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# Patentability Of Pharma Products: Indian Perspective

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## Abstract

The Patent Law of India has seen major amendments after TRIPS Agreement of World Trade Organisation came into force in the year 1995. These amendments were specifically needed as India had to introduce the product patent regime. It was till 2005 that India brought three major amendments in compliance of the TRIPS Agreement. However, with these amendments, it seems that the product patent regime especially related to pharmaceutical products in India is satisfactory. The law apart from protecting the interest of the inventors also provides for specific provisions that can uplift right to health. An ideal balance is sought through the various provisions contained in the patent law and interpreted by the Courts from time to time. The present paper describes the provisions of the patent law with special reference to pharmaceutical products. The relevant judicial decisions have also been analysed to understand the role of Courts in striking a balance between private and public interest.

**Keywords:** Product patent, pharmaceutical patentability, TRIPS Agreement, Invention, Public Interest.

## INTRODUCTION

The Indian Pharmaceutical Industry is the third largest in terms of its manufacture and is known for its low-cost, generic and qualitative medicines.[1] The financial year 2021-22 saw the total business in the pharmaceutical industry to be INR 344,125 Crores which is equivalent to 42.34 USD.[2] The growth rate of Indian pharmaceutical industry in the FY 2017-18 was 3.03 which has risen to 4.89 in FY 2021-22, and is continuously increasing.[2] The top 25 export destinations for the Indian Pharmaceutical products include the most developed countries of the world like USA, UK, Russia, Germany, France, Netherlands, Canada, Australia to name a few.[3] Apart from this, India exports its pharmaceutical products to more than 200 countries across the globe.[4] Such is the vastness of the pharmaceutical sector that, not it has marked its presence in the global market but also medical tourism is trending. The research and development in the pharma industry is constantly growing and hence it is significant to understand the nuances of patentability of pharmaceutical products in India. As generic medicines are can be made available at cheaper prices as compared to branded medicines, the Government of India has launched Pradhan Mantri Bharatiya Janaushadhi Pariyojana wherein dedicated outlets for are open for sale of generic medicines. Nevertheless, the branded and patented pharma products are also booming in the Country.

With the establishment of World Trade Organisation in 1994 and its inclusion of Trade Related Aspects of Intellectual Property Rights Agreement (TRIPS Agreement), the gates for product patent regime in the field of pharma is opened. The Patent Act, 1970 has been amended thrice to comply with the obligations of TRIPS Agreement and has a huge impact on the product patent regime. The present paper discusses the scope of patentability of pharmaceutical products in India with the help of provisions contained in the patent law.

### TRIPS Agreement and its impact on Patent Law in India with reference to Pharma Industry

The Uruguay Round (1986-1994) of Negotiations, the largest ever trade negotiations, concluded with the establishment of World Trade Organisation and it included within its framework several aspects of trade, thereby widening the concept of trade. A need to recognise Intellectual property rights in context of trade was deliberated and hence the TRIPS Agreement was the outcome. The TRIPS Agreement provided for minimum standards applicable to IPRs and also provided for preserving the interest of least-developed countries. The objectives of TRIPS Agreement as provided under its Article 7 exemplified towards promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations. Significantly, Article 8 of the Agreement laying its principles demonstrated that necessary measures to protect public health and nutrition be taken so far as they are consistent with the Agreement. The Agreement is divided in seven parts provides for minimum obligations concerning several issues in the subject of IPRs. Section 5 contained in Part II of the Agreement specifies minimum obligations pertaining to Patents wherein it is categorically mentions about making patents available for products and process in all the field of technology provided they are new, involve an inventive step and are capable of industrial application. However, specific exclusions are provided therein from the protectable subject matter. The Agreement

does delineate rights of patent holders and the limitations thereof including for a regime of compulsory licensing regime. As many least-developed and developing countries of the world had to either enact IPRs laws or amend them to comply with the obligations therein, a transition period was specified in the Agreement for different economies.

India being a Member of WTO right from its inception was to make major changes in the patent regime. Although, the evolution of Patent Law in India dates back from the year 1856, the Patents and Designs Act, 1914 continued to be in force in India till 1970 upon the enactment of Patent law. The 1970 law was based on the recommendations given by Justice N. Rajagopala Ayyangar in the year 1959. Upon the enforcement of TRIPS Agreement in 1995, the Patent Act, 1970 was amended thrice till 2005 to comply with the minimum standards and obligations. India, being a developing country with no product patent regime was given a transition period of ten years to comply with the same by WTO's TRIPS Agreement. The major change in the existing patent law was to incorporate provisions relating to product patents as before that the product patent regime was unknown to the Indian law.

