RIGHT VS. PATIENT'S RIGHT

by

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INTRODUCTION

The Indian Patent system owes its origin from British rule in India. Act VI of 1856 based on British Patent Law of 1852, provided exclusive privileges to the inventor for 14 years. The Patent and Designs Act, 1911 introduced during the colonial rule was reviewed and enacted the Indian Patent Act, 1970 which deals with process patents and acted as an effective tool in laying a strong foundation for the growth and development of pharmaceutical industry in independent of pharmaceutical industry in independent India. [1]The main provisions contained in this Act were permitting process patents of chemicals excludes pharmaceuticals and reducing the term of patent for process to 7 years from the date of application and for all other patents it was fixed for 14 years. TRIPs are one of the agreements reached at the conclusion of the 1986 - 1994 Uruguay round of the GATT Multilateral Trade Negotiation. All the WTO members will be members in TRIPs' Agreement, which came into force in 1995.[2] In recent years, intellectual property protection for inventions relating to health care was one of the major debated areas. The major concern was the need to facilitate access to essential medicines at affordable cost to the large section of the population in the developing and least developing countries. The problem is that the most dangerous illness in the world such as HIV/AIDS, malaria and tuberculosis are widely spread across the developing countries.

This concern remains acute for India in particular. The World Health Organisation's Global Tuberculosis Report 2025 identified India as accounting for roughly a quarter of the world's tuberculosis cases, more than any other single country. Such disease burdens help explain why the affordability of patented medicines has continued to occupy a central place in Indian health policy discourse long after the TRIPS Agreement came into force.[2] [3]

[1] 1. Shashi Sharma, "New Patent Regime IN India - Challenges and Future of the Pharmaceutical Industry, http://www.works.be.press.com/cgi/view content.cgi? Article.

[2] Kalyan Ray, 'WHO Report Says India Logged Highest Number of Tuberculosis Cases in 2024, Drug-Resistant Cases Show Surge' Deccan Herald (Bengaluru, 29 October 2025) <https://www.deccanherald.com/india/who-report-says-india-logged-highest-number-of-tuberculosis-cases-in-2024-drug-resistant-cases-show-surge-3795820> accessed 17 September 2026.

[3] 2. Intellectual Property Right and Global Health: Challenges for Access and R&D, The welcome Trust Genome

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Simultaneously, the majority of local population of the least developed countries lives in poverty and cannot afford expensive medicines. The fact that many countries in the developing world did not recognize patent on products or in some cases, on process was a major problem for the global pharmaceutical industry. The research oriented pharmaceutical firms were concerned that they would lose their export markets to firms that specialize in reverse engineering - copying products under patent in the developed world and selling them at the major stumbling block for many WTO members to take even the limited advantages of the TRIPs Agreement. The international patent norms facilitated the growth of pharmaceutical industries in many countries which lacked the capacity to invent and produce drugs.[4]

Many countries build up their domestic industries by the flexibilities available in the Paris Convention, because there were only process patent in the initial stages to augment the growth of their pharmaceutical industries. India is frequently cited as the clearest beneficiary of this process. Having relied on a process patent regime for several decades, Indian manufacturers built the domestic manufacturing base that today allows the country to supply around one fifth of the world's generic medicines by volume, along with a majority of the vaccines procured by major international health agencies.[5] This are enabled these countries to provide access to medicines at affordable cost. This provisions discounted prices in local and regional markets in the developing world. This will reduce protection for new pharmaceutical inventions. It was argued that this resulted in distortion of trade in the international market particularly in the context of globalization.[6]

Impact of TRIPS

The implementation, of the provisions of the TRIPs Agreement by various member states and the consequent disputes that arose in the last decade show that the provisions are more in favour of the owners of Intellectual property to facilitate global trade. The weak manufacturing capacity coupled with low level inventive activities is identified as were mainly enjoyed by the

Campus Hinxton, Cambridge shire, UK, 7-9 Dec 2000, www.whqlibdoc.Who. Int/publications/2006/929162027-eng. Pdf.

[4] Rajagopala Ayyangar, Report on the Revision of the Patent law, Government of India, 1959.

[5] MTN.GNG/NG/NG11/W/7(29 May 1987),p.2-5.(jointly by EU, Japan and US).

