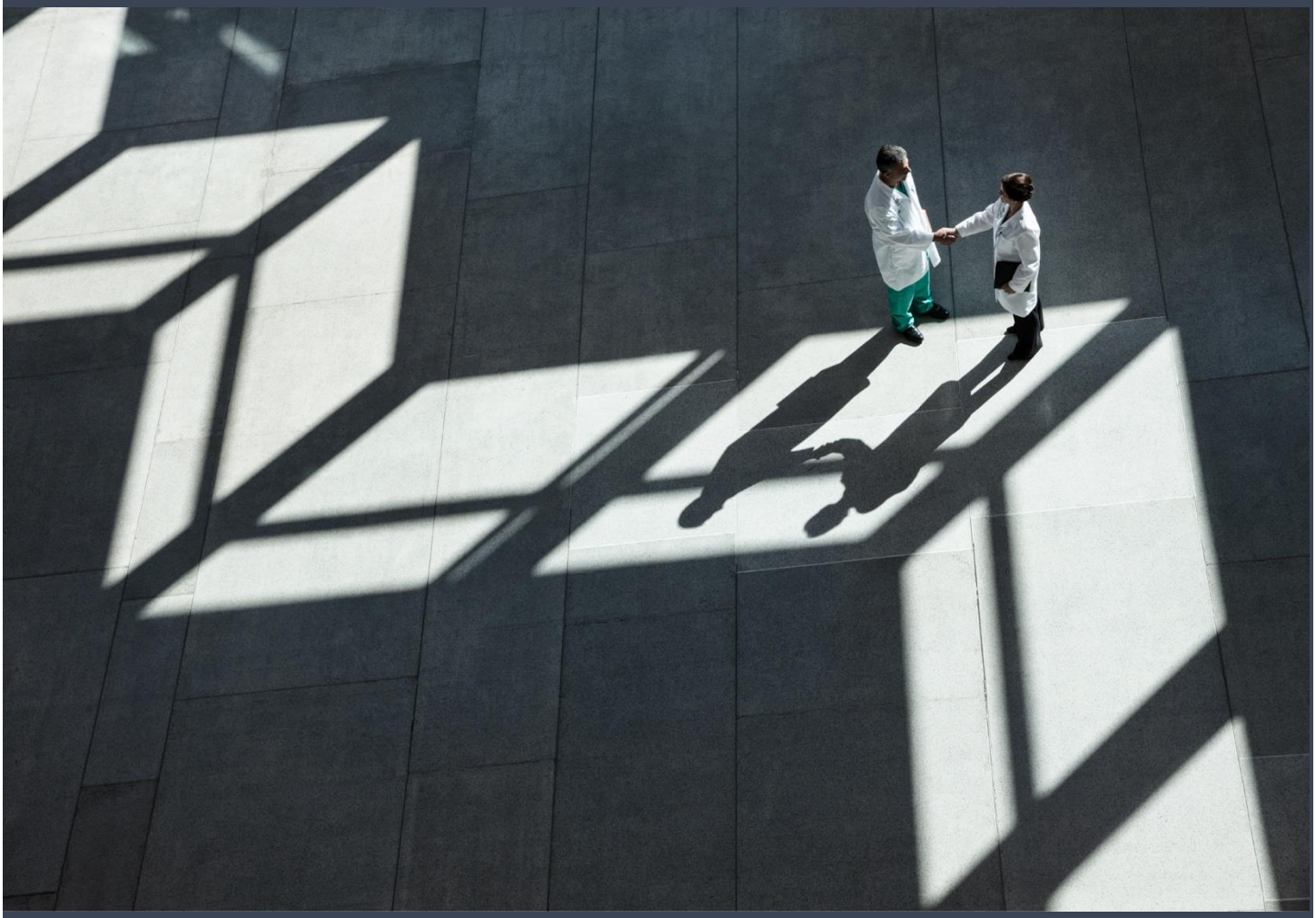

A RACE AGAINST TIME

Patents and Pandemic

Metacept® | InfoTech & IPR

About Us

Metacept® | Infotech and IPR started its journey on September 19, 2019 with the primary objective of creating a one stop platform dedicated to the enthusiasts of Information Technology Laws and Intellectual Property Rights Laws. We aim at promoting a diversity of viewpoints, ideas, and ideologies.

Metacept welcomes engagements from students, academicians, practitioners, early career researchers, policy-makers, and members of civil society organisations.

Over the past six months, Metacept has been able to create a niche for itself, and has been successful in creating engagements and making civilians aware of their rights, liabilities and risks in cyberspace. With a plethora of articles published on the site, ranging from mainstream issues to those relating to emerging technologies, every article is worth a read and thought provoking.

I owe my sincere thanks to Metacept's pillar of strength Shri Rodney D. Ryder, Founding Partner, Scriboard [Advocates and Legal Consultants], New Delhi for supporting us in all our endeavours and supplementing us with intriguing ideas. We are also obliged to have Shri Subhash Bhutoria, Partner Krida Legal, on our Advisory Board.

I sincerely hope that this handbook turns out to be a meaningful read for all of you!

