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ACCESS TO LIFE-SAVING DRUGS: SCOPE OF IMPROVEMENT

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Abstract

Improvements and innovations have changed the entire healthcare system of the world. We now even know about stem cells and its benefits. But when we think of the time in 20th century, diseases like Cancer, Tuberculosis etc. were incurable. But in today's world we have thousands of facilities and medical formulas to treat them. However, almost 10 million people died of cancer in the year 2020. The fact here is that we have achieved heights of knowledge but we fail to avail them. Extensive researches have been conducted throughout these years to innovate medicines that could save the life of humans. Despite such creations people continue to die due to lack of access to those medicines. Current patent regime fails to clear the clutter, rather it fuels them. Association of human rights has by far provided no help. This paper unveils the issues and challenges faced by people due to abuse of patent law by pharmaceutical giants. Increased rates and prices in addition to the monopoly created by the grant of patents (for life-saving drugs) have led to static inefficiency, which seems to be non-curable using the current patent legislation. This paper will have us dig into the history and analysing whether associating human rights has helped us solve this situation or not? There are certain flaws in the Patent law regime and also a need to protect the interest of our society as a whole. What will be the potential solutions of retooling of the same so that it is competent, capable, and efficient enough, by in itself, to cater to every falling possibility in front of it?

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INTRODUCTION- THE ISSUE WITH ACCESS TO THESE MEDICINES

Deaths due to infectious disease are one of the primary and major causes of death around the world, particularly in developing nations and under-developed or low-income countries[3]. Millions of people die annually due to these infectious diseases[4]. While on the face of the matter it can be said that these diseases can be cured with the help of these certain life-saving drugs, but the fact remains that this can only be done if these people had access to those medicines[5]. The crux of the matter is that the benefit of such drugs can only be availed if they are genuinely available to the public who are in need of the product, instead of it merely being a privilege. The irony lies here, where these drugs were essentially made for the benefit of the entire mankind and yet the patenting of these very essential drugs has become another major reason for the retrogression of this very mankind.

Increased rates and prices in addition to the monopoly created by the grant of patents (for life-saving drugs) have led to static inefficiency, which seems to be non-curable using the current patent legislation. Not to forget that patents were introduced in order to procure and safeguard the ideas, innovations, and potentials of individuals and society, but it appears that they have now metamorphosed into a beast that is not only deteriorating the original aim but is much faraway from achieving the real objective for which legislations for Intellectual Property were created[6].

Recent incidents clearly indicate how granting of patents has transformed into laws and restrictions that tend to snatch away people's right to health. It is not a long-gone incident when India was hit by the second wave of the COVID-19 pandemic, and everyone infected by the virus was giving their best shot to get the one "miracle" drug called Remdesivir. Although it is not clear that Remdesivir is a life-saving drug or not, the fact that doctors were recommending Remdesivir injections to COVID patients is true and must be brought to light here. The higher demand for the injection was partly due to the huge number of rising COVID cases and partly due to manufacturing and supply issues. Apparently, there are seven manufacturers of the drug

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[3] BAYLOR COLLEGE OF MEDICINE, https://www.bcm.edu/departments/molecular-virology-and-microbiology/emerging-infections-and-biodefense/introduction-to-infectious-diseases#:~:text=Infectious%20diseases%20are%20a,variety%20of%20infectious%20agents (last visited on Aug 26,2021)

[4]WORLD HEALTH ORGANIZATION, https://www.who.int/news-room/fact-sheets/detail/the-top-10-causes-of-death (last visited Aug 26,2021)

[5]WORLD HEALTH ORGANIZATION, Access to medicines: making market forces serve the poor, https://www.who.int/publications/10-year-review/chapter-medicines.pdf

[6]Akansha Mehta, Patenting of Life Saving Drugs has created a global health crisis where human life has become a commercial commodity, LSE IMPACT BLOG, (Aug. 26 2021, 5.33 P.M.), https://blogs.lse.ac.uk/impactofsocialsciences/2014/08/06/the-morality-of-patenting-life-saving-drugs/#:~:text=potentials%20and%20fulfilments.-,Unfortunately,-%2C%20applications%20of%20the

who despite increasing their production of the drug were not able to meet the demands for the drug[7]. Things and situations worsened when the demand increased and along with so did the prices for the drug, which further led to the creation of black markets and a handful of people taking advantage of the situation. Situations could have been said to have gone so out of control that people were forced to pay almost five times the M.R.P. for the drug which would in normal situations have just cost them Rs. 900[8]. With people dying on one side and protection of IPR on the other, what should ideally be chosen? Still remains one of those questions which the existing legislations fail to answer.

