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A CRITICAL STUDY ON PHARMACEUTICAL PATENTING IN INDIA: THE INTRINSIC ISSUE OF ACCESS TO HEALTHCARE.

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ABSTRACT

Intellectual - property laws are becoming increasingly mainstream these times. Patents are a type of intellectual resource to who owns them, which can be an individual, a company, or the government. It gives innovative creators peace of mind that their invention, idea, or discovery will continue to stay theirs. Patents have had a significant impact on the national and global innovation terrain. Although, when it comes to pharmaceuticals, which is a necessity for everyone, the same patent system acts a barrier to access to these essential commodities. IPR culture in India necessitates interest, in-depth knowledge, and efficacious schemes for encouraging and building IPR activities, as well as exploring industrial and scientific research and innovation in the nation. For a long time, India has been a forerunner in the evolving world, striving to acclimate pharmaceutical patent law to consider domestic health needs, focusing more on the needs of people to keeping pace with its development. In India, a significant chunk of the population lives below the poverty line, and healthcare expenses are borne by the individual, indicating that there is a noteworthy health crisis with regard to healthcare and its affordability, availability and accessibility. This paper provides insight into patent laws and analyses the same in light of issues concerned with access to pharmaceuticals and health care, as well as the right to health. Bearing in mind international commitments, the author will discuss key challenges: the implications of TRIPS compliance on pharmaceutical patenting and the issues involving access to health. Lastly, looking into certain solutions to tackle these challenges and resolve the same.

Keywords: **Intellectual property, Pharmaceutical Patenting, Patent, Patent act, Healthcare, Drugs, medication, Right to Heath and healthcare, TRIPS Agreement**

INTRODUCTION

Intellectual property law governs the establishment, use, and expropriation of both intellectual and creative labour. Patent is among the most well-known intellectual property rights. Patents have been shown to be the most utilised intellectual property in the modern scientific era. The awarding of a patent is projected to incentivize original creativity and thus nurture advanced research and development, potentially contributing to further creations and advancement. However, the patent rights are frequently abused by the patent holder.

With respect to promotion and development of the civilisation, technology has played a significant role owing to its deep-rooted connection with science. In present era, technology is a sophisticated socioeconomic venture that includes not only research but also engineering and production. Technology expands our ability to affect change in the world. We use innovation to attempt to alter

the world to satisfy us. However, the consequences of changing things are frequently complicated and uncontrollable. They may include unforseen rewards, prices, or threats.

Section 3(d) of Indian patent law is a restricted provision. It strikes a good balance between the obligation of the Agreements on Trade Related Aspects of International Trade (TRIPS) and safeguards poor people's access to medications. This has propelled India to the forefront of the pharmaceutical industry. The scenario has undeniably changed since the TRIPS regime was implemented.[1]

Medical patenting in India is especially relevant to prevailing public health concerns because the Indian market and big pharm firms are key suppliers of low-cost pharma material in the market and generic medicines. Since India signed the Doha Declaration on TRIPS Agreement and Public Health in 2001, the question of access to healthcare has taken on international implications. With its well-established and progressively export-oriented pharmaceutical sector, India is at the forefront of the national and international campaign to improve access to medications. The Indian pharmaceutical industry provided economic support to the campaign by demonstrating the viability of a substitute pharmaceutical industry.

Latest patent law rulings, such as the Supreme Court 's verdict in the Novartis case, show that India persists to prioritise public health in pharmaceutical patent law choices. As a result, pharmaceutical patents limit standard competitors and thus increase costs, and are assumed to be a notable impediment with respect to access to health care and medicine in developing countries. Pharmaceutical commercialization has prompted the corporate entities to pursue drug patents for their pharmaceutical creations. Pharmaceuticals benefit humanity in numerous ways. The standard of living of an average human has improved dramatically in the medical sector as a result of pharmaceutical industry innovations. Nevertheless, in the contemporary intellectual property age, where it grants an innovator an exclusive right to commercialise his creation, it has become a costly notion that is out of reach for the common folk.[2]

Pharmaceuticals are chemical compounds which are used to treat, make a diagnosis, or inhibit illness. In simplified terms, we refer to them as medicines. When we are identified with an ailment, the sole belief we have is that medication will cure. Because of recent advances in the pharmaceutical sector, these medications are now more accessible to the general public than they were previously. Despite these advances, a considerable number of people continue to endure due to a lack of medications. To address this issue, a landmark agreement on Global Strategy and Plan of Action on Public Health, Innovation, and Intellectual Property was endorsed. As a result, the WHO and its associates have undertaken numerous measures to make medications widely accessible in the affected regions[3]. Even so, the strategy is still not as

[1] Section 3(d) of the Patents (Amendment) Act, 2005, No. 15 of 2005 (April 4, 2005)

[2] *Zafar Mirza*, WTO/TRIPs, Pharmaceuticals and Health: Impacts and strategies, The Society for International Development, *SAGE Publications*.