I wish for the good health and happiness of all!

Nikhil Naren
Publishing Editor

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Introduction

"The idea of a better-ordered world is one in which medical discoveries will be free of patents, and there will be no profiteering of life and death" –Indira Gandhi.

Imagine a world in which a global network of medical professionals monitored for emerging strains of a contagious virus, periodically updated an established formula for vaccinating against it, and then made that information available to companies and countries around the world. Moreover, imagine if this work were done without any intellectual-property (IP) considerations, and without pharmaceutical monopolies exploiting a desperate public to maximize their profits.

This may sound like a utopian fantasy, but it is actually a description of how the flu vaccine has been produced for the past 50 years. In responding to the pandemic, the global scientific community has shown a remarkable willingness to share knowledge of potential treatments, coordinate clinical trials, develop new models transparently, and publish findings immediately. In this new climate of cooperation however, it is easy to forget that commercial pharmaceutical companies have for decades been privatizing and locking up the knowledge commons by extending control over life-saving drugs through unwarranted, frivolous, or secondary patents, and by lobbying against the approval and production of generics.

PATENTS AND THE PANDEMIC

A patent is a kind of an exchange between a national government and the innovator, wherein the innovator uncovers to the public precisely, how to reproduce the asserted invention e.g., an antibody. The patent is consequently given an eliteness period during which the inventor is free to pick by whom, where, when and how that particular innovation can be further made, utilized, and sold. Research & Development for a single diagnostic test, drug or vaccine require a lot of resources, and consequentially money. However, licenses in any case advance clinical and scientific innovation in pharmaceutical medications, and demonstrative tests far and wide by giving an approach to organizations to recover their expenses through restrictive assembling, dealing, and authorizing of their creations. Patents and Licenses generally permit the overall population to receive fundamental medications, which would have been, in some way or the other, improbable to have imagined or invented without the money coming from such patent licensing. As the COVID-19 pandemic continues wreaking havoc around the world, the world's biggest economies are competing a battle against time, as well as amongst themselves to find a definitive cure to this virus. COVID-19 has presented an entirely different contest than the world is usually subject to. The race to claim the patent rights to COVID-19 immunization. The race to emerge as a global leader in this pandemic. And the race to gain precedence in the war over Intellectual Property, and newer discoveries and inventions. Given the current worldwide political atmosphere, in any case, critics dread that a country's entitlement to control how and when a COVID-19 immunization is

appropriated may end up being employed in a very prohibitive way.[i] As of now, no vaccine or immunization for COVID-19 has been developed, which is market ready. However, a few pharmaceutical organizations in China, U.S. and Europe accept, that they are rather close to medications, which might prove effective in this war against COVID-19. European pioneers have over and again given confirmations that if any European lab is the first to create and patent an antibody, the immunization will be comprehensively authorized far and wide to guarantee access to help other helpless nations. Interestingly, China and the U.S. have been involved in a heated trade war (and exchange war) since 2018, encompassing China's absence of authorization of protected intellectual property rights and other innovation privileges of non-Chinese residents. However, the two countries have reacted to the coronavirus pandemic with solid patriotic sentiments. Specialists subsequently caution that if either China or the U.S. is first to create and patent an antibody, access to the immunization could be utilized as a political influence against the other. This could be disastrous for the world as a whole in the long run, especially in this time constrained battle against a virus, which seems to multiply and mutate faster, with each passing day. Subsequently, let’s have a look, over what this could mean for India, and what India could do to come out with its own solution over the same.

EVOLUTION OF THE PATENT LAWS IN INDIA

India's Patent regime can be categorized into three phases, i.e., Colonization, the Post-Independence era, and Globalization. Colonization is the period when India was a British Colony. The first patent statute was enacted by the Britishers in 1911, known as the Indian Patents & Designs Act, 1911.

In the post-independence period, i.e., after 1947, Britishers enacted foreign favoring patent laws that hampered the generic pharmaceutical industry in India. This period can be further divided into two periods: 1947-1970 and 1970-1995.

1947-1970

Due to strong IP protection to MNCs and extraneous patent laws, our country had to import even the basic medicines at extremely unaffordable prices. After independence, India had to look after a huge population of over 400 million people and had to further meet challenges like high infant mortality rate, poor healthcare services, quality education, water & energy sources, etc., which made it difficult for the country to focus on the Intellectual Property Laws. Thus, the Government was forced to rely on the existing Patent legislation. In 1949, the Indian Government formed a high powered committee headed by an eminent jurist of Lahore High Court, Mr. Bakshi Teg Chand, to review the existing law and suggest changes to it. The Bakshi Tek Chand Committee Report noted that the existing Indian patent law afforded "inequitably strong IP protection" to MNCs. This situation was blocking the Indian manufacturing industry in its infancy itself. The committee also observed that the patent act must include clear indication to ensure that food, medicine, surgical and curative devices are made available to the public at the lowest price by giving reasonable compensation to the patentee.[ii] The committee recommended

that the law must create a balance between social goals and economic goals by introducing compulsory licensing, commercial working of patented inventions in India, setting up of an appellate body, ensuring availability of food and medicine at cheap rates to the public, alongside ensuring reasonable compensation to the patentee.