[6] 4. N.S. Gopalakrishnan, "TRIPS Agreement and Public Health: An Overview of International Issues, Journal of Intellectual Property Right, Vol 13, Sept 2008, p.395-400.

countries in the west till the middle of the last century. Some of the Asian countries also used this approach to promote industrial growth in the pharmaceutical sector after the Second World War. The result was the emergence of strong and powerful generic industries in many part of the world including Asia. This also enabled production and distribution of low cost medicine not only in the domestic market. Some of these industries even stated to penetrate into the market of the developed counties whose industries are mainly responsible for invention and introduction of new and improved drugs in the global market. These industrial activities emerged as a potential threat to dominance of the powerful pharmaceutical industries in the developed countries particularly the US. It was argued by these industrial groups that there is a need to strengthen the international norms for the protections of new inventions to prevent distortion of international trade in pharmaceutical products in the global market. These compelled the governments of the new inventions in all new fields of technologies during the Uruguay Round of GATT negotiations stated in 1986.

The need of pharmaceutical protection finds a special mention in the submissions made by the developed countries.[6] This includes product patent for new inventions in all fields of technology, extension of term of protection to 20 years considering the time taken to put the drugs into markets, restrictions on compulsory licenses, special protection for test data submitted for drug approval etc.

For developing countries, the pharmaceutical industry as a whole was and is the strongest lobbyists for the global extension of intellectual property rights. [7]

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There is a need to protect drug company profits that pay for much needed research and development of new drugs. The pharmaceutical industry more than any other sector, thinks patent protection to be very important in maintaining their R&D expenditures and technological innovation. Inadequate public health systems are the biggest barrier to healthcare for the poor than the cost of the medicines. Many experts argues that the introduction of patent rules in developing countries will drive up the cost of the medicines especially for the complex drugs needed to treat HIV/AIDS and other related illness. At this juncture, it is to say that 1/3rd

[7] 7. www.brooking.naps.edu/books/0815776535/html.

of the world's population have no means of obtaining essential medicines. In these counties the individuals have to spend the largest proportion of their income on healthcare. This dynamic remains visible in India itself. Government figures published in the National Health Accounts Estimates for 2022-23 show that medicines accounted for close to twenty one per cent of the country's current health expenditure, with out-of-pocket spending by households rising to 43.4 per cent of total health expenditure that year, underscoring how directly the price of drugs affects household welfare in a developing country such as India.[8]

Patent protection will have an effect on generic production of medicines.There are more than 10 industrialized countries with pharmaceutical muscle capable of developing new medicines and those countries will own most of the pharmaceutical patents. The 20 years patent protection will allow effectively a monopoly over the production and pricing of the medicines, thus denying patients cheaper alternatives. The pharmaceutical products of the developing country will find themselves pushed out of the market by MNC's. The TRIPs Agreement further requires patents to be granted regardless of whether the product without 'work' the patent in that country granting the protection. This effectively defeats the argument that a tighter patents regime will increase R&D and technology transfer in developing countries. The agreement has placed certain limitation on the exclusive rights of patent holders. These include compulsory licensing and parallel importation, used for protection of health and to promote access to medicines in developing countries are warned not to use these measures to their benefit.[9]

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THE GLIVEC CASE

In the famous case, Novartis,[10] a Swiss pharmaceutical MNC filed an filed an application for a patent on the Beta Crystalline form of imatinib mesylate, market by the company under the brand name of Glivec/Gleevec in several countries. This drug is used to treat chronic myeloid leukemia. The Chennai Patent Office rejected the application on the ground that the drug was a new form of an old drug and therefore was not patentable under Indian law section 3(d) of

[8] Ministry of Health and Family Welfare, National Health Accounts Estimates for India 2022-23 (Government of India, 2025), as reported in 'India Spent Over Rs 1.6 Lakh Crore on Medicines in 2022-2023, Reveals NHA Report' Medical Dialogues (New Delhi, 2026) <https://medicaldialogues.in/news/industry/pharma/india-spent-over-rs-16-lakh-crore-on-medicines-in-2022-2023-reveals-nha-report-172268> accessed 17 September 2026.

[9] 8. Scherer F.M., "The Patent System and Innovation in Pharmaceuticals, Revue International de Droit Economique, France, (2001), p.109.

the Indian Patent Act; 2005. Novartis filed two lawsuits against the Government of India. The first case appeals rejection of patent application. The second case challenges section 3(d) of the Patent Act, 2005, the provision that seek to prevent ever greening of patent. Novartis contended before the Chennai High that section 3(d) is vague, ambiguous and arbitrary. It is violative of Article 14 which guarantees right to equality and non-discrimination. The Swiss MNC also claimed that section does not comply with Trips agreement, which mandating a strict patent which India has signed.

