PHARMACEUTICAL PATENTING IN INDIA: PROBLEM OF PUBLIC ACCESS TO HEALTH

Prakhar Singh, BA LLB, Amity Law School, Lucknow & Rajarshi Tripathi, BALLB, Amity Law School, Lucknow

ABSTRACT

The issues with public access to health in India are highlighted in this study along with an outline and analysis of the patent laws in respect to pharmaceuticals. Furthermore, patents have had a considerable impact on how both local and foreign innovation is conducted. Anyone may possess a patent as an example of intellectual property, including an individual, a company, or even the national government of the country.

In today's culture, IPR rules are becoming more common. Creative brains feel relieved in the knowledge that their idea, notion, or discovery will be theirs alone. Patent law is the most significant of these. But access to basics like medicine, which is something everyone needs, is hampered by the same patent restrictions. The use of pharmaceutical medications, their patenting in India, and issues with the general public's access to healthcare are all included in this article.

The IPR culture in India, however, is significantly short of expectations. It requires zeal, in-depth knowledge, and efficient strategies for promoting and expanding IPR activities in order to examine scientific and industrial research and innovation in India.

Key words: - Pharmaceutical, Patenting, Patent laws, Intellectual Property Rights (IPR), TRIPS

HYPOTHESIS

This paper examines the issue of public access to health care and pharmaceutical patenting in India. There are various areas of inquiry, including the following;

A. What does drug patenting entail?

B. What issues does the public's access to health care cause with pharmaceutical patenting?

C. How can the issue be resolved?

For a deeper understanding of the concept, this research paper provides the study and responses to the questions mentioned above.

RESEARCH METHODOLOGY

The researcher has adopted Doctrinal Research Methodology. The Researcher has made excessive use of primary and secondary data available on the Internet in form of articles, thesis, research projects, blogs, and other sundry miscellaneous sources including books, commentaries, legal research databases which are duly accredited with appropriate citations hereunder.

INTRODUCTION

In the developing world, India has long been a leader in the effort to modify pharmaceutical patent legislation to account for domestic health needs and place a greater emphasis on the needs of the average person in order to be in line with its development. The fact that a considerable portion of the population in India is poor and that most people pay for their own healthcare shows that there is a serious healthcare problem in the country as well as inadequate access to, affordability for, and availability of medicines.

According to Indian patent law, Section 3(d) is a mandatory clause. It successfully strikes a good balance between protecting the poor's access to medicine and the mandate of the Agreements on Trade Related Aspects of International Trade (TRIPS). Due to this, India is now a leader in the pharmaceutical sector. After the TRIPS regime, there has clearly been a change in the circumstances. Since the Indian market and pharmaceutical companies are significant suppliers of the low cost pharmaceutical products in the form of generic pharmaceuticals, the

pharmaceutical patenting in India is particularly pertinent to the present public health challenges. Since India signed the Doha Declaration on the TRIPS Agreement and Public Health in 2001, the question of access to medications has taken on a more global scope. The pharmaceutical sector is well-established and becoming more export-focused, while civil society awareness is growing. The worldwide drive to increase access to pharmaceuticals has India at its centre. The Indian industry gave the campaign a financial foundation by demonstrating the viability of an alternative pharmaceutical sector. According to recent decisions on patent law, such as the Supreme Court's ruling in the Novartis case1, India continues to prioritise public health when making decisions about pharmaceutical patent laws.

Thus, it is clear that pharmaceutical patents limit generic competition, which raises prices, and are considered to be a major obstacle to developing countries' access to medications.

INDIA'S IPR (INTELLECTUAL PROPERTY RIGHTS): HIGHLIGHTS

Intellectual property rights are legal privileges that control who may exploit works of human creativity. In the current world, intellectual property is one of the most crucial components of the business and commerce sector. The most important assets of a corporation are their intellectual properties (IP). IP can foster healthy market competition, which allows manufacturers, merchants, and owners to develop their goods more effectively. Therefore, the rights granted to people over their original works of art are known as intellectual property rights. For a set amount of time, they often grant the creator the only right to use their work, with some of these categories also including acknowledgment and financial reward.

The rights attached to intellectual property allow the owner to profit from the products of this intellectual endeavor by establishing a monopoly over it. Intellectual property is a creation of human intelligence.

Such an advantage is not necessarily a natural right and needs to be recognized by law.

"Copyright, trademark, geographical indication, industrial design, patent, integrated circuit, and other terms that relate to the works of the mind include innovations, literary and artistic works, designs, and symbols, names, and pictures used in business and commerce.

