

**INTERNATIONAL JOURNAL OF LAW  
MANAGEMENT & HUMANITIES**

**[ISSN 2581-5369]**

---

**Volume 4 | Issue 6**

---

**2021**

© 2021 *International Journal of Law Management & Humanities*

Follow this and additional works at: <https://www.ijlmh.com/>

Under the aegis of VidhiAagaz – Inking Your Brain (<https://www.vidhiaagaz.com/>)

---

This Article is brought to you for “free” and “open access” by the International Journal of Law Management & Humanities at VidhiAagaz. It has been accepted for inclusion in International Journal of Law Management & Humanities after due review.

In case of **any suggestion or complaint**, please contact [Gyan@vidhiaagaz.com](mailto:Gyan@vidhiaagaz.com).

---

**To submit your Manuscript** for Publication at **International Journal of Law Management & Humanities**, kindly email your Manuscript at [submission@ijlmh.com](mailto:submission@ijlmh.com).

---

# Patent Administration and its Footprint on Healthcare in India

---

MADHUR PATHAK<sup>1</sup> AND AKANKSHA SINGH<sup>2</sup>

## ABSTRACT

*Healthcare system is a basic necessity for humanity's existence; its provision is not only a responsibility, but also an emotional obligation of administrations and leaders throughout the world. Despite various efforts this right faces a few setbacks when it clashes with private interest of individuals and in most cases this is caused due to legal loopholes in the patent regimes of various nations.*

*This paper revolves around the topic of patent laws with reference to healthcare in India. The paper starts with a precise introduction to the topic followed by a detailed explanation of patent regime and the current Indian scenario with reference to the same. It further explains the criteria of valid patenting and then dives into the explanation of the various kinds of pharmaceutical patents available in India. Following this we jump to the discussion of the stand of various international organs and treaties and declaration signed on this matter. The paper also outlines the Indian Constitution's Healthcare guarantees and how pharmaceutical patents are limiting civilian access to health care. The study concludes with a thorough evaluation of the overall policy in terms of health, as well as potential remedies to the difficulties encountered. This paper will help you comprehend the conflict between corporate interests and the interest of the general public when it comes to intellectual property protection for vital medications, pharmaceuticals, vaccines, and treatments, among other things.*

## I. INTRODUCTION

Since the advent of patent safeguard legislations on the sphere there have occurred various instances where these laws clash with the interests of the general population at large. It is no secret that administrative authorities around the globe are pressured to restore a balance between these two sides but despite various attempts, new legal regimes, numerous international conventions, dozens of global accords not a single country in the world has been able to achieve this balance, not even one. India is no different, even though it has changed its policies many times, the new policies focus more on being in line with the international IPR

---

<sup>1</sup> Author is a student at Amity Law School, Amity University, Noida, India.

<sup>2</sup> Author is a student at Amity Law School, Amity University, Noida, India.

related treaties it has signed and less with focusing on how we should uphold public rights in this sphere too.

The Indian pharma market and enterprise is a thriving, mostly innovation-driven business that has shown robust growth over the last several years. Due to factors such as strong government initiatives and limited international competition, the present industry participants include a few exclusive Indian firms that have snatched a large offer in the domestic medication market. However, the progression of the Indian economy is upsetting Indian businesses as they rise up out of homegrown business sectors and stuff up for global contest.

As India's economy opens up to international commerce, the Pharmaceuticals institution is a fantastic example of a business that is being forced to return to its drawn-out methodologies and action plans. Factors such as intellectual property protection are becoming more important as the necessity to secure costly investments in research and development becomes more apparent (R&D). In India, attempts are being undertaken to overcome concerns with the implementation of present protected invention regulations, and the Government of Indian Republic is working to build a patent system that will favour mechanical discoveries while staying mindful of its worldwide duties.

While new and inclusive patent laws are beneficial in encouraging the rapid development of pharmaceuticals and essential drugs, they are a hindrance to the populace's constitutional guarantee because privatisation and intellectual property rights protection drive up the costs of medicines and treatments, making them difficult to access by the general public who cannot afford such high cost commodities. Access to cheap healthcare has become a global concern, particularly in under developed nations in which the poor and depressed make up the majority of the population. In a developing countries Like India, where mass production of pharmaceuticals is much cheaper, the general public is still unable to afford adequate healthcare due to low wage levels as well as the privatisation of drug sectors, which compels drug prices to skyrocket with the support of our patent laws, which provide total immunity from direct competitors for a period of 20 years as a recompense for innovation.