Humira is one of the world's top-selling drugs which helps in treating diseases in the ambit of arthritis and other chronic situations, but the irony of the condition lies in the fact that this drug is blocked or checked upon by almost 132 patients since the year 2002 (for almost a period of 39 years).

Cancer is one of the deadliest diseases out in the world. For the treatment of the same, a drug called Revlimid is prescribed. The point to be highlighted here is that the particular drug is protected by 96 patents in total and provides for 40 years of no competition.

Lantus which is a drug used to cure Diabetes in patients who rely on insulin treatment has 49 patents for its usage[9].

We are living in a world where patents have lost their aim and identity. Can human rights be of any help in such a tense situation? Are situations going to remain the same? Will the general public keep on suffering due to the war between the grant of patent licenses for essential drugs

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[7] THE ECONOMIC TIMES, https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/crisis-over-shortage-of-remdesivir-fabiflu-to-end-by-next-fortnight/articleshow/82340650.cms?from=mdr#:~:text=fortnight%20in%20India.-,%22An%20unprecedented%20surge%20in%20demand%20of%20some%20crucial%20medicines%2C%20used%20in%20treating%20Covid%20patients%2C%20has%20created%20a%20mess.,-Now%20companies%20like, (Aug 26, 2021)

[8] Prabhjote Gill, The utter chaos and confusion over Remdesivir in India is making the second wave of covid-19 worse, THE BUSINESS INSIDER INDIA (Aug. 26, 2021, 5:46 P.M.), https://www.businessinsider.in/science/health/news/remdesivir-injection-price-jumps-five-times-as-covid-19-cases-rise/articleshow/82083414.cms#:~:text=Remdesivir%E2%81%A0%20%E2%80%94%20currently%20a%20drug%20of%20last%20resort%20against%20the%20novel%20coronavirus%E2%81%A0%20%E2%80%94%20has%20become%20a%20hot%20property%20with%20its%20own%20black%20market%20where%20it%20could%20cost%2C%20sometimes%2C%20up%20to%20five%20times%20the%20price

[9]Erik Komendant, Pharmaceutical Patent Abuse: To Infinity and Beyond, ASSOCIATION FOR ACCESSIBLE MEDICINES (Aug 26, 2021, 5:50 P.M.), https://accessiblemeds.org/resources/blog/pharmaceutical-patent-abuse-infinity-and-beyond#:~:text=The%20world%E2%80%99s%20top-selling%20brand%20drug%2C%20Humira%2C%20treats%20arthritis%20and%20other%20chronic%20conditions.%20On%20the%20market%20since%202002%2C%20132%20patents%20block%20competition%20for%20up%20to%2039%20years

and their very basic fundamental right to health? The primary tiff lies in what ought to be done and what is done and that who is to bear consequences of the same.

Another point to be highlighted here is that on average there are 71 patent licenses granted in respect to only one drug with over[10], 125 applications for the grant of a patent which are filed for the same. In relation to which prices of drugs have hiked by almost 68% since the year 2012 and only out of the topmost 12 selling drugs, only one drug can be said to have its price decreased on an average[11]. In regard to the monopoly of drugs in the market about double of the 20 years monopoly seems to be intended by the US patent law, it can be said that at least 38 years of patent protection is attempted thereby blocking the industry and market competition[12], which is applied for, by the generic drug makers for each of the top-grossing drugs. This clearly means that the common man is, unfortunately, to face the harsh consequences of this blockage in the market, as increased prices and monopoly of certain drug makers is a direct implication of granting of Patent licenses for essential drugs, thereby making the weaker section inaccessible to essential drugs at affordable prices and fall prey to the monopolization of drugs by advantaged ones.