Although, TRIPS did provide for a transition period of ten years to India, still mandated to at least start accepting product patent applications from the initiation of the TRIPS Agreement, which was not complied. India was dragged before the WTO Dispute Settlement Body by USA. Upon losing the case, the first amendment to the Patents Act, 1970 was incorporated to allow applications to be filed for product patents and give exclusive marketing rights to the applicants. This opened provision for mail box wherein such applications were kept till the entire TRIPS Agreement could be implemented. It was not an easy task for the Indian Government to incorporate provisions permitting product patents as many corresponding provisions were to be incorporated for implement the regime. However, the second amendment to the Patent Act, 1970 saw major changes to bring the law in compliance with TRIPS. By the time, the third amendment was to be made; there were debates at the international levels on whether the TRIPS agreement by permitting product patent regime which would include pharmaceutical patentability would go against the human rights regime. It is here to understand that human right to health entails availability, accessibility, affordability and acceptability of the available medicines and treatment for human beings. On the other hand, by incorporating the product patent regime, the prices of such pharma product would soar bringing them directly in conflict with the human right to health. Discussions went within the ambit of TRIPS, and the Doha Declaration on the TRIPS Agreement and Public Health was adopted in 2001, positive developments were seen in context of balancing the human rights and pharma patents. The Declaration reaffirmed flexibility of TRIPS Agreement in upholding human right to health for essential medicines by limiting upon the rights of patentees. Although, Indian Patent Law did have certain provisions right from its inception which can limit the rights of the patentees and can balance human rights obligations, still amendments were needed to comply with TRIPS and Doha in toto. Much before that, the Supreme Court in the case of Bishwanath Prasad Radhey Shyam v. Hindustan Metal Industries (1978) had emphasized on the object of Patent Law as "The object of patent law is to encourage scientific research, new technology and industrial progress. The price of the grant of the monopoly is the disclosure of the invention at the Patent Office, which, after the expiry of the fixed period of the monopoly, passes into the public domain."

The following section highlights the provisions contained in the Patent Act, 1970 as amended up to 2005 on the scope of patentability of pharma products:

### Invention defined

The definition of the term 'invention' as substituted the second amendment in 2002 means a new product or process involving an inventive step and capable of industrial application. Since earlier scope of patentability included only process patents, the definition was amended to include products.

### Pharmaceutical substance defined

The definition of the term "Pharmaceutical substance" inserted in 2005 means any new entity involving one or more inventive steps. This was done to categorically specify that if the said substance is new and involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art, then it too can be patented.

### Exclusions from patentability in context to health

Section 3 of the Act provides for certain inventions that cannot be patented. Concerning health, there have been specific exclusions from patentability viz.

- inventions that cause serious prejudice to human, animal or plant life or health or to the environment contained in clause (b) and substituted in 2002
- Clause (d) provides 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 of a known process, machine or apparatus unless such known process results in a new product or employs at

least one new reactant. The said provision was challenged for being unconstitutional in the case of Novartis A.G. v. Union of India (2013)[5] on the ground that it not only violates Article 14 of the Constitution of India but is also not in compliance with TRIPS. The case involved a question of patentability for the beta crystalline form of a chemical compound called Imatinib Mesylate which is a therapeutic drug for chronic myeloid leukaemia and certain kinds of tumours and is marketed under the names "Glivec" or "Gleevec". The Appellants claimed invention in a two-stage, wherein they first produced its methanesulfonic acid addition salt, Imatinib Mesylate, and then proceeded to develop the beta crystalline form of the salt of Imatinib. The same were rejected by the Assistant Controller, hence in absence of the Intellectual Property Appellate Board being formed, the Appellants challenged the same before Madras High Court. After the IPAB being formed, the same were transferred and was ultimately dismissed by the said Authority in 2009. Although, the said product was clearly an invention as involved inventive step as per definitions contained in Section 2(j) and (ja) respectively, still the patentability was questioned and denied on the ground of Section 3(d). Referring to section 3(d) the IPAB observed:

"Since India is having a requirement of higher standard of inventive step by introducing the amended section 3(d) of the Act, what is patentable in other countries will not be patentable in India. As we see, the object of amended section 3(d) of the Act is nothing but a requirement of higher standard of inventive step in the law particularly for the drug/pharmaceutical substances."