The two main factors that have influenced the pharmaceutical patent regime of India are the Doha Declaration and TRIPS Agreement.

## **II. PATENT REGIME**

Patents are issued to protect inventions. A patent is a restricted government right awarded to the inventor in exchange for his or her work.. The creator or anybody else he or she selects can

apply for a patent. It's indeed their privilege to prohibit others from producing, using, selling, trading with, or acquiring something that is not theirs.

The patent is a negative right that does not grant the patentee (patent owner) the right to manufacture, use, or sell the invention, but rather the right to prohibit or prevent other parties from utilising the patent's creation without his or her permission.

The patent grants the right for others to produce, use, or sell the innovation. The patent protection is an agreement between an applicant/inventor and the government once the applicant/inventor has proved total honesty, the government grants the applicant/inventor the right to protect their work for a certain period. As a result, patenting offers a methodical strategy to protecting ideas while keeping their secrets hidden.

A patent is a legal document that describes a technical solution to a problem. Patents are only granted to innovations that fulfil the patentability requirements.

Patents are protected for a term of no more than twenty years. Patents are sovereign rights, but they are only valid in the country that grants them. As a result, any judicial or extra judicial proceedings for patent infringement or violation will be pursued only in that nation. Patents can be protected in a number of countries thanks to the PCT (Patent Cooperation Treaty), which grants patent protection to all signatory countries.

### **(A) Patent Law Development in India**

Patents legislation of the year 1970 is the primary piece of legislation in India that governs the patenting process. Initially, no product patents would be granted, but process patents for food, pharmaceutical, and synthetic products discoveries might be given under this criterion. In any case, product patenting has been legal in India since 2005. The Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement, signed in 1995, was clearly a WTO country (WTO).

TRIPS recommended that each of its member states follow the basic standards of IP laws. India's contractual responsibility to alter its patent laws in order to meet with the TRIPS Treaty's standards was to become a TRIPS Treaty signatory. The Patents (Amendment) Act of 1999 was the first change to this grouping, granting pipeline protection before the government began to give product patents. It laid forth the rules for registering patent applications for various products in the fields of pharmaceuticals and chemicals used in agricultural processes letter box applications, which began on January 1, 1995, and awarded them limited selling - rights (EMRs).

The Patents (Amendment) Act, 2002 has revisited the TRIPS Act of 1970 in order to assent to the second set of TRIPS duties. This change statement characterised the 20-year conventional patent term for a wide range of inventions. This alteration was also agreed upon under the TRIPS convention, and measures for reducing the continuation of genuine proof in case there is an occurrence of a valid patent contravention were introduced to the Act alongside other changes to the basic act, such as the phrase "innovation." The Patents (Amendment) Act of 2005 was passed as the third set of modifications to patent law.

This amendment established India's product patent system. Under certain conditions, such as the simple disclosure of new structures and properties or a new use of a known substance, pre-grant and post-grant objections have been modified, and arrangements have been made for the grant of an export permit, on a mandatory permit for patented pharmaceuticals, under certain conditions.

### **III. KINDS OF PHARMACEUTICAL PATENTS**

The drug business is among the 'creative- scientific driven' ventures. Drug testing is profoundly costly and possibly flighty. The aftereffects of the exploration might appear as another innovative item or technique which is helpful. For drug firms, in this seriously cutthroat climate, safeguard their creations from unapproved business use by tying down the patent right on the protected item or cycle. The accompanying classifications can be applied to Indian drug patents.

#### **(A) Drug Compound Patents**

These patents are for the entire substance structure of the pharmaceutical ingredient. Patent disputes of the Markush kind are commonly referred to. According to Markush, a few "practically indistinguishable" synthetic substances recalled for at least one aspect of the pharmaceutical mixture have interpretations.

Medicine compound patents provide the widest potential safeguards for the process's conclusion, since different firms are not permitted to set up the medication utilising any and all methods of union, or to deliver/sell any plan containing the medication before the patent expires.

#### **(B) Formulation/Composition Patent**

These kind of patents require high level advanced technology for making the drug itself or one of its main components.

**(C) Synergistic composition patents**

Medication collaboration happens when at least two medications interface so that at least one impact of these medications are upgraded or amplified. New synergistic medication details can be refined with licenses.