In 1957 another committee was formed headed by Justice N. Rajagopala Ayyangar to revisit the patent act. The committee suggested to (a) reduce social costs of foreign-owned patents, (b) prohibit patents on products useful as medicines & food and encouraged process patents (the process used to manufacture the medicine is patented and not the product so that other companies can use a different process to make a drug and make it available to the general public at lower prices), (c) shorten the term of chemical process patents, and (d) significantly expand the availability of compulsory licensing.

All the changes by the committees mentioned above led to the introduction of the Patent Bill, 1965. The bill lapsed due to the dissolution of the Lok Sabha in the following year. The bill was finally passed as The Patents Act, 1970, and it came into force on April 20, 1972, along with Patent Rules, 1972. The Act of 1911 was repealed by the Act of 1970, but it continued to apply for designs.

1970-1995

When the Patents Act, 1970 came into force, it significantly diminished IP protection to MNCs, steering them out of Indian markets, and thereby giving way for domestic companies to fill in this void. Soon, the Indian Pharmaceutical Industry dominated the global business of reverse-engineered, highly cost-efficient generic medicines, which were sold at exceptionally lower prices compared to their foreign competitors and counterparts. The generic drug industry saw a sharp growth, whilst drug discovery took a hit in the 1990s.

In the 1990s, the Indian Government adopted the new economic policy of Liberalization, Privatization, and Globalization (LPG). With the adoption of globalization, the Indian economy opened its doors to foreign investment. As a result, India became a signatory to international trade agreements. It became a member of the World Trade Organization (WTO) and a signatory to the TRIPS agreement. This built a huge pressure on the Government to transform the Patent and

Intellectual Property law in accordance with the standards of the international community. But being a developing nation and in its aim to achieve dual objectives (social and economic goals), India was hesitant to adopt the strong IP protection provided to MNCs under the TRIPS agreement. But India was obligated to modify its domestic intellectual property laws in order to comply with the TRIPS agreement. However, TRIPS did provide a ten-year grace period to developing nations to configure their judicial systems and economies, to fully comply with the TRIPS agreement.

1995-2005

Complying with the various provisions of the TRIPS agreement required complete overhauling of India's Patent Law. India decided to bring these changes gradually and systematically in three separate Patent Amendment Acts in 1999, 2002, and 2005. There were key changes that took place in the amendment bill of 2005. It provided for product patent, made reverse engineering or copying of patented drugs without a license from the patent holder illegal, and provided a 20-year guarantee term of protection to patents under Article 32 of the TRIPS agreement. To protect the domestic pharmaceutical industry from the newly enacted provisions, the Indian policymakers decided to prevent ever-greening by MNCs and retained articles to allow compulsory licensing to ensure its social goals. India decided to retain pre-grant opposition and introduce post-grant opposition.

Ever-greening refers to tactics employed by the patent holder to exploit legal loopholes of patenting to extend monopoly typically over blockbuster drugs by either filing disguised or artful patents on previously patented invention just before the end of the term of the parent patent or employing other related regulatory policies.[iii]

SERUM INSTITUTE NOT TO PATENT THE COVID VACCINE

Covid-19 has ensued an unprecedented wave of public health and economic uncertainty all around the globe. There is not even a single person who hasn't been affected in some way or the other by this disease. The virus is said to be fatal, and the implications of lockdowns and social distancing haven't been able to contain the virus completely. The only way back to normalcy is to discover an effective vaccine for this virus, which is expected to be ready in a few months. The question remains though, over what will the unprivileged do if this vaccine is patented by the various companies which are putting so much money and resources into R&D? Coronavirus has not only impacted the rich but the poor as well, and if the vaccine is patented, the lower strata will have to face numerous difficulties. In such a scenario, all the companies working to discover the vaccine must realize their social responsibility towards the humanity at large. If all companies consider it their responsibility to make the vaccine available for every person on this planet, we can surely defeat the virus. Recently, Serum Institute of India has declared that it is not going to get the vaccine for COVID-19 patented and has further urged the industry competitors to do the same. The aim of the industry must be to ensure easy and in-bulk availability of the vaccine at a time when entire human population is combating the deadly pandemic. This is a welcoming decision by the Serum Institute, for it has stepped forward and rebuked the idea of hiding behind patents and making millions in exchange for the precious lives of the poor.

WHETHER THE TRIPS AGREEMENT IS A BENEFICIAL BARGAIN OR NOT

Before the TRIPS agreement, the generic drug industry was at its peak. After the implementation of the Patents Act, 1970, the Multinational companies diminished, and the domestic market increased production of generic drugs leading to a reduction of prices. Although the TRIPS agreement has also lead to increased R&D on diseases and their cure, these benefits can be obtained in alternative ways too, without attaining high costs. Thus, the TRIPS agreement is not really in our national interest. Hence it is not a beneficial bargain.

However, the TRIPS agreement cannot be completely criticized. It incorporates various provisions that aim to achieve a balance between rights and obligations, thereby providing a way to attain public policy goals, including access to essential drugs.