[3] Nidhi Joshi, "Data Protection for Pharmaceutical Products under TRIPS: Data Exclusivity Legislation a Necessary Evil for India" 1 Delhi law review 104 (2005).

simple as it appears. Numerous obstacles exist, creating challenges in accomplishing this objective. Pharmaceutical patenting is one of the most difficult obstacles.

Drug patent protection is the grant of a negative right to the bearer that prevents people from producing that drug. Monopolistic privileges given by IPRs were viewed as critical in preventing developing nations from continuing the "catching-up" process of rapid industrialization by duplicating innovations similar to developed nations. In other words, intellectual property safeguards act as a means to restrict and preserve to comparative edge and dominance which was guaranteed to a developed nation over others.

The predicament became quite tricky following the TRIPS agreement, which confers patents to both the process and the product, as opposed to prior procedure protection. The product patent provides absolute protection for the product, whereas the process patent protects the advanced technologies and manufacturing method. Earlier, many developing nations did not provide patent protection to medical products because it was necessary to promote access to medication at reasonable prices. Accepting TRIPS provisions that recognise and fortify IPR protection on medicinal processes and products will cause many difficulties for underdeveloped and developing nations. Its implementation will culminate in increased prices, limited access, and the eroding of regional pharmaceutical industries. The prevailing legal situation is unmistakably not aiding and facilitating the pharma sector of India to thrive and blossom

PHARMACEUTICAL PATENTING

When a pharmaceutical organisation creates a drug to be used for an illness, it's at first sold through a brand so that physicians can espouse the medications for use by clients. The substance is protected by a patent, which means that only the pharmaceutical company which owns the patent is legally allowed to manufacture, market, and profit from it. The effective timespan for a drug's patent once acceptance is generally about 7-12 years. That is because businesses apply for patents prior to actually conducting clinical trials to assess the efficacy of it. After the patent expires, other organisations can start manufacturing and sell the drug, which will then be alluded to as a generic drug. With nearly 60,000 generic brands in 60 therapy areas on the industry, the Indian pharmaceutical industry has a significant generic base. which was fostered by the then-patent legal system One of the success stories of the Indian economy is the expansion of the national pharmaceutical sector. With an annual export turnover exceeds $1.5 billion. The transition from being an import-dependent venture in the 1950s to becoming a cost-effective power source of elevated standard and high-quality medications presently, the Indian pharmaceutical sector has reached international recognition.

It was possible since there was no product patent framework for pharmaceuticals at the moment. The TRIPS Agreement entered into force on January 1, 1995, which intended that India, as a participant of the World Trade Organization (WTO), had been obligated to jettison most of its long-held positions in the intellectual property domain, it required to

conform with the TRIPS provisions[4]. Following the agreement, India was granted a five-year transitional phase, in addition to modifying the operating patent laws on medicinal patent protection. Following this, numerous revisions to Indian patent laws have been made in 1999, 2002, and 2005. The latest amendment was made in 2005 which resulted in noteworthy variations to Indian patent system. The most substantial shift brought about by the Amendment is the removal of Section 5 of the Patents Act of 1970, that stated that "no patent shall be granted for claims for substances intended for use, or capable of being used, as food, medicine, or drug, or relating to materials prepared or produced by chemical processes". The chapter IV A on "Exclusive Marketing Rights" was also removed. Nevertheless, one amendment remains contentious to this day: the addition of section 3(d), which attempts to restrict access to "secondary" pharmaceutical patents, which are patents on new guises of existing substances and opiates. The case of *Novartis AG &Ors. v. Union of India &Ors*[5]. section 3(d) was brought to light. Here, Novartis International AG applied to the Chennai Patent Office under the TRIPS agreement for a patent authorization for the drug 'Glivec,' which has been used to treat Chronic Myeloid Leukemia (CML) and Gastrointestinal Stromal Tumors (GIST). In the year 2005, the Madras Patent Office denied the application, citing section 3(d) of the Patent Act of 1970, which states that a mere discovery of a new form based on an already existing substance cannot be patented without substantiation of new or increased efficacy. Following this, Novartis submitted two writ petitions to the Madras High Court under Article 226 of the Constitution, which shifted the claim to IPAB (Intellectual Property Appellant Tribunal), which dismissed the petition upon hearing the merit of the case. As a result, Novartis petitioned the Supreme Court under an SLP (Special Leave Petition). But even so, the Supreme Court rejected the request as well.