**(D) Technology Patents**

These licenses depend on innovation related methods like adjustment, taste concealing, further developed dissolvability, etc. A drug plan with a covered taste, the veiling of which proceeds all through the organization of the detailing, specifically as a dispenser a watery vessel, recognized by the way that it consists of basically the accompanying components:

- A cellulose polymer that dissolves in natural solutions but is basically non-soluble in liquids, independent of its pH; a methacrylic polymer that can be dissolved in natural solutions
- A natural soluble arrangement or a basic salt which should be chemically adequate;
- It's a type of adsorbent arrangement.

**(E) Polymorph patents**

Polymorphs are different corporeal or bodily forms or precious stone formations of a known material. Polymorphs are commonly used to eliminate impurities or increase the security of combinations. With a 98 percent immaculateness grade, the stated glasslike structure is spotless. In India, the issuance of polymorphism patents is governed by Section 3(d) of the Patents Act, 1970. 2005 Amendment<sup>3</sup> corrected this. Section 3(d) makes sure that patents are only awarded for really innovative inventions, and that patents for modest modifications are not obtained. These reveal insight into the strategy of the union administration to compensate designers/analysts for their intellectual accomplishments in the meantime likewise securing the overall population premium and making fundamental items, like meds, accessible at reasonable costs.

**(F) Biotechnology Patents**

Biotechnology combines the use of biological life forms and natural resources in the preparation of medicinal items. Biotechnology patents exist for a few analytic, restorative, and immunological products. It just so happens that, following the acceptance of the item patent system in 2005,

---

<sup>3</sup> The Patent (Amendment) Act of 2005

The Indian patent was the first awarded by the Indian patent office.

### **(G) Process patents**

These patents do not protect the patent product itself but the process or techniques used to produce the said product.

## **IV. PATENT AND HUMAN RIGHTS**

According to Black's rule, health implies "freedom from agony and suffering, the ultimate best state of creature life, and the uniqueness and concordance in the parts of the living being." A condition of ideal physical, mental, and social well-being, as well as a significant level of political and social wealth, is characterized as health.

It denotes towards the absence of illness or sickness, as well as the state of physical, mental, and social well-being. Henry Sigerist correctly said that health is one of the outcomes of life to which man has a right; the explanation for each scenario is that all actions aimed at preserving and reestablishing health are useless. Health care is described as the prevention, treatment, and management of infections, as well as "preventive, therapeutic, and palliative intervention" in all healthcare goods and administrations aimed at promoting health, as defined by clinical, nursing, and all other health care experts.

Due to this, World Health Organization report covers healthcare (2000). People's claims against the state, which is reliant on their humanity, are known as common liberties. At the heart of the current predicament, we can see that individuals deserve basic liberties regardless of their legal system.

The Universal Declaration of Human Rights, 1948, the International Covenant on Civil and Political Rights, 1966, the International conclave on Economic, Social, and Cultural Rights, 1966, and the Convention on Eventual Discrimination Against Human Rights, all centre on giving clinical consideration as a feature of individual basic freedoms.

This led to some of the writers to assume that they were complying with <sup>4</sup>Article 27(2) of the Universal Declaration of Human Rights (UDHR) and Article 15(1) (c) of the International Covenant on Economic, Social, and Cultural Rights, the grounds <sup>5</sup>for patent rights and other forms of IPRs.

Human character development is impossible without common freedoms. In the post-2015 discussion about the most effective approach to address health challenges more effectively, the

---

<sup>4</sup> <http://scholar.sun.ac.za/>

<sup>5</sup> <http://hdl.handle.net/>

job of health has gotten a lot of attention. The UN Task Team on the UN Post-2015 Development Strategy has produced a new strategy to turn health as a universal right into a measurable general health objective and public requests. Then, alongside State Parties, states are expected to refrain from clear infringements of the right to health, so safeguarding this fundamental liberty. The preceding language demonstrates numerous obligations on the part of states to preserve, defend, and meet the right, as well as entrance to health.

Thus, it is critical to focus public attention not only on the overall health of socioeconomically disadvantaged groups, but also on their financial and health success, and to strive for just an equitable distribution of the fiscal burden of chronic weakness and despair. Obtaining the right to health acknowledges that "health is the world's most essential social objective, necessitating the mediation of several other social and monetary areas in addition to the health field."

"As a result, the Sovereign states have an obligation to provide both material administrations as well as the social and financial conditions to ensure that the entitlement to healthcare is not abused as a common right." We may argue that the emergence of new invention is a critical component of their public and worldwide right to health, because the continuous advancement of modern logical and specialised innovations allows people to meet their health needs.

