WEALTH BEFORE HEALTH: PATENTING IN THE TIMES OF PANDEMIC

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ABSTRACT

Even as the debate on patents in pharmaceutical industry and affordable access to medicines goes on, the Covid-19 pandemic has brought more questions on the subsistence of patent regime during the pandemic. The economic theory of patent protection provides that patents foster innovation by protecting the efforts and investments of the innovators and this theory is generally cited for conferring patents to life saving medicines and vaccines in pharmaceutical industry. In these unprecedented times, the possibility of patent rights coming in way of large-scale production of medical equipment and devices for the benefit of masses and affordable access of the same cannot be ignored. Pharmaceutical giants usually look to recovering their R&D costs by patenting their medicines and selling them at exceptionally high prices. This poses an important question with regard to the functioning of the patent regime during such times, when a drug to fight off the virus would be no less than an essential drug after taking into consideration the number of people affected worldwide. This shall discuss the patentability criteria for drugs, the effects and ill-effects of grant of patent for such drugs to the pharmaceutical companies and the steps taken by countries to alter their patent regime for an effective administration during the pandemic. The article concludes with views of the authors on feasibility of grant of patent and suggestions on functioning of patent regime during pandemic.

INTRODUCTION

There is always a new bacterium or virus taking birth in some corner of the world, potent of harming the humankind. This results in scientific inventions and discoveries of drugs/medicines or chemical compounds that would either reduce the ailment or cure it. Gone are the times when medicines were created with the sole purpose of curing the illness; today the primary reason for spending millions of dollars in R&D is to get quick and easy recovery of the investment and earn profit in just a few years' time. This is where patents come in, enabling supra-marginal economic returns.

If a product or a process that provides a new way of doing something has been invented, patenting it would earn the Owner a boatload of greenbacks. Acquiring a patent gives exclusive rights to the Owner for making, using, offering for sale and selling for the production of the product or for following the process. In other words, except for the Owner, no one can reproduce the patented product or process, and if such exclusivity is breached, the Owner can claim infringement. Apart from protecting his rights, the Owner can also decide to license the patent in return for a payment. But the exclusive right is not timeless; the Owner has the right only for a period of 20 years from date filling of application.

Patent Laws, across the world, do not grant patent for just any and every invention. It is essential for the product or process to fulfil the patentability criteria, without which there would be no patent. Trade-Related aspects of Intellectual Properties (TRIPs) Agreement, lays down the patentability criteria, which are generally adhered to by all the nations. All the inventions are tested against these criteria to determine if they are patentable. The analysis of the inventions against the criteria is termed as a Patent Validity Analysis.

PATENTABILITY CRITERIA FOR INVENTIONS

All sizes of Pharmaceutical Companies, from all regions of the world, have been working towards finding a cure to the virus. There are over 35 drugs in the race of treating this novel disease. Even though clinical trials for a many of these drugs have been conducted, there has been no drug that has tested successfully for fighting off the virus. So as this battle between the different drugs and between the drugs and the virus continues, it is important to understand the patentability of these drugs, because that would determine the extent of commercial exploitation of this IP Right and the extent of the monopoly that may be created by granting of

patent for 20 years, especially in the time of such a crisis, where such a drug would be no less than an essential medicine and after 20 years the virus may not even exist, so the invention coming into the public domain might just be irrelevant.

So, in order to single out an invention as being patentable, it must check the boxes of Novelty and Non-obviousness, primarily. Apart from these two criteria, there are others as well, which provide that the subject matter must be patentable, there must be industrial applicability, etc. We shall focus on the first two criteria to understand the patentability of these drugs to fight the virus.

As the name suggest, 'novel' means new, in this case, a new invention. The invention must not be something that already exists, i.e., a prior art (knowledge existing in public domain before the patent application for the concerned invention was filed). In other words, the invention that seeks to be patented be different from what already exists and that all the element of the claim made for the invention cannot be found in prior art.

The second criterion, i.e., Non obviousness, is considered to be the fundamental test of patentability. It is much more stringent than the novelty requirement. It ensures that the patents are not trivial (a very small and inconsequential change has been brought). There must be real advances. Small advances would just clog the system and hinder actual development and innovation in the prior art. It allows people to invest more time and money to make an invention that would fulfil this criterion. It needs more ingenuity and skill than that of a simple mechanic. An invention is obvious when it solves a known problem with an obvious solution. The invention should be such that people having ordinary knowledge in that area of the subject matter also did not know of such a solution and could not have thought of it.