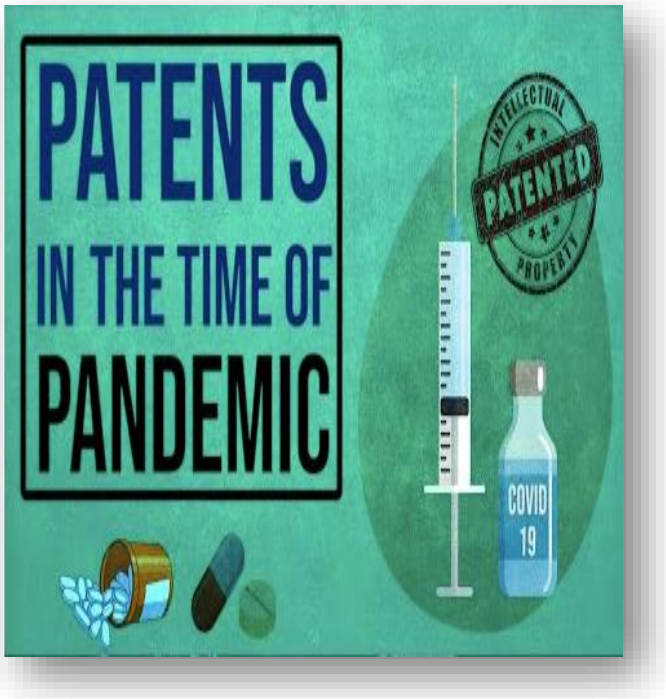
- Article 7 aims to achieve a balance between innovation and social and economic welfare.
- Article 8 gives autonomy to states to take measures to protect public health.
- Article 27(2) allows a State to restrict the patentability of inventions on various grounds, such as a threat to human life or health.
- Article 30 of TRIPS agreement provides that the WTO members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with the normal exploitation of the Patent and do not unreasonably prejudice the legitimate interests of the patent owner, provided that the legitimate interests of third parties have been taken into consideration.
- Article 31 lays down a list of provisions applicable in all situations where the law of a WTO Member country permits use of the subject-matter of the Patent without authorization of the patent-holder.[iv]

Thus, the TRIPS agreement not only provides for stronger IP protection and introduction of product patents in developing countries, but it also addresses various issues faced by these nations to make it beneficial legislation.

PATENTING SCENARIOS AROUND THE WORLD

This area sets out in solid terms some practical solutions, in view of experimental discoveries from an underlying audit of real patenting actions. No supposition is made regarding the legitimacy of the licenses or patents.[v]

PATENTING OF A FLU-VIRUS



A patent is being looked on for a flu-virus, accordingly evaluating its patentability would typically involve applying tests like the below given agendas:

Subject matter for patent: Can an infection or virus as such be bought under a category, so as to provide it patentability? For instance, is a particular virus or infection conceived as a microorganism; are licenses and patents precluded against hereditary materials in the structure happening in nature?

Novelty for patenting: Has data about the virus or infection been distributed or revealed in a structure, which makes it accessible to general public?

Do moral or other public order related issues apply? For example, would it be in opposition to ethical quality or well-being, to popularize or promote an infection or a virus, for instance, say a virus hereditarily built to be particularly pathogenic?

What 'innovative advancement' or non-clear demonstration of development with respect to the asserted creator prompted the invention of that particular virus? For example, is there a demonstration of creation more noteworthy than basically portraying an infection or virus that occurs in nature?

What characterized utility or modern application has been found for it?

PATENTING OF A BARE-GENE SEQUENCE

A wild flu-virus is grown/discovered and its genome, or a segment of it, is sequenced. A patent is being looked for, on a grouping distinguished inside the virus: For example, a case is coordinated to explicit DNA or RNA grouping or arrangements. Assessing and analyzing its patentability would ordinarily involve applying tests like the below given questions:

Is simply the DNA or RNA arrangement subject to a patent? Does it pass through the assessment for it to be called an invention so as to get patented?

What's more, does it repudiate explicit special cases, for example, for normally happening hereditary material?

Do moral or other public order related issues apply?

Is the gene grouping and sequence novel, or has it been unveiled previously, for example, in a gene data-bank)?

Was the recognizable proof of the gene sequence really inventive? Was it evident to the individual talented in the workmanship to infer the revealed arrangement of the gene sequence?

What characterized utility or mechanical application has been distinguished for the gene sequence?

PATENTING OF A TRANSFORMED GENETIC MATERIAL WITH A HELP OF A VIRUS SPECIMEN

A wild influenza virus is gathered, and the sample containing that gathered virus is transmitted to a scientist who utilizes its hereditary material while making a hereditary structure, which has all the earmarks of being conceivably valuable for a finding or an antibody creation – for instance a virus like molecule or a peptide chain that is innocuous yet has antigenic impact. An agenda of issues related to it could include:

Is simply the hereditary structure of the gene new, as in, it had not been freely uncovered to the general population previously, regardless of whether its cause or parts have been revealed to the general population?

Was the making of the new hereditary structure of a transformed genetic material genuinely new and is an invention? Was it evident to the individual talent in the craftsmanship to make this structure for the planned reason? For example, was there a startling impact, negating regular desires?