Human rights are not negotiable; they are the foundation upon which our very existence is built. As a result, it is critical that we find a way to end the tug of war between public and private interests in the field of pharmaceutical patents.

## **V. RIGHT TO HEALTH**

The healthcare guarantees has been recognized as a sacred right in India and a some other Sovereign States around the sphere. Indeed, the TRIPS Convention recognizes that member states may exempt from licencing certain innovations that should be utilized to protect public demand and ethical quality, including human, creature, or vegetation, or health, therefore avoiding actual harm to the climate. The entitlement to healthcare and admission to healthcare are widely recognised.

In a nation like India, where financial situations differ, public health frameworks should allow general health practitioners to adjust their frameworks to their specific requirements.

### **(A) Recognition of the right to health in the Indian Constitution**

The entitlement to health is not explicitly recognized in the Indian Constitution, but it is one of the derivation of fundamental rights guaranteed to Indian citizen by the supreme law of the

Indian Republic that is the constitution, regardless of race, religion, political convictions, or monetary or economic well-being.

The right to health is an integral component of the entitlement to life guaranteed by the Indian Constitution. Articles 14 and 21 of the Indian grundnorm have a knock-on effect on the healthcare system, forcing the state to discover new methods to improve healthcare for the Indian population.

Despite important rights, the Constitution stipulates some mandates or state requirements that impact admission to healthcare, including Articles 39, 41, 42, 43, and 51A.

Furthermore, Article 51 of the Indian Constitution specifies India's obligation to keep the affirmation for the international accords and concord to over which there is a direct influence on health affairs. To attain these objectives, the Administration for the Republic of India has established a variety of strategy for the underprivileged in both urban and rural regions, such as the NRHM<sup>6</sup> and the National Urban Health Project (NUM), they offer safe and expert transportation and assure the availability of approved supplies Mission Indradhanush, a Polio Drop Scheme, focuses on immunization through a get-up-and-running crusade, seeking to reach all children who have been neglected or missed out on vaccine.

Health issues affect both developed and developing countries. People are concerned about their health, and there is a strong desire for high-quality healthcare in some areas. Health-care costs are exorbitant. As a result, the government has yet to identify out how to provide general access. Contrary to popular belief, in terms of health determinants and access factors, agricultural nations have poorer access to health.

The preponderance section in these nations are either destitute or uninformed of the health and hygiene benefits and downsides. Admission to health care in India is impeded by a number of circumstances, thus established mechanisms and a variety of legal choices are available to assist with admission. The legal executive has made multiple decisions on a few areas of access, but authoritative implementation is insufficient. A lot of work in the administration sphere, and a fantastic structure should be investigated in this respect in the organized institution beside the legislative, administrative, and judicial parts.

### **(B) Judicial outlook and viewpoint to Right to Health**

In the landmark case of *Bandhua Mukti Morcha v. Association of India*, Justice Bhagwati held that states are not under obligation to accommodate these fundamental components of human

---

<sup>6</sup> National Rural Health Mission

pride by authoritative resolution or chief request, but when laws are authorized by the State providing these major conditions to workers and putting their right to live in an essential human nobility on the table. Furthermore, according to Article 256, leaders cannot be inactive until the government provides an acceptable mechanism for admitting to health.

The state's inaction will indicate denial of the potential for living with human poise, as appreciated in Article 21.

In *Consumer Education and Research Center v. Association of India*, the Supreme Court ruled that representatives had a fundamental right to protection and therapeutic care for protection and energy while working or after benefits under Article 21. In the same case, the court determined that health care is a sacred right while on assistance or after retirement, and so private businesses are required to provide health coverage to their employees.

Furthermore, the Supreme Court held in the case of *Peoples Union for Democratic Rights v. Association of India* that it is the State's basic responsibility to guarantee that no individual's fundamental right is violated. Along these lines, when conducting different social government aid campaigns, the government is obligated to conform to the Basic Principles of State Policy.

## **VI. ECONOMIC AND FINANCIAL RELIANCE ON THE INDIAN PHARMA INDUSTRY**

With almost 60000 ordinary brands in 60 helpful classes accessible, the Indian drug productivity has a indestructible nonexclusive reason, supported through the sanction patent development at that point. The improvement of the inward medication industry is one illustration of the Indian economy defeating misfortune. The Indian drug industry, which was an extraordinary medication thing maker with a minimal expense generally speaking rating during the 1950s, presently has a yearly turnover of more than \$1.5 billion. This was only feasible since there was no item patent system for pharmaceuticals and medical devices.