PATENTS ACT SECTION 3(D): A CHECK ON EVERGREENING

As shown in the WHO Report, 60% of integral medications exhibit incremental innovations, emphasising the need to incentivise pharmaceutical businesses to engage more in research and innovation and to inspire investment in the pharmaceutical sector; businesses must be compensated with effective patent protection[6]. Regrettably, as evidenced by the Novartis AG v. Union of India decision, India places itself on a distinct dais. Section 3 of the Patents Act of 1970, integrated by India, reduces the range of subject-matter qualified for patents that are not "inventions" within the interpretation of the Indian Patents Act. Section 3(d) was enforced mainly to deter "evergreening," as it expressly prohibits patent protection for the mere discovery of a novel form of a particular compound unless such product demonstrates significantly improved "therapeutic efficiency" over the original. Section 3(d) prohibits patenting the simple discovery of any new incarnation of a known material unless it improves the effectiveness of the original compound. It also serves as a

[4] "TRIPs and Pharmaceuticals: Implications for India", http://www.cuts-india.org/1997-8.htm#Pharmaceutical %20Industry%20in

[5] AIR 2013 SC 1311, [2013]

[6] Is 'evergreening' a cause for concern? A legal perspective- September 20, 2007 by Scott Parker & Kevin Mooney.

stumbling block to new use patents by stating that the mere discovery of any novel asset or new use of a already existent substance isn't patentable.

The term "evergreening" is not described in the Patents Act of 1970, but this patent tactic involves obtaining patents on minor, often superfluous, revisions to existing pharmaceutical products and systems in attempt to tacitly extend the length of patent protection over those originally patented. This is an unauthorised extension of patent life beyond the 20 years that does not favour the pharmaceutical industries. It's alleged that Novartis dared to do this by filing a patent for such compound's beta form. The Novartis AG v. Union of India decision from 2013 has huge ramifications for Indian patent laws. Novartis' announcement was made after careful consideration of numerous socioeconomic influences. By delivering a strict and restrictive interpretation of the test specified in Section 3(d) of the Patents Act, the Supreme Court affirmed the legislature's intent. According to the Supreme Court, Section 3(d) was enacted to thwart evergreening, provide the access to lifesaving drugs, and to fulfil their constitutional responsibility to provide good healthcare to their citizens.

This demonstrates that India prioritises extraneous socio - economic factors. However, this pharmaceutical-based particular test of "therapeutic efficacy" has introduced a number of complexities. It is worth noting that more unified standards offer a more dependable structure for multinational drug companies, allowing them to participate in research and innovation focused at tackling developing-country medical necessities. WHO noted in 2003 that far more than 50 % of the Asian and African population lacked access to the necessary medicines. Many elements contribute to this issue of restricted access. Another of the primary causes might be insufficient production and inability to make adjustments to specific geographic circumstances, which can be resolved if global companies are provided with the appropriate motivation, such as patent protection for progressive pharmaceutical inventions in developing countries. One of the concerns is the high cost of drugs, which can be addressed through alternative policies such as mandatory licencing.

ISSUES DUE TO PHARMACEUTICAL PATENTINGS

There seem to be various perspectives regarding its repercussions on the Indian pharma sector and access to adequate medicinal products both inside and beyond the nation. With a large number of pharmaceutical corporates, India ranks fourth in terms of volume of production. However, while pharmaceutical drug patents are an important part of the innovation system, the patent system in totality can be perplexing to the uninformed. Drug companies frequently abuse patent monopolies and charge exorbitant rates for patented products. The emergence of product patents has made drugs less accessible. A substantial majority of generic medicines, such as vaccines, are now being patented in India, rendering it challenging for the sector to generate life-saving, crucial drugs. Extortionate drug prices prevent ordinary people from accessing medication, which operates contrary to the state's anticipation that it will protect its peoples' wellbeing. Particularly in a country like India, where such a sizeable

populace continues to live in poverty and health costs are excessive, it is clear that there is indeed a pressing healthcare emergency with insufficient affordability, availability, and access to drugs. Furthermore, the patent office has been granted unrestricted discretion to develop its very own rules for ascertaining what entails appreciable improvement of therapeutic efficacy, but it does not specifically define what "therapeutic efficacy" actually means.