The dispute attracted sustained attention well beyond the parties directly involved. It was widely regarded, both in India and abroad, as a test of whether the country's newly amended patent regime would favour originator pharmaceutical companies or preserve the generic manufacturing base on which patients across the developing world depended, and contemporary reporting noted that patient groups and international humanitarian organisations closely followed the proceedings given the stakes for access to cancer treatment.[10]

The court ruled that it had no jurisdiction to decide whether Indian Patent Laws comply with TRIPs, and that section 3(d) does not suffer from vagueness; ambiguity arbitrariness and contains reasonable protection for patent applicants. The Madras High Court accordingly dismissed the petitions by Novartis. The Supreme Court also dismissed the appeal filed by Novartis on 1 April 2013, following an intervening rejection of the application by the Intellectual Property Appellate Board on 26 June 2009.[11]

IMPLICATION OF THE CASE

The chronic myeloid leukemia [CML], a form of cancer of the blood cells is reported in India every year. Novartis introduced Glivec in 2001 in India. It proved to be a really useful drug. Glivce has to be taken lifelong and the treatment for the Novartis version costs Rs 1.2 lakh a month. On the other hand nine Indian Companies were making and marketing it at a price of about Rs. 8000 per month.[11]

[10] 'Novartis in Drug Patent Fight' Al Jazeera (Chennai, 4 February 2007) <https://www.aljazeera.com/news/2007/2/4/novartis-in-drug-patent-fight-2> accessed 17 September 2026.

[11] 10. Novartis AG vs. Union of India 2007 (4) MLJ 1153

If patent would have been granted to Novartis, it would have prevented generic competition as domestic companies cannot produce the drug. Treatment cost makes the drug unaffordable and inaccessible for those who need it the most. Thus a patent enabled drug monopoly proved harmful for the majority. The real fact is that millions are dying from lack of access to affordable medicines. Peer reviewed research published in the Journal of the International AIDS Society found that Indian generic manufacturers supplied more than eighty per cent of the antiretroviral medicines purchased by international donors for HIV treatment programmes in low and middle income countries between 2003 and 2008. Findings of this kind were frequently invoked by public health advocates to argue that any narrowing of India's capacity to produce low cost generic versions of patented drugs would carry consequences reaching well beyond its own borders.[12] Criticisms against the TRIPs regime is mounting are concerns of patents on life saving drugs are global monopolies to pharmaceutical companies by patents. Thanks to the Supreme court of India for rightfully dismissing the case.

The reform in the TRIPS Agreement concerning public health, should aims to seek mutual understandings of the flexibility contained in the TRIPS Agreement, and to ensure that all WTO Members have the necessary sense of security and legal certainty that enable them to effectively use these provisions. This reform entails lots of endeavors made by various sides of the world, however, people walking out of the shadow of the fatal disease into the sunshine, singing merrily with smiles, on the green meadows, in the refreshing woods, or on the breezy beach this is a scene we may foresee optimistically.

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Indian Patent System Before 2005

During the period 1995 to 2005, Indian Patent Act was amended for three times and to complied with TRIPs provision patent laws changed from process patent regime to product patent regime. The first amendment of The Patent Act, 1970 was carried out in 1999 whereby "Mail Box" provisions were incorporated,[13] The second Amendment in 2002 provided for incorporation of all substantive provisions except for providing patents to products. [13]

[12] Brenda Waning, Ellen Diedrichsen and Suerie Moon, 'A Lifeline to Treatment: The Role of Indian Generic Manufacturers in Supplying Antiretroviral Medicines to Developing Countries' (2010) 13 Journal of the International AIDS Society 35 <https://pmc.ncbi.nlm.nih.gov/articles/PMC2944814/> accessed 17 September 2026.

[13]EPW September 2005-Battling Patent Laws: The Glivec Casehttp://www.open.ac.uk/ikd/workingpaper_11.pdf.

The important provisions includes: redefining patentable subject matter; term of protection extend to 20 years and amending compulsory licensing system. The third Amendment in 2005 provided for product patents which marked the beginning of new patent regime in India. [14]For developing countries like India, the deadline to complying with TRIPS was the year 2000.[14] In Art 65(4) of TRIPs provided a special transitional provision for those countries that did not grant product patents. India took advantage of this extra transition period. During this transitional period India provide a means to file patent applications, the "Mail Box" provision, which allows the applicant to file for patents thereby establishing filing dates, while at the same time permitting member countries grant product patents.[16]The Act is Section II A introduced a new proviso: provided that after granting patent in respect of the application made under Sec 5(2), the patent holder shall be entitled to receive reasonable royalty from such investment and were produced and market the product prices to ist January 2005 and it can be continued to manufacture the product which is patented and no infringement proceedings shall be instituted against such use.