The IPAB also referred to the judgment of the Madras High Court, dismissing the appellant's writ petitions challenging the constitutional validity of section 3(d) where the High Court had observed:

"We have borne in mind the object which the amending Act wanted to achieve namely, to prevent evergreening; to provide easy access to the citizens of the country to life saving drugs and to discharge their constitutional obligation of providing good health care to its citizens."

IPAB held that the product patent for the subject matter could not be allowed but the appellant could not be denied the process patent for preparation of Imatinib Mesylate in beta crystal form. The Appellants then filed a Special Leave Petition under Article 136 of the Constitution to the Supreme Court and the Court proceeded to hear the case on merits. The detailed judgement of the Case delved into the legislative history of patent law and pointed out the recommendations given by Justice Ayyangar Committee too. The Court also noted and referred to the growth and transformation taking place in the Indian pharmaceutical industry. The relevant provisions of the TRIPS and Doha Declaration were too given a bearing in understanding the law and the amendments in the patent law were scrutinized in context of above. Interestingly, the Court also referred to the Parliamentary Debates as while the case was pending, the third amendment to the patent law was to be made. One of the members' speeches was quoted by the Court as under:

"Sir, a company which obtains a patent by changing their chemicals, before the expiry of the patent, they will again apply for a patent and again get a patent. So, in this way, they will continue to get a patent for the same medicine.

The Court further looked into the details of the pharma product which was questioned, compared the laws of US and UK with India. The final outcome after much of arguments and deliberation was the rejection that Imatinib Mesylate does not qualify the test of "invention" as laid down in section 2(1)(j) and section 2(1)(ja) of the Patents Act, 1970 and held that the beta crystalline form of Imatinib Mesylate being a pharmaceutical substance and moreover a polymorph of Imatinib Mesylate, it directly runs into section 3(d) of the Act with the explanation appended to the provision. The Court finally held that subject product, that is, beta crystalline form of Imatinib Mesylate, is thus clearly a new form of a known substance, i.e., Imatinib Mesylate, of which the efficacy was well known and therefore, fully attracts section 3(d). The Court rejected the unconstitutionality of the said provision and prevented the evergreening of the pharma products. The judgement was a major setback for many of pharmaceutical companies but at the same time, however, it gave a major relief to those who needed high priced lifesaving drugs, thus inclining a balance more towards public interest as compared to private monopoly rights.

- Clause (i) as originally inserted puts a limitation on inventions for any process for the medicinal, surgical, curative, prophylactic, diagnostic, therapeutic or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products. The clause devoid all the above processes from its patentability.

### Deposition of biological material

Section 10 of the Act which provides that if the subject matter of patent has an inclusion of any biological material then the applicants to specify the origin of biological material and submit a sample of the same in the International Depositary before the application for patent is filed. This obligation is in tune with the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, 1977. The same is also a ground for pre-grant opposition and post-grant opposition as per Section 25 and a ground for revocation under Section 64.

### Patent Rights subject to certain conditions

Section 47 of the Act clarifies that the patentee gets a grant of patent which is subjected to certain conditions. Although, the patentee avails monopoly rights upon grant of patent, but still the law provides limitations on the property. These limitations are that the patented product may be imported or made by or on behalf of Government for the purpose merely of its own use and it may be used, by any person, for the purpose merely of experiment or research including the imparting of instructions to pupils. Further, sub-section (4) clearly imposes a restriction on the rights of patentee of pharma products by stating that the same may be imported by the government for the purpose merely of its own use or for distribution in any dispensary, hospital or other medical institution maintained by or on behalf of the government or any other dispensary, hospital or medical institution which the Central Government may, having regard to the public service that such dispensary, hospital or medical institution renders, specify in this behalf by notification in the Official Gazette. The very objective of insertion for this provision is to ensure that any pharma product that is patented do not enjoy so much of monopoly that public interest especially right to health gets violated.