PUBLIC HEALTH VIS-À-VIS PHARMACEUTICALS PATENT

(a) Right to Health as Fundamental Rights

Article 21 of the Constitution assures the right to life, which encompasses the right to health. Via judicial precedents, the courts deduced that the right to life incorporates the right to health and "access to medical treatment." The state must strive to make sure that its citizens have access to life-saving opiates. The state is required by the constitution to ensure that no one's fundamental rights are violated. Our Constitution's Preamble and Directive Principles of State Policy (DPSP) require initiatives to maintain social and economic rights. As a result, when developing patent legislation, a balance must be struck among public health and the economic objectives of pharmaceutical industry.

As per Ayyangar Committee Report, because India is a developing nation, granting a patent rewards monopoly power rights that will prevent the majority of our country's population access to medications. Regulations that grant monopoly rights, therefore, violate both the Preamble and the fundamental rights guaranteed by Article 21 of our Constitution. Achieving the requirements of the people must come first, followed by catering the requirements of foreign innovators. Privileged communities, evidently, devote massive amounts of money on the quest for new products and technologies to assuage suffering and extend life. Drug manufacturers are becoming a potent market as a result of this process.

(b) Patent and Right to Health

Health is a fundamental human entitlement, and availability of medicine as well as access is an underlying step in ensuring wellbeing. Although, in the present administration, both the right and the means to obtain it are major issues. Pharmaceutical patents play an important role in ensuring health by ensuring access to drugs.

A completely operational patent system, these have been asserted, would contribute in an opposite relationship among the price of such goods and the affordability of access. Some argue that international intellectual property system is confronting an emergency of public credibility because patents are preventing regular people from accessing medications and exercising their "right to health." It’s a critical test for the Indian authorities. As a result, they are taking a number of projects to secure this predicament, such as compulsory licencing (on the denial of a voluntary licence) and parallel trade policies as substitute forms to assist developing nation governments in making vital medications more economical to their people. Compulsory licencing lowers prices for consumers by increasing healthy competition in the industry for the patented items.

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TRIPS AGREEMENT AND PHARMACEUTICAL PATENTS

The Uruguay Round of trade negotiations established among the most notable and foundational improvements in global trade policy, with the pledge of World Trade Organization members to comply with regulatory conditions of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which establishes minimum threshold of protection for intellectual property rights and its enforcement, which are imperative for WTO participating countries to incorporate. The TRIPS agreement is by far the most extensive multilateral treaty on intellectual property, defining patentable subject as well as technical and substantive elements of patentability. TRIPS' primary goal is to preserve and implement intellectual property rights in order to promote innovation and technology exchange and propagation, to the mutual benefit of producers and consumers of knowledge, and in a manner that is amenable to social welfare and a balance of rights and responsibilities. The World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) seeks to find the balance between long-term social goal of incentivizing future innovations and creative processes and the short-term goal of permitting citizens to utilise operating advancements and inventions[7].

Patents in the pharmaceutical industry have provided an impetus to the private industry in the areas in which they are awarded. The private health sector considers them crucial in the pharma industry. One of the benefits of patenting in pharmaceutical industries is that it encourages private participants to invest more in additional research and development in order to find cures for diseases and new treatments for illnesses prevalent in developing nations. Invention and creativity must provide technological and social rewards. Intellectual property provision inspires innovators and creators so that they can presume to profit from their efforts in the future. This urges new inventions, including new medicines, whose production costs can generally be exceptionally high, so private rights may provide social welfare benefits as well to the public. With that very broad goal in mind, pharma patents were made mandatory in Signatory countries under the TRIPS agreement[8]. Regrettably, opposite effects have been observed. Rather than embracing TRIPS rules, developing nations have protested to its implementation. The developing and under developed nations didn't consider TRIPS to be an advantageous negotiation because the regime will raise drug prices, making drugs unattainable to their common people. Although TRIPS agreement may contribute to higher studies on illnesses prevalent in underdeveloped nations, these benefits can be realized in less expensive ways. As a result, the TRIPS agreement may not be in the country's interest, and thus it is not a favourable bargain.