The following are the various intellectual property laws in India:

- The Copyright Act, 1957
- The Patents Act, 1970
- The Trademarks Act, 1999[1]
- The Geographical Indications of Goods Act, 1999
- The Designs Act, 1999
- Semi-Conductor IC Layout Designs Act, 2000
- The Protection of Plant Varieties and Farmer's Rights Act, 2001
- The Biological Diversity Act, 2002"[2]

"Intellectual property rights are customarily divided into two main areas:

(i) Copyright and rights related to copyright

The rights of authors of literary and artistic works (such as books and other writings, musical compositions, paintings, sculpture, computer programs and films) are protected by copyright, for a minimum period of 50 years after the death of the author.

Also protected through copyright and related (sometimes referred to as "neighbouring") rights are the rights of performers (e.g. actors, singers and musicians), producers of phonograms (sound recordings) and broadcasting organizations. The main social purpose of protection of copyright and related rights is to encourage and reward creative work.

(ii) Industrial property

Industrial property can usefully be divided into two main areas:

[1] Madhurima Mohajon, Pharmaceutical Patenting In India: Problem Of Public Access to Health, IPR LAW INDIA, *https://iprlawindia.org/wp-content/uploads/2021/04/Madhurima-Mohajon.pdf?cv=1&session-id=8ead8ca91fc841098d35763b273112d8 (last visited Feb. 9, 2023).*

[2] Madhurima Mohajon, Pharmaceutical Patenting In India: Problem Of Public Access to Health, IPR LAW INDIA, https://iprlawindia.org/wp-content/uploads/2021/04/Madhurima-Mohajon.pdf?cv=1&session-id=8ead8ca91fc841098d35763b273112d8 (last visited Feb. 5, 2023).

- One area can be characterized as the protection of distinctive signs, in particular trademarks (which distinguish the goods or services of one undertaking from those of other undertakings) and geographical indications (which identify a good as originating in a place where a given characteristic of the good is essentially attributable to its geographical origin).

  The protection of such distinctive signs aims to stimulate and ensure fair competition and to protect consumers, by enabling them to make informed choices between various goods and services. The protection may last indefinitely, provided the sign in question continues to be distinctive.

- Other types of industrial property are protected primarily to stimulate innovation, design, and the creation of technology. In this category fall inventions (protected by patents), industrial designs and trade secrets".

  The social purpose is to provide protection for the results of investment in the development of new technology, thus giving the incentive and means to finance research and development activities.

  A functioning intellectual property regime should also facilitate the transfer of technology in the form of foreign direct investment, joint ventures and licensing.

  The protection is usually given for a finite term (typically 20 years in the case of patents).

  "While the basic social objectives of intellectual property protection are as outlined above, it should also be noted that the exclusive rights given are generally subject to a number of limitations and exceptions, aimed at fine-tuning the balance that has to be found between the legitimate interests of right holders and of users".[3]

PATENT

Meaning

[3] WORLD TRADE ORGANISATION, https://www.wto.org/english/tratop_e/trips_e/intel1_e.htm (last visited Feb. 8, 2023).

An innovation, which can be a product or a process that generally offers a new method of doing something or the latest innovative solution to a problem, is given an exclusive privilege called a patent. The public must be made aware of technical details regarding the invention in a patent application to get one.

Patents are essentially a type of intellectual property that the proprietor or the business holds or has in its possession. It is given for an innovation that is special in nature and the result of the creative effort of the person or individuals who performed the creation.

A patent gives its owner the power to prevent third parties from making use of the patented technology, such as by producing, utilising, or marketing the patented innovation.

With the use of this "unique right," the patent holder can recover development costs and get a return on their investment in the creation of the patented technology. In addition to promoting research, strong patent protection is a prerequisite for obtaining venture financing. Additionally, it is essential for general economic expansion. When a business decides to submit patent applications, it should take a strategic tack that maximises value from patents while reducing expenditures related to patent acquisition.

A patent's owner can benefit from a variety of benefits, some of which may be particularly relevant to specific industries or types of businesses. First off, patents give an organization the right to freely move about its industry. This freedom of mobility can be extremely beneficial to many businesses, particularly in congested markets with lots of rivals or markets where one player dominates.

Registration Process For A Patent Under Patent Act, 1960

The Procedure for Patent starts even before an application is filed with the patent office in India.

Step 0 - Decision of doing it yourself or engaging a professional

Before you proceed with the filing of patent application you need to decide if you will be taking any help of patent professional or undertaking the patent process itself. Considering the no. of deadlines it is recommended that you hire a professional who has experience in the world of patent.