WHAT SHOULD PREVAIL BETWEEN HUMAN RIGHTS AND PATENT RIGHTS?

How come we labelled this lack of access to life-saving drugs with Human Rights? To find the answer to this question we will have to dig into the history. All of it started in South Africa, during the AIDS outbreak in the country when thousands and millions of people died due to lack of access to anti-retroviral drugs[13]. When these Africans were dying some of the developed nations decided to deny them access to these drugs, such as the society we live in, because they were not willing to sell those drugs at lower prices. However, some lives were saved after gaining a lot of international political attention which ensured that these lives were saved at all costs, without letting these monopolies getting in their way[14]. But now as it seems required for us is to understand whether associating human rights has helped us solve this situation or not?

[10] I-MAK, https://www.i-mak.org/wp-content/uploads/2018/08/I-MAK-Overpatented-Overpriced-Report.pdf (last visited Aug. 26, 2021)
[11] *Id.*
[12] *Id.* at 6.
[13] S. Thambisetty, Improving Access to Patented Medicines: Are Human Rights Getting in the Way? , 3 LSE Law, Society and Economy Papers, 2 (2018), www.lse.ac.uk/collections/law/wps/wps.htm and the Social Sciences Research Network electronic library at: https://ssrn.com/abstract=3130703
[14] *Id.* at 2.

Farida Shahid the UN General Rapporteur (in the field of cultural rights) once said that "where patent rights and human rights are in conflict, human rights must prevail"[15]. No doubt those human rights should be given higher importance when it comes to saving people's lives from diseases and patent monopolies. Again this leads us to ask another good question, can we really establish a hierarchal system here when both of these rights generate from widely different platforms and have varying reach? Patent rights and human rights are two distinct approaches and, therefore, associating both of them together and then establishing an entire system of hierarchy would not be beneficial. I would like to support this statement with the help of a current example- the TRIPS waiver initiated by the Indian Prime Minister and South Africa. They have demanded a waiver of IP Rights in case of the COVID vaccine, which is justified while following the hierarchal system where we are, ought to put human rights to health over everything. Soon after it was proposed it gained a confidence vote by the second and third world countries, whereas, European Nations seemed to disagree. However, United Nations seem to agree with the proposal of waiver of TRIPS[16]. European Nations are disagreeing with this motion because they will not be able to draw the required economic incentives if they allowed the waiver. Apparently, the hierarchal establishment seems to distort.

Therefore, in the view of this article, this establishment could not be the solution for improving the access to life-saving drugs. These parallel rights cannot be treated together and, thus, we need a different system where none of the parties have to compromise and settle for anything less than what they deserve. Talking historically, Patent rights or any other Intellectual Property rights were created to incentivize and encourage creators so that mankind could achieve perpetual growth. But the juxtaposition of two widely different legal rights is intellectually incoherent and it seems to corrode the original aim of IP Laws and Rights.

EUROPEAN COMMISSION'S PHARMACEUTICAL SECTOR INQUIRY: FINDINGS

It is the European Commission that has actively shown concern for the abuse of patents by pharmaceutical companies. This committee has been the first among others to unveil certain practices performed by originator pharmaceutical companies that tend to delay the introduction

[15] UNITED NATIONS HUMAN RIGHTS OFFICE OF THE HIGH COMMISSIONER, https://www.ohchr.org/en/Issues/CulturalRights/Pages/impactofintellectualproperty.aspx (last visited on Aug 26, 2021).

[16] OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, https://ustr.gov/about-us/policy-offices/press-office/press-releases/2021/may/statement-ambassador-katherine-tai-covid-19-trips-waiver#:~:text=This%20is%20a,the%20issues%20involved (last visited on Aug 26, 2021).

of generic medicines in the market[17]. As has been discussed earlier, these pity practices are commonly called strategic patenting where patents are filed with a strategy to delay the introduction of generic competition for quite some time or even forever.