Because Indian legislature only acknowledged method patents and not product patents, they enacted the Patents Act of 1970, which considerably prioritised the Indian players and the poor segments of

[7] Thawani V, Gharpure K, Thawani M. Patent laws must be in the national interest. Indian J Pharmacol 2006; 38:70-2.

[8] Qaiser M, Chandran MP. Patent holder deserves monopolistic rights. Indian J Pharmacol 2006; 38:73-5

society. This culminated in the decrease in transnational corporations share because pharm companies centred in developing nations expected a surge in demand and revenues from the grant of a global patent. As a result, the number of patent applications by international institutions has reduced. It also led to an increase in the generic medicines in manufacturing industry and a decrease in drug prices in India. National players were given a quick uplift to duplicate and trade the new innovative opiates in the Indian market by simply modifying the manufacturing procedures. With such conditions, Indian drug manufacturers succeeded in producing drugs at a lower cost, make them accessible to the disadvantaged sections of society. Nevertheless, the TRIPS agreement hampered the system's reliable working. As a consequence of the WTO's dispute settlement body, all WTO member nations were forced to adopt TRIPS. India was orginally hesitant to integrate the same, but India was forced to do so after the US made complaints that India was not adequately incorporating the TRIPS by not offering an efficient protocol for filing patent applications and, furthermore, by not offering exclusive commercial rights. As a result, India modified its patent law in the year 2005.

This example demonstrates that adherence with TRIPS is a requirement rather than a choice. The patent protection bestowed prior to the TRIPS regime was comparatively less restrictive, which more supportive as it paved way for the availability and access of medicine and treatments, however, post-TRIPS rule, medicines are valued far beyond grasp of the lower sections of society who struggle to make a day's living, functioning detrimental to their interests and resulting in serious loss since they can't obtain new medications that ordniarily could have had access to during the pre-TRIPS period. It should be recognised that TRIPS agreement as well as the Doha Declaration reflect an intercontinental effort to implement the delicate task of balancing the requirement for incentivizing for R&D on the one side as well as the objective of protecting and preserving public healthcare and welfare interest by making drug access an actuality on the other[9]. Despite the existence of such a framework, the sufferings of developing and underdeveloped countries remain unresolved.

Patent Exclusions:

The Patents Act must construe the principle of patentability exemptions using the textual rule of interpretation. This rule invariably implies that the exclusions have a human rights component. The principles of health and community welfare codified in the Constitution must be taken into account as they are held in high regard.

COMPULSORY LICENSING

Fears regarding compulsory licencing have grown significantly in India since the advent of a product patent system for pharmaceuticals around 2005, and the resulting increment in the scope of patent. Compulsory licencing is defined broadly as authorities granting a licence to use an invention even without approval of the patentee. A compulsory licence is a forced agreement foisted or enforced by the law among a prospective buyer and a reluctant

[9] Sean Flynn et al, An Economic Justification for Open Access to Essential Medicine Patents in Developing Countries, 37 Journal of Law, Medicine and Ethics 184, 188-190 (2009).

seller. As part of the agreement's cumulative effort to strike the right balance in both furthering access to operating drugs and boosting research and innovation of novel drugs. The TRIPS agreement enables compulsory licencing. However, the term "compulsory licencing" is not mentioned in the same. Rather, the statement "other use without the right holder's authorization" here seems in the headline of Article 31. Compulsory licencing is only one aspect of this, because "other use" involves state use as well. Representatives could provide specific exemptions to exclusive rights guaranteed by a patent, stipulated that such exclusions do not outrageously contradict with ordinary exploitation of the patent and therefore do not unfairly prejudice the patent owner's legitimate rights, considering third-party core interests[10].

Compulsory licencing occurs when the system allows another to start producing a patented product or utilise a patented process without the assent of the owner, or when the state desires the use of the patent-protected invention for itself[11]. The Government of India's effort in 2016 to furnish a National IPR Policy resulted in incentive, enabling powerful and reliable IPR laws that reconcile the desires of rights holders and public interest. Furthermore, the 2017 reform broadens the range of compulsory licencing so that if any developing nation needs to turn to compulsory licencing to generate necessary affordable pharmaceuticals, manufacturers from other countries can step it up and produce that which is needed, even when a compulsory licence is required in that nation to produce the same.