If you decide to take the help of professional make sure that you sign a NDA (Non-Disclosure Agreement) with the patent professional before revealing about your invention.

Step 1 - Check the patentability of an invention.

Before filling a patent application in India, First step is to do a detailed patentability search to determine whether a patent can be granted or not. It should include both patent and non-patent references. Based on the information discovered during the search, you have the option of calibrate your patent application so that you don't end up filing for a patent which already exists.

A patent should meet all the criteria as per Indian Patent Act:

- Novelty
- Inventiveness
- Industrial Application
- Enabling

Step 2- Drafting Patent Application (Provisional or Complete)

A patent application is filed in Form-1 with the prescribed fee mentioned in Schedule 1 at a patent office in accordance with the jurisdiction. Each patent application is accompanied with patent specification (Form 2).

According to the state of invention, you can either file a provisional or complete application. If it is still in development mode it is recommended to file a provisional application to block all important filing dates. A complete specification shall be filed within twelve months from the date of filing of the application, and if the complete specification is not filed, the application shall be deemed to be abandoned.

A patent specification should include- Title of the patent invention, Background of the invention, Summary of the invention/ Object of the invention, Explanation if any of the patent

drawings, Description of the invention, Patent Claims, Patent Abstract of the disclosure and Sequence listing.

Step 3 - Filling the Patent Application in India

First filing in India - Once the application is drafted, you need to file the patent application in India and secure the filling date. If Provisional application is filed then complete specification shall be filed within twelve months from the date of filing of the application, and if the complete specification is not filed within that time, the application shall be deemed to be abandoned.
Foreign filing decision If you are interested in protecting your invention in other foreign jurisdiction you have to file it within 12 months from your first filling date Based on the countries you are interested in.

Every application for patent needs to be filed in the forms mentioned below:

- Form 1 Application for grant of a patent
- Form 2 Provisional/Complete specification
- Form 3 Statement and undertaking regarding foreign application under section 8 as per the Patent Act Herein after re offered to as, The Act(only required if a corresponding patent application is filed in another country)
- Form 5 Declaration as to inventor ship (only to be filed along with the complete application)
- Form 26 Form for authorization of a patent agent (only required if you are using a patent agent to help you file the application)
- Form 28 To be submitted by start-up or small entity (only required if you are claiming start up or small entity status)

Priority documents:
In case you are claiming priority from a foreign patent application and entering India, you may be required to provide the priority document as well.

Step 4 Publication of Patent Application

Ever application is published in the official journal after 18th months period from the date of filling of application or the date of priority of application whichever is earlier.
There is a provision for early publication of an Indian Patent application by filling a formal request.

The early publication rule does not apply if:

a. Secrecy directions are imposed under Section 35 of The Act.

b. Application has been abandoned under Section 9(1) of The Act.

c. The applicant has withdrawn his application three months prior to the expiry of said prescribed period of 18 months

Step 5- Examination of Patent Application

Every patent application is not examined; Applicant or any other third party has to file a request for examination under Form 18 and for expedited examination in Form 18A (under conditions as prescribed in the Rules).

Process of Examination (Objections by examiner & responding to objections)

Once the application is filed it will end up on the desk of examiner. During examination process examiner will scrutinize application that it is in accordance with Patent Act and Rules.
The examiner creates first examination report of the application and will state ground for objections if any. Thereafter the applicant is required to comply with the requirements within a period of 6 months from the date of FER which can be extended by 3 months by filing Form 4.

Step 6- Grant of Patent

The order of grant is given when all the requirements of patent Act are compiled and it will be published in Patent Journal.

Step 7- Renewal

After the grant of patent it needs to be renewed from 3rd year onward by paying renewal fee as prescribed in Schedule 1. A Patent in India can be renewed for maximum period of 20 years from the date of filing".[4]

PHARMACEUTICAL PATENTING

Meaning

"Whenever a pharmaceutical company first develops a treatment for a disease condition, it is originally traded under a brand name so that doctors can recommend the drugs for usage by patients. The medication is covered by a patent, which means that only the pharmaceutical business holding the patent is allowed to manufacture, market, and ultimately making the profit from the drug".

Following approval, a drug's patent typically has a useful life of 15 to 20 years. It is because businesses file patent applications before conducting clinical trials to evaluate the efficacy of medicines. The medicine can be produced and sold by other businesses after the patent has run its course. At this time, the medication is considered to as a generic medication.