Coronavirus, also called as 'Novel Coronavirus', has been alleged to have been created by China to let all hell loose on the world; if this is the case, the virus itself could also be patentable if it fulfilled the criteria, but that is not what this paper deals with. Since the virus itself is novel and innumerable pharmaceutical companies are conducting trials to find a cure, it is abundantly clear that there is no pre-existing knowledge of a drug or compound that would cure the ailment. So whatever the pharmaceutical companies develop is very likely to be novel and non-obvious. But this does not mean that the patent would be granted at the first instance. The content of the invention will have to be checked against all the existing inventions so that there is certainty that changes haven't been made in already existing drugs; secondly, drugs to fight this virus, will also have to be checked with other drugs that have already filled for patent and

are also for fighting off this virus. So, if a drug fulfils all these criteria, it will be eligible for being patented as a drug that cures Coronavirus.

PATENTS: IS IT THE CORRECT PATH FOR THESE DRUGS?

The gravity of the pandemic and the extent of loss of life that it has already caused and is likely to cause cannot be undermined. The hospitals and medical care institutions are overflowing with the patients, even though there is no medical treatment for the virus yet. The number of cases is so high, that the hospitals have refused to admit patients because they have reached maximum capacity. The private medical institutions are an already bad situation worse by charging exorbitantly, for just a bed in the hospital with primary medical care. So even in these terrible times, the economic barriers and class segregation remain, as only the richer section of the society can afford to pay the hospital bills that are running into lakhs of rupees, while the poor, who may be needing more medical attention, are dying at their homes, due to lack of affordability. On this behaviour of the private hospitals, the Gujarat High Court, on a *suo moto* action ordered that "*At any cost, the private hospitals should not be permitted to demand exorbitant amount for the purpose of treatment of COVID19 patients. These are difficult times and not the time to do business and earn profit. The medical services are the most essential services and in times like the present one, the private hospitals cannot demand lacs of rupees from a patient*". Similar orders and government circulars have been notified in different states, but the overcharging still continues. Until now, one would have thought that it was just the hand sanitizer companies or the mask manufacturing firms that were printing money in lieu of this pandemic, but the ringmaster is actually the private hospital; and once the suitable drug is produced, the pharmaceutical companies will join this race too and will most likely run the show.

Since the issue of patentability has been dealt with, it is now time to dive into the actual issue at hand, which is, whether the drugs that are being developed to fight the virus should be granted a patent at all. There are two conflicting opinions to this issue; one view is that patent must be granted because of all the resources that have been spent to develop the drug, while the other denies it on the ground of public interest; both these views are extremely relevant.

Till date, no drug has been successfully tested to cure the virus, which raises a series of questions for when such a drug is manufactured. The most important of these questions are –

how the pharmaceutical companies would be able to commercialize the cure? How would the drug be available to the masses at affordable prices? Will there have to be a trade-off between these two, or can they both be achieved simultaneously?

Patent Laws are very clear when it comes to granting of patent for medicines and medical instruments, as they allow the inventor to patent these inventions and derive economic benefits by their production or usage. 'Economic benefits' is one of the major reasons why any invention, small or big, is filed for patent and as a result, there is a lot of pending patent applications with the Patent Offices. It wouldn't be wrong to say that one of the major driving forces behind inventing is profit generating capacity that an invention has once the patent has been granted. Take for instance the HIV drugs, which are priced up to $1000, just because they are patented; so, another question that arises here is whether the drugs that will fight coronavirus must be treated at par with all the other medicines?

Ban on domestic and international travel, a worldwide lockdown and situations of quarantine are just some instances that set this virus apart from all other virus and bacteria that affect the human body; so the way to deal with the medication or treatment of this virus must also be different than the others, and so must be the patenting of the drugs. Unlike many other diseases, neither is this virus a part of medical school curriculum, nor is there a prescribed manner of treatment available as pre-existing knowledge. This point towards giving a different treatment to Coronavirus, as against all other virus, and the treatment or the medication of this virus must also be treated differently.

Pharmaceutical companies have been involved in the research of finding a cure since February-March of 2020; and there hasn't been any success yet. So once they do, if like all other medications, the drugs to fight the virus are given patent, then the inventors would have sole right to sell the drug for twenty years, unless they grant licenses for production; and this time frame will be more than enough for them to draw commercial benefit from the patent because they would resort to price gouging. This would definitely cause hardships among the public, because the cure would neither be available easily, nor would it be affordable by all segments of the economy. As the cases rise with every passing minute, it is only safe to presume that the demand for the drugs may substantially exceed the supply, if there is only one producer in the market, national or international. As equilibrium would not be struck between the demand and supply, the chain reaction would be the increase in prices of these limited quantities of drugs, resulting in making the already costly drug, even costlier.