What characterized utility or mechanical application was recognized for the new invention of this transformed genetic material? Is it revealed so as to help an able skilled man to make duplicate of the guaranteed outcome? Is the creation asserted so that all structures fitting inside the patent case would have the ideal impact?

Is the scientist bound by and obliged to lawful commitments emerging from access to that invented genetic material? For example, a particular agreement overseeing the utilization and any application for licenses on innovations? While this would not influence the patentability of the innovation but, it might decide the privilege of the candidate to look for or to hold a patent.

PATENTING OF A TRANSFORMED GENETIC MATERIAL WITH THE HELP OF A SEQUENCE DATA

A wild flu virus is gathered, and its arrangement decided and reported. The distributed arrangement is then utilized by a different analyst in developing another hereditary structure, which is conceivably helpful for determination or immunization creation. An agenda of applicable issues could include:

Was the grouping of a gene sequence, accessible to people in general here? Whether the patent application was documented – at the end of the day, was it then a piece of the 'earlier workmanship' against which the innovation's curiosity is surveyed? Is the hereditary structure, asserted as an innovation, particular from the distributed quality succession, in the feeling of placing new data in the open space, past the original grouping of the sequence?

On the off chance that the invented gene sequence had been distributed at the hour of the development, was it evident in the light of foundation information around then to make the guaranteed hereditary structure? Was this basically following set up methods with unsurprising outcomes, or was making of the new gene sequence structure genuinely imaginative? Was it evident to the individual gifted in the craftsmanship to make this structure for the proposed reason? For example, was there a sudden impact, negating regular desires?

What characterized utility or modern application was distinguished for the new hereditary structure? Is it unveiled so as to be possible to make it's duplicate? Is the development guaranteed so that all structures fitting inside the patent case would have the ideal impact?

PATENTS RIGHTS & EXCEPTIONS

PATENT'S RIGHTS

As discussed above, the patent is an intellectual property, so it gives the owner a large number of rights over others. The rights which a patent holder has can be enforced only after securing the patent. Patent restricts others to make use, offer for sale, sale or import the patented product. The patent holder also has the right to decide whom to give patented invention for the time period. Even the patent holder can gain the edge from the competitors who are using patented invention unlawfully by issuing a court order known as injunction.[vi]

PATENT'S EXCEPTION

The exceptions sometimes become necessary so that things which are patented can be used in a proper sense. These exceptions are made for the purpose of things which have got patented, such that then too, there use can be made in a proper sense and no monopoly in the market can be established by a particular entity just because of their patent. For the substantial development of their countries the government has adopted exceptions to the patent rights. The exceptions which

can be made can't exploit the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with normal exploitation of the patent and does not unreasonably prejudice the legitimate interest of the patent owner, taking into account the legitimate interest of the third parties. The exceptions which are followed by India are the result of it being a signatory of the World Trade Organization's Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). Article 30 of TRIPS allows for limited exceptions to the exclusive rights conferred by a patent.[vii]

PRIVATE AND NON-COMMERCIAL USE EXCEPTION

The exclusive rights conferred by a patent does not allow the private use or monopoly over commercial activity. If a patentee is neither using nor vending the invention for profit, the Government has the power to grant a license, known as Compulsory License (CL), to a third party to use the patented invention so as to restrict the rights of the patentee for the purpose of preventing the abuse or misuse of the rights by the property holder and to prevent the negative effect of such action on the public. It is done primarily such that there can be no monopoly in the market for a particular entity. This is also done when patent holder is reluctant to pass the right of the patented invention to the next person. The private and non-commercial use exception are provided under Section 84 (Compulsory licenses), Section 85 (Revocation of patents by the Controller for non-working) and Section 92 (Special provision for compulsory licenses on notifications by Central Government) of Patents Act, 1970

The government can grant compulsory license in some circumstances only, like if the patented invention is yet not commercialized in India or it has not been available to public for a reasonable price or its invention is not manufactured in a requisite amount, etc. Currently in India this is seen as an optimum solution and is used when there is an extreme need for it.

EXPERIMENTAL & SCIENTIFIC USE EXCEPTION

Under this exception the grant of a patent is subject to the condition that any product or process, in respect of which the patent is granted, may be made or used by any person for the purpose merely of experiment or research including the imparting of instructions to pupils. The idea behind

this exception is that the things should not be commercialized and should not hamper experiment or research at same time. This is incorporated under Section 47 of Patent Act, 1970.

This is the most widely known, and used exception. This use of this exception has only increased with the passage of time. The main intent behind this exception is to not put any hamper on the "bona fide" experiments and scientific processes. This form of experimental use exception permits third parties to carry out experimental or scientific activities relating to the subject matter of the patent without infringing upon the rights of the patent holder. With respect to the recent developments in the scientific activity this exception is widely used.