Numerous nations expected that patent insurance in the drug business would smother data dispersaland impede public-interest related logical advancements. Nearly every single agro - based nation has been concerned that once a product has been granted, a comparable product cannot be developed during in the defensive time. If the cycle is ensured without anyone else (measure licences), a predominantly "designed" interaction may be used in the creation of a comparable item, as an item can be made by more than one technique in drugs.

Over the last three decades, the Indian pharmaceutical sector has grown steadily and has emerged as a major global player in generics. In Today's. time Indian Republic is one of the

world's major helpful creation state, accounting for around 20-22 percent of its total proposal in nonexclusive creation as the fourth-largest creator by volume and thirteenth in esteem.

Since this sector is such a large donator to India's economic development most law makers hesitate to change its workings and laws due to the fear that it might lead to our economic destruction and downfall. But for the betterment of our society this fear needs to go and soon so that we can act before it's too late.

## **VII. FUTURE AND PROSPECTS OF PHARMACEUTICAL INDUSTRIES IN INDIA**

Because of the lack of patenting for drugs and agrochemicals, many global organisations have limited their holdings to terminated licences or potentially to a few protected items.

This has resulted in a shortage of its share of the overall industry, as nearby manufacturers have completed picking apart, which is one of the most progressive medications. Unfamiliar firms need to pay worldwide eminences for prescriptions while Indian organizations approach and reformulate the most recent atoms for homegrown deals from everywhere the globe. Hence, licenses for drug items in India have been steadily debilitated and numerous unfamiliar Pharmaceutical think-tanks have been departures. The commitments put on India under the TRIPS Agreement would directly affect the Indian drug industry.

Indian firms would have to compete with multinationals by assembling prescriptions and developing restrictive legal products. Indian firms may also focus on assembling endorsed exclusive medications by unknown organisations or profiting from nonexclusive medication development. The remarkable rise in innovative work consumptions will be the key to Indian drug organisations' survival. Indian associations require item protecting to propel examination into minimal expense prescriptions that accommodate the patent profile of the Indian sickness.

Besides, the methodology of thing licenses will without a doubt increment multinationals that have recently been reluctant to put resources into India without thing patent protection, just as further foster rivalry in the homegrown market.

## **VIII. COMPULSORY LICENSING**

Compulsory licenses, as characterized in the TRIPS Agreement, are relied upon to find some kind of harmony between the community interest and the genuine interests of patent holders. The TRIPS Convention likewise incorporates explicit prerequisites for the utilization of obligatory licenses, and various explanations behind necessary licenses might be given relying upon the circumstance: instant and authentic criticalness; non-genuine practices; public non-business use; and secure licenses.

Compulsory licencing is a grant in which the administrative authorities allows another person to create a protected item or interaction without the concurrence of the patent holder. This is one of the primary pillars of the licence arrangement.

Compulsory licences for protected inventions are remembered for the Paris Convention and TRIPS Agreement. Except in special cases, such as a public crisis or crises, which can be used for a permit to be vouchsafe on the prior date, according to Indian patent law, an application for a compulsory vouchsafe must be made sufficient time after the patent is discharged. As a result, three broad requirements for granting compulsory licences have been established;

- (i) The reasonable needs of the general public in relation to the protected innovation have not been satisfied.
- (ii) The licenced innovation is non-economically available at a reasonable cost;
- (iii) The patented innovation is essentially unable to word in the Indian jurisdiction.

The Patent Act silhouette the conditions in which "sensible general population guidelines" may not have been satisfied. Such conditions might exist <sup>7</sup>if the patent holder refused to issue a permission on fair terms, therefore influencing:

In a country, the creation of a new trade or industry;

Establishment or development of business or commercial operations within India;

In the pharmaceutical business, where India has the ability to establish itself as a large conventional provider to agricultural nations with insufficient domestic manufacturing plants, the basic consequences of this arrangement are to be felt.

It entails ensuring that protected ideas are manufactured commercially in India and that the interests of everyone involved in developing or delivering an invention are not jeopardised. The innovation does not require a licence. The implementation of a wonderful and competent patent system will give numerous advantages, including data sharing and interest in new item and cycle manufacturing, which will eventually be freely available.