As a result, it is a mandatory licence, particularly for manufacturing in one region for export to satisfy the health needs of the population of one or more nations. The rationale for compulsory licencing is that patents conferred really shouldn't hamper public health safeguards and thus should serve as a tool to endorse public interest in industries critical to the nation's socioeconomic and technological advancement. Patents are awarded in order to make the advantages of the patented product affordable to a large segment of the public. A compulsory licence can be accorded to gain access to benefits of an invention.

INDIAN LEGISLATION

Sections 82 till 94 under the chapter XVI of the 1970 Patents Act along with the rules 96 to 102 of the Patent Rules of 2003 in chapter XIII, stipulate the provisions regarding the grant of compulsory licence in our country.
In India, The Controller of Patents has the relatively higher level of authority to grant compulsory licences, to some extent even being discretionary in nature. It should be acknowledged that the *Natco case*[12] ushered in a shift in the Indian pharmaceutical industry regarding the operation of patents and developed a link among TRIPS and domestic legislation. It has demonstrated that

[10]s Jean O Lanjouw, "The introduction of pharmaceutical product patents in India: Heartless exploitation of the poor and suffering?", Center Discussion Paper No. 775.

[11] Divya Murthy, The Future of Compulsory Licensing: Deciphering the Doha Declaration on the TRIPs Agreement and Public Health, 17(6) American University International Law Review 1299, 1310-1314 (2002)

[12] Bayer Corporation v. Natco Pharma Ltd., Order No. 45/2013 (Intellectual Property Appellate Board, Chennai), available at http://www.ipab.tn.nic.in/045-2013.htm.

all developing nations, including India, can efficaciously use TRIPS versatility to provide healthcare to the public while also fulfilling the constitutional mandate of the right to life as envisioned in Article 21. Furthermore, the Bombay High Court concurred with the Controller General of Patents as well as the Tribunal's findings on compulsory licencing as per Section 84 of the Patents Act. Numerous different requests for compulsory licencing were also submitted, but the Controller rejected them. BDR Pharmaceuticals filed such an application to produce and sell the basic variant of the anti-cancer drug 'Dasatinib', which is innovated by Bristol-Myers Squibb in India. Furthermore, in the year 2015, Lee Pharma submitted an application for a compulsory licence to manufacture and distribute the drug 'Saxagliptin', which is used to treat type-2 Diabetes mellitus. Both requests were denied because they did not persuade the Controller of Patents that there was a prima facie case for the approval of compulsory licencing.

Despite the fact that the comparative analysis infers that India's compulsory licencing regulations are compliant with the TRIPS agreement in entirety. Compulsory licences, on the other hand, are theoretically oxymoronic and intrinsically objectionable. In India, only one compulsory licence has really been issued till date. The chief reason for such limited use of flexibilities can be chalked up to procedural challenges. The premise is very daunting on paper, but the true project is in the grip of the patent office. Public policy is required to further enhance India's compulsory licencing regulations. The Indian Patent Office should initiate a comprehensive framework.

SOLUTIONS TO THE PROBLEM OF PUBLIC ACCESS TO HEALTH

One might wonder as to if such a harmony among the right to healthcare as well as the right to obtain pharmaceutical patents is even necessary. Is it a necessity to balance one set of rights against that of the other when one evidently subsists as a fundamental right. It is a well-established position of law that fundamental rights enshrined in the constitution prevail over all other laws, provisions and other statutory or constitutional rights. Once might wonder if this would even constitute a matter that must be pondered upon and discussed when one set of right is battling a fundamental right, the answer is yes. Even though the right to health is paramount, some provision must be made for inventors to safeguard their credible interests in the shape of patent rights and, through which they earn a living. Therefore, this stability is crucial for the subsistence of both groups and must be carefully considered. TRIPS Agreement, in Article 7, reaffirms this and emphasises the importance of meeting the needs of both “in a manner conducive to social and economic welfare“, for the interest of the producers as well as the users of the innovated knowledge or products. Ultimately, it can be inferred that this is an unyielding battle between the two. Aside from the currently operating remedies, we can even see the advent of potential solutions postulated by prominent scholars who have dedicated their time and energy, and expertise into conceptualising them. The global community will have to determine if these suggested alternatives will be materialised and become a reality for all

those who direly require a long-term workable alternative.[13]

Few of the currently operational solutions are lauded as excellent workarounds, whereas others are unjustly overlooked since they don't yet endorse the aspirations of the high-profile players, despite being of comparable quality. Article 30 options, compulsory licencing, standard competition alternatives, and so forth are available; the key is to effectively execute those. India is an emerging member country that has signed the TRIPS Agreement. Drug product patents were not awarded in India prior to the TRIPS regime. Despite the rigorous patent regime in developed countries, the generic drug industry thrived in India at the time.