REGULATORY-USE/ PRIOR-USE EXCEPTION

This exemption is also referred to, as the Bolar Provision and this is a statutorily created exemption to the patent rights that exclusively allows the manufacturers of a generic drug to undertake steps that are reasonably related to the developments and submission of information related to obtaining marketing approval anywhere in the world with respect to the patented product without the consent of patentee. This in a way harms the rights of patentee, but when allowed as it is, can lead to benefits in the long term. This is done because patents provide economic incentive to innovate, but on the other hand patent holder has the exclusive right to monopolize its product. The exception is used to avoid such situations in pharmaceutical industry.[viii]

This provision allows the generic producers to market and manufacture their goods as soon as the patent term expires. Bolar Provision has been upheld as conforming to the TRIPS agreement and is used in several countries to advance science and technology.

FOREIGN VESSELS, AIRCRAFT OR LAND USE EXCEPTION

According to this exception patent rights are not infringed when the patented invention is used exclusively for the needs of foreign vessels, aircraft, or land vehicles and other accessories thereof, when such foreign vessels, aircraft, or land vehicles temporarily or accidentally come into India. This exception wasn't initially inscribed in the Indian Patents Act, but was laid down as per Article 5 of Paris Convention, as this exception was not optional for the country. Regardless, being a part

of the convention and in order to comply with this exception they have incorporated it under Section 49.

EXHAUSTION OF PATENT RIGHTS

The Doctrine of Exhaustion or First Sales Doctrine refers to the exhaustion of the exclusive right of the patent holder once the patent invention is sold without any restriction. As per this Doctrine the first unrestricted sale of a patented item exhausts the patentee's further control over that particular item.

The reason behind the patent holder exhausting their rights once they have sold the patented product is that, first, by sale of the patent invention, the Patent holder has already used the exclusive rights to prevent others from making, using, selling, offering for sale in the territory of patent grant or importing an invention into the territory of patent grant and therefore has already reaped the benefits conferred by a patent.

COMPULSORY LICENSING OF PATENTS

Amidst the ongoing pandemic because of COVID-19, numerous nations are presenting Compulsory Licensing solutions to negate the crisis, and slow down its growth. India being a Compulsory Licensing system from the very beginning, has laws to deal with the crisis, and license things which are important. That being said, a few nations lack any such system, which could help them deal with situations, which require mandatory authorizing set up.

MEANING

The Patents Act, 1970 was amended in 1999, 2002, 2005 to incorporate the idea of 'compulsory license' i.e. mandatory permit, and these provisions have been dealt with under Sections from 84-92 of the said Act. Compulsory licensing is an approval by a sovereign state to permit a third party to make, use, sell or potentially disseminate an item which has been patented, without getting the assent or the unequivocal consent/permit of the patent proprietor. Sections relating to compulsory licensing are also governed internationally by the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement, among all the member states of the World Trade Organization (WTO). In spite of the fact that this provision works against the patent holder, for most part, the provision of compulsory licensing is considered rarely, in specific instances of health crisis, and/or national emergency. There have been provided, some pre-requisite conditions which should be satisfied if the Government needs to concede an obligatory permit for somebody under the Indian Patents Act, 1970.

PRE-REQUISITES FOR COMPULSORY LICENSING

Chapter XVI, S.84 and S.92 of the Indian Patent Act, 1970 govern the provisions of Compulsory Licensing in India.

U/S 84, any individual, following three years from the date of award of a patent, can apply for an application for award of an obligatory permit or a compulsory licensing, on any of the accompanying grounds:

a) The sensible prerequisites of general society regarding the patented innovation have not been fulfilled;

b) The patented creation isn't accessible to the general population at a reasonably moderate cost.

c) The patented invention has not worked in the region of India.

U/s 92(1)(4) of the Indian Patent Act,1970, in the event of a National Emergency, in conditions of outrageous earnestness, or if there should arise an occurrence of an open non-business use, the Government of India, whenever satisfied, may give Compulsory Licenses in regard of any patent in power.

Any individual after such declaration, may apply to the Controller for a necessary permit, which will be allowed with no delayed procedure. The Controller, in any case, will try to make sure that the articles produced under the patent will be accessible to the general population at the most minimal costs, ensuring that the patentees get a sensibly favorable position from their patent rights. Moreover, Section 100(5) of the Indian Patents Act, 1970 permits the Central government to give explicit organizations, approval to utilize any licenses or applications pending award of patent for the "purpose of government". Section 100(3) of Patents Act, 1970, further states, that if the Central government or any organization so approved fails to agree with the patent proprietor regarding the measure of eminence, a reference to the High Court might be made under Section 103(6) of the Patent Act, 1970. The High Court will thereby fix the sensible eminence that is payable to the patent proprietor. The Center would thus, be under an obligation to inform the concerned patent proprietor in such a circumstance at the earliest, aside from, on account of National Emergency, in conditions of extraordinary direness, or if there should arise an occurrence of public non-commercial use.

Finally, the Central government, u/s 102 of the Patent Act, 1970, may basically obtain the licenses being referred to alongside their reserve. Upon the receiving of the Gazette Notification, much like a notice for land procurement, the new invention or patent and all rights regarding it will stand moved to, and be vested with the Center.