## **IX. INTERNATIONAL PERSPECTIVE**

Compulsory licencing has long been used to manage exclusive patent rights. In the case of pharmaceuticals, it is appropriate to ensure that the ownership of a patent does nowhere result

---

<sup>7</sup> Jae Sundaram. "India's trade-related aspects of Intellectual Property Rights compliant pharmaceutical patent laws: what lessons for India and other developing countries?", *Information & Communications Technology Law*, 2014 (Publication)

in a situation in which a protected drug is unavailable to the broader public for non-health reasons.

Both compulsory licences and rights were accommodated in a complex plan in the 1970 Patents Act. The TRIPS Agreement does not rule out the possibility of compulsory licences, but it provides a more rigid framework than the current Indian framework.

Tolerating the flexibility provided in the Doha Declaration that TRIPS member states may use, such as a discriminatory justification for issuing compulsory licences, is to be viewed as a component of an increasingly restrictive global patent system. The study tackles a number of critical issues regarding clinical patent implementation. In any event, the obviously more significant concerns of patentability and the length of licences in the medical area cannot be addressed. The Doha Declaration is still a powerful weapon in India for two reasons.

Above all, during the pastoral assembly on policy problems, India was one of the most vociferous created nations in advocating the interests of non-industrial states. Furthermore, the Joint Parliamentary Committee supported the statement following its report.

The World Trade Organization (WTO) is still a long way from being a successful response to agricultural nations' overall health needs. To some extent, the Doha Declaration provides temporary relief in some confined areas. The assertion does not imply that transactions would primarily aim at facilitating TRIPS state and shape in the upcoming set of trade agreements in the same area.

This new assailant position of the US pharmaceutical industry demonstrates the danger of generous campaigning to work on patent laws later on. The Patents (Amendment) Act of 2002 substantially follows TRIPS in general, and the 1970 Act's provisions are repealed. To begin, no official change has occurred to justify such drastic changes in the methodology concealed by the Patents Act. Furthermore, notwithstanding recent changes, Indians have not abdicated their local and global responsibilities in terms of the fundamental right to health. Third, the requirement to show item licences by 2005 appears to have a detrimental impact on human patients' access to medications. The government's goal of developing its commercial drug sector may have played an influence.

Nonetheless, it is noteworthy that today's business, which is still wholly or mostly domestic, lacks consensus. Some large organisations that primarily manufacture conventional medications have opposed changes to the 1970 Patents Act, while others that have established major R&D frameworks accept that the new system can offer them an opportunity to develop

outside the world, and small organisations appear to have perceived that they are insignificant enough to generously influence strategy making.

Despite numerous conventions held, treaties signed and steps taken on a global scale no worldwide institution or forum has yet been successfully in achieving a balance between private and public interest when it comes to the field of IPR. Each and every international organisation has been looking for a way to deal with this problem but none have been entirely successful so far. Though progress is being made in the same but the rate at which this is being done is too slow to match the need of the hour. We exigency to find a way out of this problem and we need to find it fast.

## **X. CHALLENGES FACED BY THE INDIAN PATENT LAW REGIME**

Since India is the signatory of the TRIPS agreement it is bound by its IPR laws and also because it is a signatory of the World Trade Organisation and a member to all its various treaties in favour of TRIPS with respect to Intellectual property rights. The problems in this area arise not only from the developmental process of these laws but also in its execution where solidarity has to be maintained by administration between the legitimate and legal -interests of the Patent right holders and the citizens of the nation. This problem is becoming more and more complicated due to the increase of for companies from abroad filing in great numbers, patent applications in our country. In our country there are not many special IP related courts that hear matters regarding this issue and when it comes to Civil courts, they mostly rule their judgement in favour of the patent holder rather than the citizens. Other than global and international laws the only unique feature of the Indian patent system is Article 3 of the Patent Act which has a few specific provisions regarding matters such as computer related patents, expert opinion etc.

## **XI. NORVATIS V. UNION OF INDIA CASE AND ITS IMPORTANCE IN THE PATENT REGIME OF INDIA**

The case of Novartis AG v. Union of India (Civil Appeal Nos. 2706-2716 of 2013) is India's most illustrious judgement on patent rights. Novartis was denied a patent for the drug 'Imatinib Mesylate,' marketed under the brand name "Gleevec," due to a lack of invention, novelty, and non-obviousness. On April 1, 2013, a two-judge Supreme Court bench comprised of Hon'ble Justice Aftab Alam and Hon'ble Justice Ranjana Prakash Desai rendered this decision.