European Union launched a survey in 2008 to ascertain the root causes behind the lower rate of competition in the pharmaceutical sector[18]. Then in 2009 European Union released a report- Pharmaceutical Sector Inquiry Report, 2009 based on the survey conducted in 2008. The primary observations of the Report were that the number of medicines reaching the target was declining and the introduction of the generic medicines was significantly delayed.

The Commission came across some, very disturbing facts about the patent culture. The ratio for primary to secondary patents is 1:7[19]. This confirms that the increase in the value of drugs and that the monopoly is not only sustained but also is properly maintained through the grant of secondary patents.

This paper strongly argues that the abuse of patents by taking advantage of one's dominant position in the pharmaceutical industry is completely unethical as it not only reduces the chances of clear and easy access to drugs but also it hampers the ultimate goal of the patent system of incentivizing the innovator for furthermore inventions. Strategic Patenting techniques attract and limit the innovation to the already existing products rather than focusing on new ones. Innovators use all of their resources in the creation of secondary patents and newer versions of the same products which cut the scope of new inventions. Also, this further affects the Generic industry as they are not able to invent alternatives of the patented products. Together, all these factors contribute to the increase in the price of drugs, and in absence of generic alternatives people are left with two options, the first being to be able to afford those medicines and the second is to die without them. In the coming paragraph, we will try and understand Strategic Patenting in brief.

STRATEGIC PATENTING- THE NEW INFINITY STONE

These Pharmaceutical businesses have come with an infinity stone of their own called Strategic Patenting. And we are in a dire need of Avengers. Pharmaceutical Companies are the player of their own field and now are immune to the checks. They know how to maintain their profits

[17]PHARMACEUTICAL SECTOR INQUIRY FINAL REPORT, https://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf (last visited on Aug. 26 2021)

[18] *Id.* at 10.

[19] Olga Gurgula, *Strategic Patenting by Pharmaceutical Companies- Should Commercial Law Intervene?* , SPRINGER LINK (Oct 28, 2020)

through years of patenting and almost earning from it until infinity. Thus, strategic patenting serves the interest of the patent owners to maintain their monopoly and ends up creating havoc for society.

There are various pillars in the pharmaceutical industry, for example, the Originators, the Generics, the Patients, and the Doctors Etc. who regulate the access to medicines. But the access is adversely affected by the competition between the Originators and the Generics. Originators are the innovators and Generics are the other companies who produce cheaper variants of the original drug after the expiration of Patents. But in order to secure their profitable monopoly, these Originators have adopted a strategy where they do not only file for *basic patents* but also for *secondary patents*[20]. Secondary Patents are granted on various other aspects of the drug-like the process of formation etc., unlike Basic Patents which provide protection for the main active compound. This benefits the owner of the IP to continue with their market position because of the fact that even after the expiration of the *basic patents*, *secondary patents* remain alive. Due to these existent patents monopoly sustains and hence, the clear access stands suspended. So IP owners have now extensively engaged themselves in strategic planning and creating modified versions of the existing drugs rather than putting their effort into newer innovations. Therefore, the aim of incentivizing innovators for new innovations is hindered.

So, basically, Strategic Patenting is a practice adopted to increase and maintain the patent monopoly by delaying the entry of generic competition and applying for *extra* or *secondary* patents over *basic* ones. Many researchers called this practice ***ever-greening of patents***[21]**.** These originator or innovator companies follow these practices for recurring the high cost spend in the research and development of the drug. What happens is, suppose when a drug is launched and is granted with patent protection on its original molecule for 20 years from today[22]. Then the pharmaceutical company will file a patent for a minor modification or a crucial step involved in the manufacture of the drug, just before the expiration. Since the generic companies are again prohibited from the manufacture, patent monopoly sustains. This can be understood by ***AstraZeneca's Case***[23]**.**

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[20] *Supra* note 18.

