical companies, access to them becomes pretty difficult for the people in other countries.

Due to this, the WTO Ministerial Conference in 2001 issued a 'Declaration on the TRIPs Agreement and Public Health' in Doha, Qatar. The declaration is an important step in access to essential medicines for the underdeveloped countries that usually face issues in gaining access to them due to patent protection.

The Doha Agreement explicitly states that the TRIPs agreement (Agreement on Trade–Related Aspects of Intellectual Property Rights) does not and should not prevent countries from taking measures to protect the interest of the public and that it should be interpreted in such a way that it supports countries' right to protect public health and also to promote access to medicines.

Paragraph 5 of the declaration deals with the objective stating that each TRIPS member has the right to grant compulsory licenses having the freedom to determine the grounds upon which they are granted. The members are free to determine which conditions constitute a national emergency.

The declaration imposes an obligation on the developed states to make available the essential life–saving drugs in countries that don't have access to them and can't afford them for the protection of the health of the public. In short, States not only have a duty to ensure that existing medicines are available within their country; they also have a responsibility to take reasonable measures in order to ensure that much–needed new medicines are developed and thereby become available at the earliest.

4. PROVISIONS UNDER PATENT ACT

Under Section 107 of the Patents Act, anyone can produce, use and even market the patented medicine without the permission of the patent holder for obtaining regulatory approvals. This brings relief to Indian generic companies as they are free to produce and use patented drugs during clinical trials although the restriction on marketing approval from the regulatory authority is to be taken care of. In reality, these provisions would be of little use because the private sector companies will not make any investment unless there is a guarantee to market in the future.

The other four provisions in the Patents Act would be useful to provide a predictable and long–lasting solution. The first option is the compulsory license provision under Section 84. Under this, a private pharmaceutical company can approach the patent office to seek a compulsory license with regards to any one of the following three grounds: unmet demand, excessive pricing and lack of local manufacturing. Any interested person can apply for compulsory licenses from three years from the date of grant of the patent after the failure of efforts to obtain a voluntary license from the patent holder.

Though the Patents Act says the "reasonable period shall be rendered as a period not ordinarily exceeding six months", in the current situation, six months is a long period. Further, the issuance of a compulsory license requires hearing of the patent holder and it can delay the issuance of the license. The threat of litigation also makes the generic companies stay away from using Section 84 as in the case of Favipiravir. Therefore, a compulsory license under Section 84 is not an option.

The second option is under Section 92(3)—in a situation of national emergency or circumstances of extreme exigency, public non–commercial use arises during a public health emergency or during a public health crisis,

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like an epidemic. At this time, the controller of patents has the power to grant a compulsory license even without hearing the patent holder. In this option, the applicant does not need to make any attempt to obtain a voluntary license. The precondition to seek a compulsory license is a government notification saying it is necessary to issue a compulsory license.

The third option is that the government should issue a Government issue license on a patent under Section 100. Under this provision, the government directly uses or authorises a private company to make use of the patents.

The fourth option is under Section 102, whereby the government can take control of the patents and allow the generic companies to manufacture the patented medicine.

Only the last three options look feasible as of now—but require government action. The government is a bit reluctant when it comes to using compulsory licenses, often due to bilateral political pressure from the US. A US–India Business Council submission to the US trade representative in 2016 revealed that Indian officials gave an oral assertion to not to grant any compulsory licenses.

Currently, India is in an extraordinary position, and these desperate times demand extraordinary measures, like allowing the generic production of patented medicines.

Other than the countries mentioned here, the recent country to apply for a patent is none other than China from where COVID originated. A patent was filed by Wuhan Institute of Virology though it might be very difficult to prove originality and non–obviousness because of the many prior references that have already been put forward by Gilead sciences.

Even if the patent can prove its originality and non–obviousness, it might take as long as three to five more years for it to be granted in countries outside of China via the Patent Cooperation Treaty application (PCT). A PCT is an international law treaty which provides for applicants to seek protection for their invention in the contracting states. By the time the application will be approved it will be very difficult to decide whether the novel Coronavirus will still be an issue of concern.

5. ROLE OF NON–PROFIT GROUPS

In order to cater to the public at large two advocacy groups have written to the Indian Government asking it to take back the patents given to Gilead Sciences for the drug Remdesivir so that it can be made available to COVID–19 patients around the world, particularly in underdeveloped nations.

In response to this Gilead Sciences signed nonexclusive licensing pacts with India and Pakistan allowing them to make and sell the drug on a large scale. But another school of thought claims that the pact does not ensure availability of the cheaper forms of the drug on the large scale.

The Nobel winning organization Doctors Without Borders (Médecins Sans Frontières, or MSF) claimed that such pacts are highly unacceptable in a situation like this. Releasing a clarification to the above claim Gilead Sciences has issued a statement that it is highly committed to providing a vaccine at this stage without thinking about the profit it can obtain out of it.

6. CONCLUSION

Many companies are working tirelessly in order to find vaccines, side by side clinical trials are also underway in order to find a drug which can cure the affected without the need for a vaccine. It is imperative that many companies will aim to earn profit out of the vaccines but several organizations call for a more liberal approach and demand to allow the vaccine companies to produce the vaccine on a large scale.

Patent on drugs do act as a barrier in order to make the vaccine available to the public at large but still many shortcomings in the legal system are being used to make sure that the public does not suffer as a result of the pertaining patent issues. The situation calls for coming together of various vaccine makers in order to avoid more fatalities to take place.

The vaccine is still under clinical trials and two of the most prominent vaccine makers of the world which are SERUM Institute of India and Gilead Sciences have ensured that the moment a solution to the deadly virus is found it will make sure that it is available in large quantities and maximum people can get cured by it.

While a general vaccine takes at least 20 months to develop, the SARS Cov2 vaccine is ahead by 5 months and by next year we might be able to heave a sigh of relief. While many claimed that Bill Gates got a vaccine patented under his company's name, the truth was that it was a patent owned by Pirbright Institute that receives some funding out of the Bill and Melinda Gates Foundation and the vaccine is in no way fully owned by them. At last, I would like to mention that the situation demands us to

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stand together against this virus while maintaining the novelty of the patent.

With regard to this the following points have to be kept in mind pertaining to the current scenario:

- Public interest should be seen as foremost before passing any law or judgement.
- The drugs that bring respite, in case of pandemics, should be outside the purview of Patent Act.
- Drugs and vaccines should be developed by a public–private partnership.
- Patent for vaccines and drugs required for controlling the pandemic should be for a short duration and the interest of the inventor should be compensated.
- Government investment in research in the health sector can help in controlling the stringency of patent laws.
- Reducing bureaucratic constraints for the companies who are front runners in development of drugs can enable the faster outcome of results with a moral obligation of the companies to release the drugs for use of humankind outside the lifetime of the patent.

The companies that forego patenting should get full financial support and incentives from the government so that the release of drug is expedited.

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