The Supreme Court's judgement is a big relief for individuals who cannot afford the life-saving medications manufactured by the enormous pharmaceutical corporation. These multibillion-dollar corporations prevent people from purchasing medications at lower prices, thereby

jeopardising the poor's very existence by patenting the products. The importance of a patent cannot be overstated if such an invention is made available to all people at a reasonable cost. Contrary to popular belief, corporations such as Novartis are establishing monopolies in the market, putting poor people's lives in jeopardy.

In any case, this decision made it apparent <sup>8</sup>that India is a developing country, and the availability of affordable drugs is critical to <sup>9</sup>the lives of 1 billion people. The Apex court of Indian Republic was correct in prohibiting the liberal approach and granting Patents only to genuine and significant inventions.

## **XII. SOLUTIONS TO THE EXISTING PROBLEMS**

Despite the fact that TRIPS includes provisions to protect common people's public health, TRIPS has not been as successful as it should be in developing and least developed countries for public health promotion. TRIPS should be amended to include a medication pricing system that requires patent holders to sell pharmaceuticals at a lower price in order to provide underprivileged people in developing countries with access to life-saving therapies. TRIPS should strike a balance between pharmaceutical companies' drive for profit and their obligation to society's most vulnerable people. Its goal should not be to prohibit, but rather to promote the availability of inexpensive drugs that meet national public health requirements.

These are a few additional ideas to consider:

- Patent legislation in each country should be based on its socioeconomic requirements and goals, including public health, while complying to international responsibilities.
- Changing patent regulations to improve access to medications, especially for the poor, is a top public health goal.
- Governments should be able to act rapidly in times of disease crises within a health-responsive legislative framework.
- The government must develop a pharmaceutical patent system that regulates access to life-saving medications clearly.
- Compulsory licencing should be used in emerging and least-developed nations. For the issue of obligatory licences, a straightforward method must be established.
- Parallel importation of such critical life-saving medicines should be permitted.

---

<sup>8</sup> Submitted to Damodaram Sanjivayya National Law University (Student Paper)

<sup>9</sup> Submitted to Damodaram Sanjivayya National Law University Student Paper)

With the assistance of such changes healthcare will become more accessible as well as cost friendly for the Indian masses and this in turn would help improve the mortality conditions in our country.

### **XIII. ANALYSIS**

Intellectual property laws in India is everything except satisfactory. It demands interest, inside and outside information and viable system for empowering and building intellectual property right activities and investigate scientific research and innovations in India. The Indian pharma industry gave the drugs campaign a monetary support by showing that another pharmaceutical industry was conceivable. The plethora of judgments given by the Supreme Court including the Novartis A.G. case demonstrates that India keeps on putting a charge on general health corresponding to patent law decisions. Thus, the patent of pharmaceutical invention confines the competition of generic drugs and subsequently increased the prices of drugs, and are believed to be a huge obstruction to accessibility to drugs in under developed nations.

Patent protection might be very important for the pharmaceutical industries because apart from various backdrops of patent rights it also provides various safeguards against the maltreatment of monopoly rights granted under the act and lays out for better admittance to medicines, but at the same time, this law clashed with public health rights.

The Indian pharmaceutical market has a solid generic base with about sixty thousand generic brands in the market which was sustained by the then general set of laws concerning patent. The Indian pharmaceutical industry has witnessed many developments over the last three to four decades and the growth of domestic pharmaceutical industry is phenomenal and is considered as one of the successful industry in India. In today's time Indian pharma sector is the biggest exporter of generic drugs around the world and it accounts 20% of worldwide fares as far as volume, but despite this huge monopoly and availability of drugs, due to inappropriate laws, Indian citizens have yet to benefit properly in terms of healthcare facilities and are still struggling to achieve the same.

Section 3(d) was brought into limelight in the case of Novartis A.G & others vs. Union of India & others. The judgment of this case comes as a huge relief in the developing countries in which most of the people cannot afford the essential drugs on account of unreasonable prices charged by these big pharma companies. The life of these poor people are putting in question by these big pharmaceutical companies by misusing the monopoly right over their manufactured drugs. On the off chance that Novartis had won the case, getting pharmaceutical patent on medicines would have likely been endorsed more in India, limiting generic competition and in this manner

preventing the access to reasonable medicines in the under developed nations. But even after this judgement no major improvement can be seen in the case of patent laws. Patent act grants monopoly rights to the manufacturer which, restrains others from manufacturing, selling or utilizing the patented products without the approval of the inventor. On the other hand big pharmaceutical companies misuses this monopoly right by charging unreasonable prices for the pharmaceutical products.