[21] Arun Kumar and Arun Nanda, *Ever greening in Pharmaceuticals: Strategies, Consequences and Provisions for Prevention in USA, EU, India and other countries,* 6 PHARM. REGUL. AFF.1, 1 (2017), https://www.hilarispublisher.com/open-access/evergreening-in-pharmaceuticals-strategies-consequences-and-provisions-for-prevention-in-usa-eu-india-and-other-countries-2167-7689-1000185.pdf

[22] *Id.* at 1.

[23] AstraZeneca v. Commission, C-457/10 P, EU:C:2012:770

AstraZeneca Case[24]

In this case, European Union held AstraZeneca liable for abusing the patent rights and misusing its dominant position in the pharmaceutical market. AstraZeneca basically committed two patent fits of abuse. Firstly, it used its dominant position for grant of supplementary patents. It was alleged that the company misled patent offices by its representations for the grant in Germany, United Kingdom, Denmark, Belgium, Norway, and the Netherlands. And later on, it went for delaying the entry of generic competition in the market. AstraZeneca had filed for deregistration of market competition for its drug *Losec* in Denmark, Norway, and Sweden. Astra Zeneca also tried to launch its newer version of its product, named *Losec MUPS* capsules. AstraZeneca had a monopoly in the market for its *Losec* capsules which were helpful in treating ulcers.

This was the first time when the commission recognized the patent abuse and discovered traces of strategic patenting. The Commission held AstraZeneca liable for breach of Article 102 of TFEU[25] and Article 54 of EEA with 60 million Euros as a fine[26].

Later, AstraZeneca went on and appealed in the General Court against the Commission's Decision. General Court upheld the Commission's decision and confirmed the applicability of Article 102 of TFEU[27] in the pharmaceutical sector.

General Court's decision laid down the stepping stones for checking the process of curbing down practices like strategic patenting. At least, now it is in our knowledge that these practices are unethical and abusive.

Generic Industry promotes and facilitates one more kind of invention known as ***Follow-on inventions***. These inventions are basically alternatives and newer versions of the products that are off the patent. But, with the presence of strategic patenting in the market these innovations are put off and innovation is demolished. There is a sheer need to eliminate strategic patenting from the pharmaceutical industry because it increases the life of patients thereafter contributing to the lack of access to medicines and helping for the creation of a sustainable monopoly. This practice should be strictly restricted in the case of life-saving drugs because they are crucial to life. There is a need for adequate proctorship and monitoring over the pharmaceutical industry, especially focusing on giant businesses.

[24] *Id*.
[25] Treaty on the Functioning of European Union, art. 102, Mar. 25, 1957, OJ C202/1.
[26] Supra note 22.
[27] *Supra* note 23.

REMEDIES

A. Is Compulsory License Efficient and Enough?

When talking about regulations on an international level, the TRIPS (Trade-Related Aspects of Intellectual Property) agreement[28], to which India is also a signatory, comes into the frame. TRIPS was an initiation of WTO which provided a means of "balance between providing incentives for future inventions and creations in the long term, while simultaneously allowing for the people to use current inventions and creations". The TRIPS agreement has nowhere explicitly mentioned or defined the term "Compulsory Licensing", however Article 31[29] of the agreement clearly puts forward the idea that other use of patents can be entertained, without the patent owner has authorized the other party for the usage of the same.

Now, coming down to the topic of compulsory licensing it must foremost be noted here that compulsory licensing is a way out to strike the balance between the rights of the patent holders and the public interest at large. Article 31(a)[30] specifically deals with compulsory licensing in regard to the TRIPS agreement. Moreover, to understand what compulsory licensing means it is important to know that it is a way when the government or any other national authority of a country, without the permission or will of the patent holder grants itself or any other entities/organization, the permission to basically exploit the patented products or drugs.