### The Regime of compulsory licences

The Indian Patent Law provides for a very strong mechanism for grant of compulsory licences. Any interested person can make an application for grant of compulsory licence, three years after the grant of patent and upon proving its credentials, the Patent Controller may grant such licence upon specified terms and conditions. Compulsory licensing regime has its roots from Paris Convention, 1883 and also the TRIPS Agreement. A patentee upon the grant of patent gets monopoly rights for a period of 20 years from the date of application of patent. The conduct of the patentee during this period is significant as the objective of patent law is also to provide benefits to the society by working on the invention. However, at times, when the patentee acts conversely, the law can impose limitations on the rights by way of granting compulsory licences. Section 83 provides for the general principles applicable to the working of patents and with respect to pharma patents, clause (d) categorically specifies that patents granted do not impede protection of public health and nutrition and should act as instrument to promote public interest specially in sectors of vital importance for socio-economic and technological development of India. Further, clause (e) mentions that patents granted do not in any way prohibit Central Government in taking measures to protect public health. While considering any application on compulsory licence, the Patent Controller is bound to relook Section 83 and accordingly grant such application. The law provides for three specific grounds on the basis of which compulsory license can be granted as under:

(a) that the reasonable requirements of the public with respect to the patented invention have not been satisfied, or

(b) that the patented invention is not available to the public at a reasonably affordable price, or

(c) that the patented invention is not worked in the territory of India

Once, compulsory licence has been granted, it can be revoked too under Section 85 if the licensee does not work upon the patent. A very important decision on grant of first ever compulsory licence is Bayer v. Natco (2012), wherein Natco wanted to manufacture an affordable generic version of Sorafenib tosylate, the anti-cancer drug for which Bayer had obtained a Patent in India in 2008. The ground for seeking compulsory licence was that Bayer has supplied the drug only to 2% of patient population and that the price of the drug is exhorbitant to the tune of Rs. 2.8 Lakhs for a month's dose. The licence was granted by the Patent Controller which enabled Natco to sell one month's dose for not more that Rs. 8880/- and to pay to Bayer 6% royalty on the sales on a quarterly basis. An appeal was also in Intellectual Property Appellate Board, but the same was not approved.

Section 92 provides for increased restrictions upon the rights of patentee by providing for compulsory licence on notifications by Central Government. The provisions of this section can be invoked by the Central Government when it is of the opinion that there are circumstances of national emergency or circumstances of extreme urgency or there is a case of public non-commercial use and a patented invention can be made use of. If such is the case, the Central Government can make a declaration any time after grant of patent in Official Gazette and any interested person by making an application to the Controller obtain a license. Upon grant of this license, the Controller shall ensure that the invention is made available at the lowest prices. All the procedural requirements as they are provided for grant of compulsory license under section 84 shall be followed. However, if there is public health crises, relating to Acquired Immuno Deficiency Syndrome, human immune deficiency virus, tuberculosis, malaria or other epidemics no such procedure will be followed and the Controller is such to inform the patentee about the circumstances as soon as possible.

As discussed earlier, Post-TRIPS Agreement when there arose concerns regarding public health, Doha Declaration was adopted. The 2005 Amendment to the Patent Act incorporated provisions to comply the declaration and hence Section 92A was inserted. This was done to ensure that sufficient supply of pharmaceutical products is made to countries having insufficient or inadequate manufacturing capacities for the concerned product to address public health problems. Upon application to the Controller under Section 92A by any interested person, compulsory licence solely for manufacture and export of the concerned pharmaceutical product to such country upon specific terms and conditions can be granted. To give a wider meaning to the term 'pharmaceutical

products', the explanation therein states it to mean any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address public health problems and shall be inclusive of ingredients necessary for their manufacture and diagnostic kits required for their use.

It is pertinent to note that as per the Annual Reports published by the Patent Office in past 5 years, a total of only 3 applications have been received under Section 84, 92 and 92A of the Act. Further, there is no mention about whether these applications have been granted or not. Thus, an assertion can be made that although, the provisions and the mechanism are contained for compulsory licence, but it is most underused.