INDIAN PHARMACEUTICAL PATENTING AND PATENT LAWS

With around 60,000 generic products available in the market across 60 therapeutic categories, the Indian pharmaceutical business has a solid generic base that was cultivated by the previous patent law. One of the success stories in Indian economic history is the expansion of the indigenous pharmaceutical industry. The Indian pharmaceutical sector has gained international prominence as a cost-effective producer of high-standard and high-quality pharmaceutical products today, having once been an import-dependent company in the 1950s. Its annual export sales reach $1.5 billion. This was possible since medications and pharmaceuticals did not have a product patent system at the time.

"When it comes to pharmaceuticals, patents are only issued for the methods used to manufacture substances that are intended for use as food, drugs, or medicines, or compounds

[4] Aarti laddha, Registration Process for a Patent under Patent Act, 1970, LEGAL SERVICE INDIA, https://www.legalserviceindia.com/legal/article-3720-registration-process-for-a-patent-under-patent-act-1970.html (last visited Feb. 9, 2023).

created through chemical processes. Patents are not issued for the substances themselves. As a result, Indian law currently does not offer patent protection to medicinal products".

Under the "Patents and Designs Act of 1911", India established a system of product patents for all inventions. The government did, however, enact the New Patents Act in 1970, which disqualified agrochemicals and pharmaceuticals from being eligible for patents. This restriction was put in place to reduce India's reliance on foreign imports for large-batch medications and preparations and to foster the growth of a locally based pharmaceutical industry.

"The absence of product patent protection in the pharmaceutical and agrochemical industries had a big impact on the Indian pharmaceutical industry and led to the development of considerable expertise in the reverse engineering of drugs that are patentable as products throughout the industrialised world but unprotectable in India".

Due to this, the Indian pharmaceutical industry experienced tremendous growth as it created less expensive copies of some drugs that had domestic patents and later aggressively entered the global market with generic medications once the patents on those medications had expired internationally. Several protections are also offered under the Patents Act to stop the infringement of patent rights and to improve patient access to medications.

"The Patents Act also has provisions relating to compulsory licensing. On the completion of three years from the date of sealing the patent, any person interested in working the patented invention may apply for a compulsory licence with respect to the invention. The controller of patents may direct the patent holder to grant such a licence upon the terms as may be deemed fit, only if he or she is satisfied that the reasonable requirements of the public with respect to the patented invention have not been met or that the patented invention is not available to the public at a reasonable price".[5]

"Section 3(d) of the Patents Act, 1970 says that the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use

[5] Novartis AG vs. Union of India, AIR 2013 SC 1311.

of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant, is not patentable".[6]

"The WHO Public Health Innovation and Intellectual Property Rights Report, 2006 has given its approval to the provision under section 3(d) that states that nations may adopt laws and standards for patent applications that demand a level of inventiveness that would prevent the issuance of ever-greening patents". The Novartis case's Indian patent law judgement signifies a significant victory for communities' access to affordable medicines in developing countries and has an impact on the poor's ability to get medications. If Novartis had won the lawsuit, medication patenting would probably have gained wider acceptance in India, limiting generic competition and obstructing access to affordable medicines in underdeveloped countries. Additionally, the approach is anti-competitive in that it will provide multinational corporations (MNCs) in the pharmaceutical industry the ability to eliminate generic manufacturers' competitors and extort astronomical prices for their proprietary medications. As a result, many vital medications will no longer be available to the general people due to exorbitant prices, which will negatively affect public interest in emerging nations.

How Is Availability To Healthcare For The Public Being Compromised By Pharmaceutical Patenting?

Regarding its effect on the Indian pharmaceutical business and access to necessary medicines both inside and outside of India, there are various points of view. India has many pharmaceutical firms and is ranked fourth in terms of manufacturing capacity. The patent system can be confusing to those who are unfamiliar with it, even though pharmaceutical medication patents are a crucial component in promoting innovation.

Drug corporations frequently exploit the patent monopoly and charge exorbitant rates for copyrighted medications. Drug accessibility has decreased because of the introduction of product patents. In India, a significant proportion of generic medications, including vaccines, are being patented, making it challenging for the industry to create life-saving medications.

Excessive drug prices that prevent regular people from accessing medication go against the expectation of the government to preserve the health of its people. Particularly in a nation like

[6] IPINDIA, https://ipindia.gov.in/writereaddata/Portal/IPOAct/1_31_1_patent-act-1970-11march2015.pdf (last visited Feb. 9, 2023).