Article 31(a)[31] provides for the conditions in which the government can issue the same, in furtherance of a farsighted objective. In certain conditions like in cases of an emergency or where it can be said that there is a compelling need for the same a compulsory license can be issued. Moreover, it must be noted that this is done because the patent holder is either unwilling to grant voluntary licenses or that the product is unavailable to the public at large due to economic reasons or in regard to improper and unconditional usage by the Patent Owner and the curb the creation of monopoly of the pharmaceutical entities. This is done where such drugs or products are essential for the public interest at large, which is why the public authority has the right to exploit the patent rights of the patented product by either itself or through others on a given compensation to the patent owner. It must be noted here that compulsory licensing can also be given in cases of copyrights in cases of few intellectual properties upon due compensation given to the owner, however in the due course we would like to restrain to our

[28]TRIPS Agreement: Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M.1197 (1994)

[29] TRIPS Agreement, *supra* note 27, art. 31.

[30] *Id.* art. 31(a).

[31] *Id.*

topic of the research paper and would keep it limited to the scope of Compulsory Licensing in the light of Patenting of essential drugs.

Compulsory Licensing is extremely imperative not only at the national level but also needs to be addressed at the international forum as almost one-third of the worldwide population is inaccessible to basic essential drugs and the fact that is not only leading to a monopolization of such pharmaceutical companies but has led us to such a situation where such medications have surpassed the inflated rates as well.

Now considering the fact that the patent owner is once granted the exclusive license over his now patented product, he officially and legally is empowered to prevent his patented product and debar others from making, using, selling, or distributing the same. The minimum time span for the existence of patent rights is 20 years, however, there are certain exceptions to the same. They include-

- Such means and methods may be diagnostic, surgical, or therapeutic in nature which is used to cure humans and animals.
- Such animals and plant-related inventions; and
- Such other necessary inventions whose exploitation needs to be curbed in other to prevent the human, plant, and animal life and health on the planet.

When we talk about the provisions of the TRIPS agreement, Article 8 of the same is to be mentioned here along with Article 5A of the Paris Convention which deals with the measures that the government can resort to in situations of patent abuse by the patent owner. Such situations of patent abuse are said to arise when the quantity supplied is unable to meet the quantity so demanded in the domestic market (including both, the domestic production of the drug along with the imported quantities of the same), in cases of extremely high rates of the patented drug such that the public cannot avail it at reasonable and affordable rates. In addition to this, another factor remains that if the patented invention is unable to satisfy the public's need in respect to its reasonable requirements that it is expected to perform. When the drug is unable to work or meet the demand of the required quantity of the drug in a particular geographical zone of the same nation, is also another case of patent abuse.

Now that we have spoken about the aspects and provisions for compulsory licensing, it might seem too many to be a boon on one side, however, like there are always two sides of a coin, so does compulsory licensing as a procedure. On one hand, where it seems to be a very lucrative alternative to suppress the patent abuse by the patentees, however on the other hand Article

31(b), (c), (g), (d), (e), (f) and (h)[32] implement certain restrictions over the grant of these licenses which makes the grant extremely difficult to get a compulsory license and thereby prove ineffective and of no use in cases of urgency, like in the present case of the pandemic. These provisions include stating that reasonable efforts must have been made by the potential patentee to get a voluntary license from the Patent owner, along with which if the Compulsory license is granted, the patent owner is to be paid and compensated with adequate remuneration, the license of the same is to also remain exclusive and cannot further be assigned. The restrictive and limited scope of the compulsory license must also be highlighted here, which is limited only to the national market in respect of the country which has been granted the compulsory license thereby not catering to issue of need and usage, and demand of the product in regions which actually require the product but are facing obstacles to obtaining a compulsory license. This issue can particularly be observed in India as of the current situation, where big pharmaceutical companies decide to export drugs to India, which are patented in various other nations, as the Indian Patent law only provides for the grant of Compulsory licenses for those drugs which are patented in the land. These large pharmaceutical organizations find it to their benefit, the above-mentioned loophole which they very conveniently use to suit their needs and avoid compulsory licensing and exploit the needy. Lastly, the fact that this compulsory license so granted shall terminate to have effect when there is a change in conditions upon which the patent under compulsory license was granted, i.e. when the scope or the purpose for which the license was granted is said to have changed or obliterated.