Furthermore, healthcare costs were very low, even for drugs that were very expensive in other nations. One of the most essential prerequisites of developing nations is the availability of medicines at low prices. As a result, compulsory licencing must be implemented in such a way that regulations are neither too restrictive such that they impede drug regulatory oversight, nor are they too liberal that people are inclined to abuse them.

The preceding section discussed operating solutions to these problems of access to essential medicines in developing and underdeveloped nations. Regardless of how well formulated they are, these remedies haven't yet led to substantial advancements in this domain. This is probably the rationale as to why numerous organisations and intellectuals have put in significant work to identify viable alternatives that are satisfactory to both parties. Reduction in price, the health benefit fund, good and honest corporate citizenship, and other alternatives are feasible and can be posited. These should provide delicate balance as a workable solution. Drug costs are a hot topic among the patient populations, activist groups, practitioners, funders, pharmaceutical industry, as well as legislators[14]. The accessibility of competitive products is indeed a factor influencing prescription drug prices, although it's not the only element. Specific competing goods, such as standard or biosimilar renditions of endorsed and accredited drugs, are not instantly accessible due to the government's award of market exclusivity to the inventor business in the form of exclusive commercial and distribution rights and/or patent privileges. The reasoning behind authorising such exclusivities is to encourage innovative thinking and the advancement of new, superior, and/or healthier prescription medications. Thus, reduction in cost in such manner can be accomplished by establishing productive relationships between both the patent holder or creator and other parties such as the authority empowered to regulate the production and approval of pharmaceuticals or the users of the medication.

[13] https://lawsisto.com/legalnewsread/Mjk5MQ==/Pharmaceutical-patenting-in-India-problem-of-public-access-to-health

[14] He J. (2019) Indian Patent Law and Its Impact on the Pharmaceutical Industry: What Can China Learn from India? In: Liu KC., Racherla U. (eds) Innovation, Economic Development, and Intellectual Property in India and China. ARCIALA Series on Intellectual Assets and Law in Asia. Springer, Singapore

CONCLUSION:

Indian laws regarding patent is a model piece that seeks to balance the interests of both ordinary citizens and creators. Following the implementation of the product patent rule, a huge spectrum of pharmaceutical products can now be patented in India. Patent rights can also be assigned or licenced to other individuals or businesses once they have been acquired. Patents can be an effective method for transfer of technology for organisations that lack adequate manufacturing or marketing capabilities. In certain circumstances, a compulsory licence allows for the marketing of patented products. Inventions and technology advance at a rapid pace as time passes. Which is why it is critical to safeguard people's ideas, creations, and innovations. This is the operation of the Patent System, which grant the inventors the right to benefit from his invention. However, the picture changes whenever it relates to the medications that almost every individual requires. As a result, the nation must strike a constructive balance between using patenting law to encourage pharmaceutical companies to establish new medicines for illnesses that cannot currently be treated and, on the other hand, the needs of patients to benefit from those drug combinations without impoverishing themselves or federal and state budgets. The manner in which the healthcare system is organised in developing countries like India, the conditions for gross violations of fundamental rights has increased. When the vast bulk of the populace lacks access to the bare minimum healthcare, the principle of justice is flouted. The fate of public health in India is heavily reliant on how the pharmaceutical companies react to the TRIPS agreement. Innovative action must lead in development, resulting in the advent of technology and economic and industrial welfare, that is only viable through the local application of patented inventions.

The monetary interests of major players in the pharmaceutical sector continue to pose a persistent danger to India's access to vital drugs at reasonable rates. Patents and innovative thinking are sides of the same coin. Patent protection shouldn't have just the single goal of profit, and inventions should be about the benefit of mankind, particularly in the field of healthcare.

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