WORLD-WIDE PERSPECTIVE ON GRANTING OF COMPULSORY LICENSE

Most of the developing nations are opting for necessary authorization, as a result of the inaccessibility and exorbitant prices of the medicines, which are prevalent in such markets. While the developed nations like U.S.A and Europe are restricting this view as it would make advancement hard for the pharmaceutical organizations, their developing counterparts are consistently allowing an ever-increasing number of compulsory licensing of the aforementioned products.

However, in a crisis situation like this, compulsory licensing can act more as boon, than as a bane. On March 19, 2020, Israel gave mandatory patent licenses identified with Lopinavir/Ritonavir (brand name Kaletra), a medication used to treat HIV, which as referenced above, is at present being tested for viability in the treatment of COVID-19 in blend with different medications. The permit allows the importation of lopinavir/ritonavir from a nonexclusive organization.[ix]

On March 25, 2020, the COVID-19 Emergency Response Act got the Royal \Consent in Canada. The Patent Act was revised, to acknowledge corrections to include the area of utilization of licenses by the government, giving another obligatory authorizing system.[x]

CURRENT SCENARIO IN INDIA

Shortage of PPEs like N-95 masks, three ply masks and other important protective gear is being faced by India. With the raw materials costs sky rocketing because of the pandemic, and some getting resources becoming inaccessible, India might be compelled to accept exceptional measures as expressed previously. This would surely result into an enormous push-back from the Big Pharmaceutical giants, who reserve most of the patents around the world and are the patent

proprietors in most of the cases. Subsequently though, the organizations do indeed need to fix the expense of their protected module as indicated by the monetary status of the nation, on the off chance that they need to shield their item from obligatory permitting i.e. compulsory licensing. In spite of the fact that India has just passed one mandatory permit yet, the quantity of compulsory licenses allowed overall is on the ascent.

SOME INDIAN AND INTERNATIONAL CASES OF COMPULSORY LICENSING

BDR PHARMACEUTICALS INTERNATIONAL PVT. LTD V. BRISTOL-MYERS SQUIBB CO.[xi]

In BDR Pharmaceuticals, the controller rejected BDR's application for a compulsory license (4 March, 2013) for the Bristol-Myers Squibb cancer drug SPRYCEL. The controller rejected the compulsory license application, made by BDR by stating that BDR had failed to make a *prima facie* case for the grant of the compulsory license. The controller observed that BDR had made no credible attempt to procure a license from the patent holder and the applicant had also not acquired the ability to work the invention to public advantage. Thus, the request for grant of the compulsory license was refused.

EBAY V MERCEXCHANGE[xii]

The U.S. Supreme Court issued an opinion in *eBay v MercExchange*, which set the standards under which a court should evaluate requests for injunctions to enforce a patent owners' exclusive right to authorize the use of a patented invention. To get an injunction, a patent owner must show the court:

1. That it has suffered an irreparable injury.
2. That other possible legal remedies, including the payment of royalties are inadequate to compensate for that injury.
3. That the public interest would not be disserved by a permanent injunction.
4. That considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted.

Under this standard patent, a court can choose to issue a compulsory license to use the patent, rather than enforce the exclusive right, a path that has been taken several times since May 2006.

TRANSWRAP CORP. V. STOKES & CO[xiii]

In ***Transwrap corp. v. Stokes & Co.,*** a patent licensing agreement granted an exclusive license to manufacture and sell in the United States, Canada and Mexico, a patented machine under the patents then owned or later acquired by the licensor, subject to a condition that the licensee assigned to the licensor, any improved patents applicable to the machine and suitable for use in connection with it. It was for the very first time in this case that the United States exclusively allowed compulsory licensing in the event of exclusive grants back.

IMS HEALTH V. NDC HEALTH[xiv]

The former had copyrights over certain pharmaceutical data, and refused the grant of the license to top competitors. The European Court of Justice held that, IMS health should grant the license of the pharmaceutical data to NDC health. The reason laid down by the European Court of Justice was the application of doctrine of essential facility to the said patented data, as per which it was dominant industry principle. Moreover, the other customers also needed the pharmaceutical database to provide the service value to the customers, and thus, the exceptional circumstance was created which was earlier held in Magill's case.[xv]

NATCO V BAYER CASE[xvi]

India's first ever compulsory license was granted by the Patent Office on March 9, 2012, to Natco Pharma for the generic production of Bayer Corporation's Nexavar, a life-saving medicine used for treating Liver and Kidney Cancer. Bayers sold this drug at exorbitant rates, with one month's worth of dosage costing around Rs 2.8 Lakh. Natco Pharma offered to sell it around for Rs 9000, making it affordable for people belonging to every stratum. All the 3 conditions of Section 84 of the Indian Patents Act, 1970 were fulfilled and the decision was taken for the benefit of general public.