India, where a substantial portion of the population lives below the poverty line and healthcare prices are excessive, it is evident that there is a serious medical emergency with an inadequate supply of pharmaceuticals that are affordable, accessible, and available of drugs.

"This is a crucial challenge to the Indian Government. Wherefore, a lot of initiatives are being taken by them to protect this situation such as compulsory licensing (on the refusal of voluntary license) and parallel trade policies as alternative ways that can help developing country governments to make essential medicines more affordable to their citizens. Compulsory licensing reduces prices to consumers by creating competition in the market for the patented good".[7]

First, it offers a framework for organising the various pro-health elements under patent laws. This encourages the adoption of similar clauses in nations where patent laws do not already contain them. Second, it highlights the conflicting claims made by consumers and patentees. "For instance, the South African Pharmaceutical Manufacturers Association and 4016 pharmaceutical companies-most of which were multinational-started legal proceedings against the South African government in 1998. They claimed that the South African constitution guaranteed their property rights and that the Medicines and Related Substances Control Amendment Act 17 violated those rights". With the help of transparent pricing, generic substitution of off-patent medications, and the parallel importation of proprietary medications, the Amendment Act established a legislative framework to expand South Africa's access to cheap medications. Given that the State is required by the Constitution to "take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of this right", it would have been interesting to see how the court would have balanced the patentees' property rights against the right to health care services had the case gone to judgement. This issue is still moot, though, because the lawsuit was dismissed before a decision could be made.

REMEDIES TO THE ISSUE OF PUBLIC HEALTH ACCESS

"One can question if attempting to establish a balance between the right to health and pharmaceutical patents is even necessary. Given that the right to health is a fundamental human

[7] Madhurima Mohajon, Pharmaceutical Patenting In India: Problem Of Public *Access to Health, IPR LAW INDIA, https://iprlawindia.org/wp-content/uploads/2021/04/Madhurima-Mohajon.pdf?cv=1&session-id=8ead8ca91fc841098d35763b273112d8 (last visited Feb. 9, 2023).*

right that is required for the exercise of all other human rights, do we really need to compare it to other "trivial" and less important trade norms? Yes, it is the answer. The right to health is extremely important, but it also needs to give innovators a way to protect their liveable interests in the form of patented medicines and, through them, their livelihood"[8]. Naturally, it is important to carefully consider this balance. With a few notable exceptions, I believe the pharmaceutical business has been too greedy in its attempts to increase the cost-free scope of patent protection. This runs counter to the TRIPS, which they view as their most effective tool for advancing their profit-driven goals. As was already indicated, Article 7 of the TRIPS emphasises the importance of establishing a balance between the demands of those who develop technological knowledge and those who use it in a way that promotes social and economic wellbeing, "while Article 8 permits Member States to adopt measures necessary to protect public health and nutrition". But this never-ending conflict is still very much in play. In addition to the problem's existing solutions, some of which are undoubtedly better than others (some of which were put forth by the WTO itself), "we can observe the emergence of potential solutions put forth by renowned academics who have dedicated their time, effort, and expertise to conceptualising them. Additionally, there are already some instances of "good practises" carried out by major pharmaceutical corporations in association with NGOs and PPPs, which are excellently facilitating improved access to medications. The international community will have to determine whether these suggested solutions will have a chance to develop and become a reality for people who urgently require a long-term solution".[9]

Available Remedies

This section provides an overview of some current strategies for overcoming the conflict between pharmaceutical patents and patient access. While some of these are praised as wonderful ideas, others that are of the same calibre or higher are just ignored since they do not support the interests of the big actors. "I'll go over each one individually beginning with the two concepts that attracted the greatest attention from the international community: the TRIPS flexibilities in the form of required licences and the Article 30 remedies. It is required to fully implement already existing choices, including alternatives to generic competition and those

[8] Madhurima Mohajon, Pharmaceutical Patenting In India: Problem Of Public Access to Health, IPR LAW INDIA, https://iprlawindia.org/wp-content/uploads/2021/04/Madhurima-Mohajon.pdf?cv=1&session-id=8ead8ca91fc841098d35763b273112d8 (last visited Feb. 9, 2023).

[9] Madhurima Mohajon, Pharmaceutical Patenting In India: Problem Of Public Access to Health, IPR LAW INDIA, https://iprlawindia.org/wp-content/uploads/2021/04/Madhurima-Mohajon.pdf?cv=1&session-id=8ead8ca91fc841098d35763b273112d8 (last visited Feb. 9, 2023).

mentioned in Article 30".