In view of such restrictive scope, a compulsory license is hardly and rarely issued. If and when it is so issued, it is taken care of under Article 31(k)[33] of the TRIPS agreement, where the grant of compulsory license in order to fix anti-competitive practices by the Patentee is spoken about. So, it can be said that it is actually very difficult to effectively prevent patent monopolies with the help of Compulsory Licensing. However, it must be noted here that the need of the hour remains that efficient rules and laws in regard to compulsory licensing must be framed. The primary reason for the same being the fear of "parallel trading" or "arbitrage", which is a situation that arises when big pharma companies or individuals buy patented drugs at an extremely low price and export the same to other nations where these drugs are sold at higher prices thereby sabotaging the efforts that are presently being made in order to make the essential patented drugs available to the general public and the needy at reasonable and

[32] Supra note 27.
[33] *Id*. art. 31(k).

affordable prices. Adding to this is another bottleneck where fake/ counterfeit substitute drugs are also sold in the mainstream market. The problem lies in here where the common man who is unable to buy the essential drug at such sky-touching prices due to monopolization of the drug, is yet forced to buy the similar-looking drug at cheaper prices not being aware of it being a counterfeit product thereby risking the health of the society at large. Thus, clear demarcations as to the standard, process, and rights and liabilities of parties in regard to compulsory license should now be issued at both the national and international levels.

CONCLUSION

The system of hierarchy of two such rights from completely different worlds is just not fair and is blight in my view. It is only dampening and reducing the chances of better and significant changes in the subject. The patent law regime needs a significant change, and it is definitely through stricter regulations.

Generally, patents are granted when the patent office runs certain legal tests stating the position of the grant. Later, at the time, of the grant, it is impossible to conduct a complex analysis because patent examiners are not equipped with tools and techniques to calculate as to what will be the outcomes of such grants. This, ultimately, creates a void in the system and the results or after-effects are terrible sometimes. Thus, it is difficult for anyone to analyse something which is contingent on future events, making this system flawed.

Also, the most crucial area of improvement lays over the regulation of patents post their grant. In fact, this is the step which in my view has the ability to improve the entire system. Mostly, chances of patent abuse and monopolies exist after the grant of patent especially when it comes to drugs that are as important as air to some patients. Practices like compulsory licensing and discrimination of pricing are adopted but they are equivalent to that of no use. Regulation relative to public interests on what happens to patents after they are granted is important.

To conclude in our view, we need nothing but a retooling of the patent law regime so that it is competent, capable, and efficient enough, by in itself, to cater to every falling possibility in front of it. Also, it should prove to be beneficial for all, the developing, the developed, and the underdeveloped nations. Suggestions on our part would include that primarily, certain diseases be suggested on an international forum for which granting of Compulsory License becomes mandatory. Secondly, recognition of grants of Compulsory License must be made on an international platform and in several nations instead of recognizing it on a national scale, by those countries who have compliant governments granting those Compulsory Licenses. Another effective method would be the “Buy-out” of Patents of Essential drugs by the government which would help in creating clear price demarcations and regulations thereby

reducing exploitation of the common man. Moreover, in addition to this a standardized model as to grant of Compulsory License which must be adopted, at yet again the international forum, clearly setting the boundaries as to under which circumstances can Compulsory Licenses be granted, in order to prevent and stop abuse by nations willing to granted Compulsory Licenses for availing cheaper drugs. The best method to curb the abuse would be to improve the pharmaceutical industry which could only be done by financing (both government and private) of research and development of the pharma industry. Lastly, a suggestive method would be that where a company has targeted no profits and investment in case of a developing or underdeveloped nation and the essential drug is to be granted a compulsory license, the provisions of Article 31(h)[34] of the TRIPS agreement which talks about "adequate remuneration" must be considerate towards both the developed and the developing and the under-developed nations and such adequate remuneration should be conceived more liberally considering the economic status of the developing, under-developed nation which would mean either low, less or as the circumstance demand, compensation. Quoting John F. Kennedy, who very correctly said, "Economic growth without social progress lets the great majority of the people remain poverty, while a privileged few reap the benefits of rising abundance". The foremost consideration in our opinion and in all cases should be social benefit and welfare of people and society at large.

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[34] *Supra* note 26.