### Use and acquisition of Inventions by Government

The Patent Act as originally enacted did provide for the use of inventions for purposes of government and acquisition of inventions by the Central Government in its sections 99 to 103. The insertion of these provisions was recommended by Justice Ayyangar in its report considering the need to uphold public interest in certain circumstances. Unlike other provisions imposing restrictions upon patentee after grant of patents, the provisions of this Chapter are made applicable even after the application for patent is filed. It means in any circumstance when the Government is wanting to use or acquire inventions, it does not even have to wait till the patent is granted. The use of inventions can be done by the Central Government or by any person who is authorised thereto. Further, if the invention has been duly recorded in a document, or tested or tried, by or on behalf of the government or a government undertaking, then such use will be made royalty free else reasonable royalty has to be paid. Further, the Central Government can also acquire the invention or patent for a public purpose by publishing a notification in Official Gazette. Provisions for payment of reasonable compensation however are provided under the law in case of acquisition.

### Bolar Exemptions

One very important provision in the patent law of India concerning pharmaceutical patentability is with respect to Bolar exemptions contained in section 107A(a), which permits the use of patent by interested parties even before the patent is expired. The provision clearly mentions that any art of making, constructing, using, selling or importing a patented invention solely for uses reasonably relating to the development and submission of information required under any law for the time being in force, in India, or in a country other than India, that regulates the manufacture, construction, use, sale or import of any product would not amount to infringement of patent. Usually, when a pharma company has to launch a product, it is required to do tests, experiments and gather data so that necessary approvals from the drug authorities can be obtained before the product is launched into the market. If a pharma company can do these entire necessary processes for obtaining regulatory approvals from drug authorities only after the patent expires, then the said patentee can enjoy an extended monopoly.

The jurisprudence of Bolar Exemption was developed in USA in the case of Roche Products v. Bolar Pharmaceutical Co. Roche was in possession of patent for flurazepam hydrochloride, an active ingredient in its brand 'Dalmane' till 1984. In the year 1983, Bolar which is generic drug manufacturer used the patent so that it can obtain marketing approval from the Food and Drug Authorities. Roche filed a case against Bolar on the ground of infringement of patent, however, the US District Court held that there is no infringement of Roche's patent and also held that the use by Bolar was use was de minimis and experimental. Being aggrieved by the decision, an appeal was filed in Court of Appeal for the Federal Circuit which overturned the decision of the District Court and held that the use by Bolar was infringement of Roche's patent as the experimental use was ultimately to be used for business gains. The decision was then overturned by the US Congress upon enactment of US Drug Price Competition and Patent Term Restoration Act 1984 commonly known as the 'Hatch-Waxman Act', and provided provisions to balance the rights of patentee and generic drug manufacturers. It is for this reason, that the exception is well known as Bolar Exception.

India, too upon moving towards product patent regime inserted Section 107A (a) in 2002 to ensure that a patentee cannot enjoy an extended monopoly beyond the period of 20 years. This provision can be looked from two different dimensions, both contradicting with each other. The first dimension is that because of the applicability of this provision, generic and branded medicines can come to the market immediately upon expiration of the patent. The patented pharma product which has enjoyed monopoly for 20 years will face competition in the market and hence the said product will be available at affordable prices. The other dimension is looked from the perspective of the patent holder, as it undermines the rights of patentee even while the term of patent has not expired.

In India the Drugs and Cosmetics Act, 1940 is in force under which the Drug Controller of India (DCGI) is the Central Licence Approving Authority. A question arose in the case of Bayer v. Cipla and Union of India[6] before the Delhi High Court as to whether there is any linkage between the Patents Act and Drugs and Cosmetics Act and whether marketing licence can be granted to a third party for which the patent is in force. Bayer was in possession of a patent for "sorafenib tosylate", prescribed for the treatment of advanced renal cell carcinoma and Cipla made an application to DCGI for the grant of licence. Bayer contended that since it is possession of IPR Rights, DCGI is restrained from granting a licence to Cipla. The Single Judge

rejected the contentions of Bayer and held that both being separate codes enacted for different purposes, there was no merit in the contention that there was a "patent linkage". On an appeal before the Division Bench, the order of the Single Judge was upheld. Hence, it was made clear that while granting of marketing approvals, DCGI is not required to check whether a patent exists or not. If at all, the patentee's rights are infringed the remedy can be availed under the Patents Act, 1970.