LEE PHARMA V ASTRA ZENECA[xvii]

In this case, Lee Pharma, a Hyderabad-based Drug manufacturer, filed a Compulsory Licensing Application in accordance with Section 84(1) of the Indian Patents Act, on 29th June 2015. The Compulsory Licensing application was made against one of the patented drug "Saxagliptin" used in the treatment of Diabetes Mellitus. The Patent on Saxagliptin was granted to Bristol Myers Squibb (BMS) in India on 30thApril 2007 which was assigned to AstraZeneca by way of Deed of Assignment. Lee Pharma alleged that AstraZeneca had been importing the drug at less than a rupee but charged as much as Rs 45 for each tablet, driving up the cost of therapy beyond the reach of most Indian patients. It also contended that AstraZeneca had not made sufficient efforts to make the drug in India, running in contravention to the existing patent laws of the country. The Controller however found that, a *prima facie* case could not be made out for making an order under Section 84 of the Patents Act and issued his decision on the 12th of August, 2015 in favor of AstraZeneca.

EMCURE PHARMACEUTICALS V. ROCHE[xviii]

In the case of *Emcure Pharmaceuticals v. Roch*e, a compulsory licensing attempt was made for Roche's Drug "Trastuzumab" commonly known as Herceptin. However, the Department of Industrial Policy and Promotion (DIPP) denied the Ministry of Health in proceeding with this application, which had made a request under Section 92 of the Patents Act, 1970, which allows for the government to file for a license in cases of National Emergency.

SOCIAL RESPONSIBILITY IN THE TIME OF COVID-19

At a time when the whole world is struggling with this life threatening pandemic, it is important to discuss the need to be prudent, and exhibit traces of Social Responsibility, instead of trying to reap benefits from the pain of the people. The virus has already taken many lives so far and has continued to wreak havoc, especially in a developing country like ours. When the whole world is working and experimenting to find a vaccine to this virus in order to curb the effect of this virus, it is important that rapid responsiveness takes precedence over competitiveness and commercialization.

Now, with respect to the pattern we follow for patenting drugs the inventor is granted rights over the patent for a definite period of time. This often creates a monopoly in the market for some duration. This monopoly sometimes acts as a motivating factor, since it creates incentives for companies to invent new products, by letting them charge whatever price they want in the free market. This approach can be good for generic drugs or for those drugs that are common and can be made available easily.

Same approach cannot be used for the vaccine of COVID-19 though, which is a pandemic and whole world is fighting against it. All the companies are working very hard to find a vaccine for COVID-19 but it is a fact that one of companies will get their first and there are chances that other companies might take some time. There may be cases that the companies will receive nothing for their work, effort and time, and in all likelihood, a law suit alleging patent infringement will be abound.[xix] This means that in these difficult times where all the nations are fighting against this deadly virus, they might also have to fight against the attempts to establish monopoly by various companies, over a product which is desperately needed by everyone right now. Many countries are willing to pay huge sums for this vaccine.

At this point, when the whole world is in a desperate need of a COVID-19 vaccine, it is the responsibility of the governments to work together and pool their resources, such that the chances of the development of a vaccine can propagate and grow. This can ensure not only the welfare of one nation but the welfare of the humankind, as a whole. Moreover, if we engage in the

nationalistic competition of vaccine at this crucial moment, then all humankind will be harmed where government and inventor will try to seek monopoly over a health product which is desperately needed by all the nations.

If we as responsible citizens are expected to show cooperation in these times of crisis, then the governments too should look for a way to work together instead of engaging in destructive economic nationalism and relying on a patent system. The deploying and enforcement of such patent based regulations at this crucial time will cost us more than we tend to gain from such commercialization, in the long run.

CONCLUSION

A Patent is a part of Intellectual Property, the statute of which was first adopted in the year 1911, known as the Indian Patents and Design Act, 1911. After India gained independence, it had to face certain issues, with respect to the monopolization of the market, because of the loosely drafted patent law, which had resulted in high prices, for even some of the most basic commodities, that we take for granted today. Accordingly, to deal with the same, time India adopted the Indian Patent Act, 1970 which tried to amalgamate both social and economic goals. In 1990s, when India adopted the new economic policy of Liberalization, Privatization and Globalization, it lead to changes in Patent Law. India became a member of World Trade Agreement (WTO) and a signatory to the TRIPS agreement. This lead to a lot of changes in the Patent Law and made it compliant to the international standards.

For a developing country like India, to be a signatory to the TRIPS agreement had its own sets of advantages, but at the same time, disadvantages. Although it gave many rights to the patent holder, but at the same time there were exceptions to these rights for using the patents in a correct manner. In a way there are many pros and cons for India to be a part of the TRIPS agreement, but they provide stronger protection to IP and also address the issues faced by these nations in making it a beneficial legislation.

Now coming to the concerns which are arising everywhere about the patent of a COVID-19 vaccine. In a way, in these times of crisis, getting a product patented can create a situation of monopoly in the market for one of the most essential products at this crucial time. At this point of time, the said product is required by every nation because this deadly virus has impacted everybody. Thus, it is time, that we put our differences aside, and for once not think of economic gains, and rather come together for the betterment of humanity. Recently, institutes which are busy developing the vaccine of this virus have declared that they are not going to get the vaccine patented and have also urged the other industry giants and counterparts to do the same. This provides us with a ray of hope, that one day, when the vaccine comes out, then whole world is not going to engage into a legal war for getting it patented but will think of the welfare of all of humankind for once and ensure the easy availability and affordability of this vaccine.

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