But are Pharmaceutical companies wrong if they wish to recover all the cost that they have incurred? Looking at this from the perspective of these companies, if they charge high prices, their act will be justified, because they put in time, money, human and other resources, so that they could develop the cure; what would be the point of all these efforts if they could not use the fruits? But if this is looked at from a public perspective, the pharmaceutical companies would be called out for their selfish behaviour, because they would be considered to be fixated on their own benefit, rather than public benefit.

This is without a doubt, the most difficult and unprecedented times that the world has ever seen. These times demand a change of behaviour from everyone; be it the profit-centric pharma companies or the social animal, man himself. The economies have taken a stumble, and it would all be for nothing if the drugs are not accessible by every person in the society. As per WHO, essential medicines are those which satisfy the priority health care needs of the population. Adhering to this definition, the drugs to cure COVID-19 would cater to the priority health care needs of the world population, so it is all the more important that they are priced after taking into consideration the economic status of all the users.

So, the Governments of different nations, primarily, and the Pharmaceutical companies have a crucial decision to make. They can either try to bring balance between profitability and affordability, or they can decide to completely forego one private interest viz-a-viz public interest, or vice versa. From the outsiders' perspective, no balance can be seen between these two goals, and there will have to be a trade-off; so, the question actually is, which interest will prevail?

COMPULSORY LICENSING: A CURE TO PANDEMIC PROFITEERING?

The Agreement on Trade Aspects of Intellectual Property Rights (TRIPS)[i] is the most comprehensive multilateral agreement on intellectual property between member nations of the World Trade Organization (WTO) which came into effect on January 1, 1999. It provides for minimum standards of protection and enforcement that member nations must adhere to in relation to regulation of intellectual property. The basis for compulsory licensing is found in Article 31 of TRIPS though it does not use the words "compulsory licensing" *per se*. A "compulsory license" is an authorization given by a national authority to a person, without or

against the consent of the title-holder, for the exploitation of a subject matter protected by a patent or other intellectual property rights.[ii] Article 31 provides for conditions to be adhered for use without authorization of the right holder.

Despite these flexibilities, by virtue of product patents and exclusive rights provided under TRIPS, pharmaceutical companies were able to set high prices for medicines to recover their R&D. This resulted in lack of access to important medicines by developing and least developing countries especially during their fight against HIV infection. A widespread criticism of TRIPS ensued which resulted in adoption of a Declaration on the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) and Public Health on November 14, 2001 by the 4th World Trade Organization Ministerial Meeting at Doha, Qatar. Clause 5 of Doha Declaration reaffirmed the right of compulsory licensing by providing that "Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted."[iii]

Under the Patents Act, 1970 of India, compulsory licensing is provided under Chapter XVI. The conditions for grant of compulsory licensing are provided from Sections 84 to 92 of the Patent Act. Under Section 84 of the Act, any person interested, after expiration of three years from the date of grant of a patent, may make an application to the Controller for grant of compulsory license on patents on any of the following grounds: (i) reasonable requirements of the public with respect to the patented invention have been satisfied; (ii) patented invention is not available to the public at a reasonably affordable price; (iii) patented invention is not worked in the territory of India. The interested party shall file an application for a compulsory license as per Form 17 along with prescribed fee with the Indian patent office.

In the current situation of pandemic, it shall be the government of India who shall be willing to acquire such compulsory licenses to see that demand of the citizens are met. There is special provision for compulsory licensing on notifications by Central Government. If the Central Government is satisfied, in circumstances of national emergency or in circumstances of extreme urgency or in case of public non-commercial use, that it is necessary that compulsory licenses should be granted in respect of any patent in force, it can make a declaration to that effect by notification in the Official Gazette.[iv] Post such notification, the Controller shall grant license to any interested person making an application and shall endeavour secure that articles manufactured under the patent shall be available to the public at the lowest prices consistent with the patentees.[v] According to the Act, exceptional circumstances can also include public

health crisis relating to AIDS, HIV, Tuberculosis, malaria or other epidemics and in such cases Controller can waive off the procedure of hearing prescribed under the Act.[vi] The situation of Covid-19 pandemic shall fall under public health crisis and the Central Government can exercise its power accordingly if required.

Section 90 of the Act states that in settling the terms and conditions of a license, the Controller shall endeavour to secure, *inter alia*, following: (i) royalty and other remuneration, if any reserved to the patentee or other person, is reasonable; (ii) patented invention is worked to the fullest extent by the person to whom license is granted and with reasonable profit to him; (iii) patented articles are made available to the public at reasonably affordable price; (iv) license is a non-exclusive license; (v) right of licensee is non-assignable; (vi) license is for the balance term of the patent unless a shorter term is consistent with public interest; (vii) license is granted with a predominant purpose of supply in the India market.[vii] These conditions ensure that the interests of the patent holders are not unduly prejudiced. Thus, compulsory licensing as a tool could be successfully used by Indian government to see that any potential patented drug for treatment of Covid-19 reaches its population at a reasonable price.