The Courts in India have made a liberal interpretation of Section 107A (a) which needs a specific mention. A noteworthy decision of the Delhi High Court in the year 2019 combined two appeals as the matter was same in cases of Bayer Corporation v. Union of India and Bayer Intellectual Property GMBH v. Alembic Pharmaceuticals. The Facts of the case are Bayer filed a suit in 2011 for injunction against Natco from making, importing, selling, offering for sale "Sorafenib Tosylate" or any generic version or any other drug or product thereof which was a subject matter of Bayer's patent. When the suit was pending, Natco applied to the Patent Office for grant of compulsory licence against that patent which was granted by the Patent Controller in 2012 under Section 84. The compulsory licence was granted solely for the purposes of making, using, offering to sell and selling the drug covered by the patent within the territory of India. However, Natco manufactured the product covered by the compulsory licence for export outside India. Bayer filed a writ petition seeking a direction to the Customs Authorities to seize the consignments for export containing products covered by compulsory Licence manufactured by Natco. Later, in 2014, Natco pointed out that it has already been granted a drug license and it was permitted to export the drug Sorafenib Tosylate not exceeding 15 gm for development/clinical studies and trials. Natco, then applied for permission to export 1 Kg of Active Pharmaceutical Ingredient to China to conduct clinical studies and trials for development of drug for regulatory purposes. Bayer contended that if permission were granted to Natco, it would be contrary to Section 107A and that such a transaction would be a commercial sale and hence, a patent infringement. Another, case which was clubbed was filed by Bayer against Alembic Pharmaceuticals wherein it wanted to restrain Alembic from making, selling, distributing, advertising, exporting, offering for sale and in any manner directly or indirectly dealing in Rivaroxaban to the European Union. Finally, adopting a liberal approach and combining both the cases towards public interest it was decided by Delhi High Court that Sale, use, construction of patented products (by individuals and entities that do not hold patents) in terms of Section 107A of the Act for purposes both within the country and abroad is authorized and legal provided the seller ensures that the end use and purpose of sale/export is reasonably related to research and development of information in compliance with regulations or laws of India (or the importing country), for its submission in accordance with such laws. Further, it also held that any dispute of such sale should be relegated to civil remedies and no writ petitions under Article 226 should be entertained. It was a major setback for Bayer as two of its applications were set aside and the Court adopted a flexible interpretation of the Bolar Exceptions.

## CONCLUSION

The Pharmaceutical market of India is huge and with the patent law providing for a robust mechanism in patenting the pharma products has led to a boost to all the pharmaceutical companies. The statistics as per the Annual Reports[7] shows a positive trend towards pharmaceutical inventions as under:

| Year | Number of Patent Applications filed in the field of Pharmaceuticals | Number of Patent Applications granted in the field of Pharmaceuticals |
|---|---|---|
| 2017-18 | 2741 | 733 |
| 2018-19 | 2683 | 761 |
| 2019-20 | 5622 | 1930 |
| 2020-21 | 80 | 1264 |
| 2021-22 | 5179 | 3317 |

India is heading towards making the patent procedures more streamlined. To ease the processes for filing and obtaining patents over pharma products, the Indian patent office has issued guidelines for examination of patents in October 2014. These guidelines also provide specific directions for the Patent Authorities to understand the scope of patentability of pharmaceutical products. It would also enable the inventors to understand and apply the procedural aspects with respect to pharma product patents. Also, the National IPR Policy[8] declared by the Government of India in 2016 has an objective of Creative India; Innovative India and it lays the future roadmap for IPRs in India. The Policy recognises the abundance of creative and innovative energies that flow in India, and the need to tap into and channelize these energies towards a better and brighter future for all.[9] It recognises the contribution of the Indian pharmaceutical sector in enabling access to affordable medicines globally and its transformation to being the pharmacy of the world. Objective 5 of the Policy that provides for Commercialization of IPRs, in its point 5.10 clearly it mentions about making efforts to reduce dependency on active pharmaceutical ingredients imports, including incentivizing manufacture of APIs in India and revitalizing public.

An overview of the Indian Patent Regime related to Pharmaceutical patentability suggests that adequate provisions are available for protecting the interest of pharma inventors on one hand. It is also been observed that over years, there have been early grant of patents to the inventors with policy changes being incorporated. On the other hand, there has been a well balance of patent rights with public interest. The approach of the Patent Authorities and Courts has always been inclined towards uplifting right to health and public interest. It is because of this comprehensive framework contained in the Patent Act, 1970 that India had no requirement to amend the patent law even in the COVID 19 pandemic unlike countries like Canada, Chile, Germany and Israel which had to bring changes in its existing framework to enable the Government to use and acquire the patents.

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