India is one of the key parties to the TRIPS Agreement, which became effective in India in 2005. Prior to the TRIPS framework, India did not award any patents for pharmaceutical products. India's generic drug industry was booming at the time despite the strict patent rules in industrialised countries. This system offers benefits of its own, such as the ease of access to drugs in India. Additionally, even for drugs that were very expensive in other nations, the price was extremely low. One of the most critical needs of poor countries is the availability of medicines at extremely low prices. Therefore, mandatory licencing must be implemented in a way that avoids having regulations that are either excessively restrictive and make it difficult to regulate pharmaceuticals or too liberal and encourage overuse.

Possible Solutions

In the paragraph that came before this one, it was discussed how difficult it is for people in developing nations to receive medical care. No meaningful improvements in this area have been made because of these concepts, no matter how well-framed they may be. For this reason, a lot of organisations and academics have put a lot of effort into coming up with alternative solutions that might please both parties. I'll begin by talking about the idea for price reductions for underdeveloped countries, which is strongly opposed by the industry yet, if correctly executed, could considerably enhance access to drugs. A few ideas that might be recommended are price reduction, the health impact fund, excellent corporate citizenship, and others. These will provide a healthy balance as a solution to this problem.

LANDMARK CASES

Novartis Ag & Anr. vs. Cipla Ltd. Case (2015)

This was a significant case that dealt with the issue of evergreening of patents in India. Novartis had applied for a patent for a new form of its drug, Glivec, which was used to treat leukaemia. The Indian Patent Office rejected the application on the ground that it was not an invention, but an alteration of an existing drug. The case went all the way to the Indian Supreme Court, which upheld the decision of the Patent Office, stating that mere improvements to known drugs would not qualify for a patent under Indian law.

This case serves as a classic example of Indian patent law's efforts to uphold patent rights fairly and prevent the improper exploitation of exemption clauses under the Patent Act by parties with a vested interest in violating the patentee's rights. Additionally, it was determined that there was no discrimination between MNCs and Indian companies under the Indian patent law[10].

F.Hoffmann: La Roche Ltd. vs. Cipla Ltd. (2016)

This case was related to the sale of generic versions of the anti-viral drug, Valganciclovir, by Cipla, which is used to treat a type of lung cancer. Roche, the original patent holder, filed a lawsuit against Cipla, alleging infringement of its patent rights. The Delhi High Court held that Cipla's generic version did not infringe Roche's patent, as the generic drug did not have the same properties as the patented drug[11].

Pfizer vs. Natco Pharma (2012)

In this case, Pfizer claimed that Natco had infringed its patent for the anti-cancer drug, Sorafenib Tosylate, by selling a generic version of the drug. The Delhi High Court rejected Pfizer's claim, stating that the patented drug was not being sold at an affordable price and was not accessible to the public, and that Natco's generic version would be more affordable and accessible.

These cases highlight the Indian judiciary's efforts to strike a balance between protecting the interests of innovators and ensuring public access to health. The courts have consistently upheld the principle that patents should not be granted for mere improvements to known drugs, and that affordable access to medicines is an important public policy consideration.

CONCLUSION

Pharmaceutical patenting in India has been a controversial issue due to the conflicting interests of promoting innovation and providing affordable access to essential medicines. On one hand, patents encourage pharmaceutical companies to invest in research and development, leading to

[10] INDIAN KANOON, https://indiankanoon.org/doc/68879740/ (last visited Feb. 12, 2023).
[11] SankalpMirani, F.Hoffmann: La Roche Ltd vs. Cipla Ltd., LEGAL SERVICE INDIA, https://www.legalserviceindia.com/legal/article-8424-f-hoffmann-la-roche-ltd-v-s-cipla-ltd.html#:~:text=Judgement%3A,5%2C00%2C000 (last visited Feb. 12, 2023).

the creation of new and improved drugs. On the other hand, patents can also restrict access to essential medicines, leading to high prices and reduced availability, especially in low- and middle-income countries like India.

"The Indian Patent Act of 1970" contains provisions for compulsory licensing, which allows the government to grant a license to manufacture and sell a patented product without the consent of the patent owner in certain circumstances, such as in the interest of public health. However, the implementation of compulsory licensing has been limited and slow, and the process for obtaining a compulsory license can be lengthy and costly.

In conclusion, the issue of pharmaceutical patenting in India is complex and multi-faceted and requires a balance between promoting innovation and ensuring access to essential medicines. While progress has been made in recent years, much more needs to be done to ensure that everyone has access to the health care they need.