COMPULSORY LICENSING MEASURES ADOPTED ACROSS JURISDICTIONS DURING COVID-19

The governments across the world took various measures ranging from imposing lockdowns to closing the borders to contain the spread of Covid-19. The governments soon realised that apart from containing virus it was also necessary to ensure that there is affordable access to drugs and medical equipment necessary in the fight against the virus. There was a need to see that patents do not come in way of such access. For example, drugs under clinical trial for Covid-19 like remdesivir, favipiravir and lopinovair/ritonavir are under numerous patents across world which might hamper its large-scale production. Therefore, governments across the world took steps to alter the patent regime to prevent private companies from profiteering.

Germany: Section 13(1) of the German Patent Act empowers Federal government to issue orders for the use of patented inventions in the interest of public welfare. On March 27, 2020, the "Act for the Protection of the Population in case of an Epidemic Situation of National Importance" (Epidemic Protection Act) was passed which, inter alia, amended the German Infection Protection Act to empower the Federal Ministry of Health and its subordinates to

order the use of a patent in accordance with Section 13(1) of the German Patent Act. Hence, Section 5 of German Infection Protection Act empowers Federal Ministry of Health to issue order for use of patented products necessary for public welfare such as medicinal products, medical devices, personal protective equipment, laboratory diagnostics and products for disinfection.

Canada: The Canadian Patent Act by virtue of Section 19 empowers the government to authorize the use of a patented invention. Under this provision, the government is required to negotiate with the patentee, except in cases of national emergency or extreme emergency or public non-commercial use. On March 25, 2020, the Canadian government passed Bill C-13 into act called "An Act respecting certain measures in response to COVID-19" which added a new provision section 19.4(1) to the Canadian Patent Act. The new provision allows the Federal Minister of Health to apply for government authorization to make, construct, use and sell a patented invention in case of public health emergency and it allows the government to issue a license without negotiating with the patentee first. This provision shall remain in force only till September 30, 2020. Further, the patentee shall be compensated and shall receive an amount considered to be adequate remuneration by the Patent Commissioner.

France: On March 23, 2020, a new Emergency law No. 2020-290 was enacted by France government. The newly enacted law does not make any direct changes to the patent legislation in response to the pandemic. It introduced Article L. 3131-15 in the French Public Health Code which authorizes the Prime Minister (i) to order the requisition / seizure of all goods and services necessary to fight against the sanitary disaster as well as any person necessary for the operation of such services or the use of such goods; (ii) to take temporary measures to control the prices of certain products made necessary to prevent or correct the tensions observed in the market of certain products; and (iii) if necessary, to take any measures to make available to patients appropriate medicines for the eradication of the health disaster.[viii] According to the Minister of Health such broad provision could be used for compulsory licensing or price ceiling of drugs not produced in France.[ix]

Certain efforts in this direction were also made in countries like Chile and Ecuador. On March 17, 2020, a resolution was passed by the Chile's Chamber of Deputies asking government for grant of compulsory licenses on patented products necessary for treatment of Covid-19.[x] On March 20, 2020 a resolution was passed by the Education, Culture, Science and Technology Commission of the Ecuadorian National Assembly asking government to issue compulsory

license on products which are necessary for public health response to COvid-19.[xi] However, the resolutions passed in both countries are not binding on their respective governments.

CONCLUSION

Compulsory licensing is a very powerful tool in the hands of government to prevent pandemic profiteering however it is also imperative that interests of pharmaceutical companies be protected to foster innovation in future. Compulsory licensing may lead to discouraging pharmaceutical companies from using abundant resources for discovering cures in future. Hence, any approach taken by the governments must be a balanced one. According to the authors, compulsory licensing should only be used as a last resort. Governments should try to negotiate with pharmaceutical companies for providing voluntary license at reasonable price as well as granting of these licenses in different countries so that they can fulfil their on demands and would not have to rely on importing. In case these negotiations do not materialise into anything concrete then only governments should explore the option of compulsory licensing. The governments must also ensure that the practices of price gouging are avoided, by keeping a price ceiling, so that the consumers are not exploited in the times of this pandemic.

World Health Organisation launched voluntary patent pool to collect knowledge, intellectual property and data to realize global access to Covid-19 health technologies. Countries such as US and UK where major pharmaceutical companies are headquartered are not signatories to this pool. Since it is voluntary patent pool it is to be seen how many pharmaceutical companies which actually participate in the same. Thus, lack of support from large countries and pharmaceutical companies can undermine its success.

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