Although the patent act provides incentives to the pharmaceutical industries for the innovation and development. In order to earn more profit the pharmaceutical companies charge more cost as compared to the manufacturing cost. Next issue is misperception towards branded generic medicines and non- branded generic medicines. Drug manufacturers and pharmaceutical marketing companies always think that branded generic medicines are better than non-branded generic medicines. Surprisingly medical practitioners also thinks the same that branded generic medicines are better than non- branded generic medicines. Even the learners and academicians have also dived the pharmaceutical products into two groups: branded and non- branded pharmaceutical drugs. In order to earn more profit doctors refers and branded drugs which are costlier than non- branded drugs. Consequently pharmacies also store branded generic drugs which led to the problem of general public access to essential drugs. What could be concluded that the interest of pharmaceutical companies are given more importance than the rights of the general public access to essentials medicines? whether a product is branded or not whether the product is being promoted by the medical practitioners or not matters more to medical practitioners as well as the learners and the academicians rather than public's access to health, public's safety and the reasonable prices of the drugs, it is of utmost importance that we change this perception.

#### **XIV. CONCLUSION**

India is challenging in terms of health — economically, demographically, and epidemiologically. <sup>10</sup>While the preceding decade saw significant economic development, particularly in terms of GDP growth rate, this achievement was accompanied by growing disparities <sup>11</sup>between the wealthy and the poor. There is convincing evidence that wealth inequality or socioeconomic disparities are associated with lower health outcomes. The rising wealth inequality between rich and poor has significant health and cultural consequences.

---

<sup>10</sup> Submitted to Tata Institute of Social Sciences (Student Paper)

<sup>11</sup> Submitted to Holland Christian High School (Student Paper)

While the <sup>12</sup>government implements financial inclusion and social security measures to bridge economic inequalities, the health sector must also ensure that health disparities within and across social and economic classes are handled correctly. The tremendous demographic transitions that are occurring are expected to <sup>13</sup>contribute to a considerably increased labour force. However, it will only benefit the country if the population is healthy.

The country is today dealing with a triple sickness burden: an unfinished agenda of infectious illnesses, as well as the introduction of new pathogens that are causing <sup>14</sup>epidemics and pandemics. Furthermore, the health-care infrastructure is already overcrowded and must be upgraded to meet the demands of the twenty-first century.

In such a time the need to reduce the gap between the rich and the poor is of utmost importance and especially this is required in the health care sector where skyrocketing and ever increasing prices of medicines, vaccinations, therapies and other treatments are also skyrocketing day by day in the view of the monopoly held by the pharmaceutical associations that enjoy numerous patent rights due to the lack of stringent and balanced laws in this field. It is time that our government joins hands with experts in this field to formulate laws that will benefit the masses at large but at the same time the laws should be such that they do not compromise personal and private interest. Agreed patent protection is necessary to encourage innovation and scientific development, but this cannot be done at the cost our people's health and by further pushing them down the road of poverty.

In developing countries like India, health-care organisation has been a precursor for grave abuses of basic rights. When the majority of people shortfall approach to basic wellness program, the idea of justice is violated. The pharmaceutical industry's adherence to the TRIPS Agreement is critical to the future of public health in India. Local patent activity refers to the creation of a patented upshot or the application of a patented technique in the local sector. The inventive phase can lead to innovativeness, which can contribute to technical development and industrial and economic well-being, but only if patented inventions are used locally.

The financial interests of big pharma industry companies continue to pose a constant danger to India's ingress to life-saving medications at reasonable rates. Patenting and innovation are two periphery of the same coin. Patents should not put use of merely for profit, and innovations, particularly in the medical field, should be in the greatest interests of humanity.

---

<sup>12</sup> Submitted to Deakin University (Student Paper)

<sup>13</sup> Submitted to Holland Christian High School (Student Paper)

<sup>14</sup> R. Vinodh Rajkumar. "RESISTING MORBIDITY AND MORTALITY (RMM): AN EQUITABLE PUBLIC HEALTH", *International Journal of Physiotherapy and Research*, 2020 Publication