In India generic drug manufacturers have been manufacturing generic drugs. Such manufactures had made significant investment and were marketing the product before January 2005, continued marketing their product in the new regime.[15] A majority of 7520 patent applications in the mailbox belong to Multinational Companies (MNC), while Indian Drug Companies have filed 1406 applications.[17] Contemporaneous trade press coverage of the mailbox exercise identified Pfizer as the single largest applicant, followed by Johnson and Johnson, while Dr Reddy's Laboratories emerged as the most active Indian filer with over two hundred applications. This concentration of filings among a small number of large multinational originators indicated, even before product patents formally took effect in 2005, which companies were likely to shape the Indian pharmaceutical patent landscape in the years that followed.[16] Compare to these numbers, the US Food and Drug Administration (USFDA) approved only 297 New Chemical Entities (NCEs) in the period from 1995-2004.[18] India also had provided "Exclusive Marketing Rights" (EMRs) in exchange for permission to delay the granting of product patent until January 1, 2005. [17]The terms EMR means the exclusive

[14]13. Chapter iv A of the patent (Amendment) Act, 1999 provides grant of Exclusive Marketing Rights(EMR) for a period of 5 years if the product in these applications is granted patent by any of the WTO member countries.
[15] WTO fact sheet: TRIPS and pharmaceutical patents.
[16] 'Patent Mailbox Opened in India' HIV i-Base HTB (London, 18 April 2005) <https://i-base.info/htb/7415> accessed 17 September 2026.
[17] 17. KG. Narendranath, Patent mailbox open, pizer is top applicatant (March, 21,2005), http://www.financial express.com/fe-full-story-php? Content-id=85782

marketing rights to sell or distribute the article or substance covered in a patent or patent application in a country. EMRS are supposed to apply where a patent is granted and the same product in another WTO member country, provided the other member country obtained marketing approval for the product. In 1999, the first amendment of the Patent Act, 1970 introduced the requirements under the "transitional arrangements through Sec 5(2), allows product patent applicants to be filed through a "Mail box", while chapter IV A provides grant of Exclusive Mark Rights (EMRs), conditions are to be fulfilled.[19] The amendment is a major step in Indian Journey towards TRIPS compliance. The final requirement introduced product patents in the area of chemicals, pharmaceuticals and agricultural chemical and food.[18]

Post TRIPS Impact on Patents

Comply with the TRIPs requirement India had taken substantial timing, this reflects the significant opposition to TRIPs in India. An ordinance was introduced before TRIPs came into effect. But it was lapsed because it could not followed by necessary legislation within the time prescribed. Then the government introduced a Bill it was not passed in Rajya Sabha (the Upper House). Later the European Commission (EC) filed a dispute against India at the WTO alleging that India had not complied with the provision of Articles 70 (8) and 70 (9) of TRIPs. The Dispute Settlement Body (DSB) of the WTO ruled against India, not comply with the requirement of WTO. Ultimately an ordinance was promulgated followed by an Act passed in March 1999. The Patent (Amendment) Act, 1999 amended the patent Act, 1970 with retrospective effect from 1st January, 1995 to implement mail box filing and EMR. With the introduction of full product patent protection in pharmaceuticals from 1st January 2005, the generic companies are prevented from introducing new drugs, the lack of competition will make price high. Supply of low cost drugs to Indian and other countries market were threatened. But TRIPs provides for some flexibility to member countries to tackle flexibilities to member countries to tackle negative consequences of product patent protection, Under Article 27 (1) of TRIPS, patents are provided for inventions, which are "new, involve an inventive step and are capable of industrial application. Patents basically confer on the patentee the right to prevent other from using the invention. But such rights are not absolute. Article 30 of TRIPS permits member countries to provide limited exceptions to the exclusive rights conferred by a patent. Such exception should satisfy certain conditions that it does not unreasonably conflict with a

[18] http://www. Patent office.nic.in/ipr/patent-99.pdf(march 26, 1999.)

normal exploitation of the patent and so not prejudice the legitimate interest of the patent owner. TRIPs does not contain any other explanation about the terms, "limited exceptions", "unreasonably conflict", "legitimate interest", it depends on the interpretation of the conditions. The most significant and common exceptions which many of the countries provided in their national laws, when TRIPs came into effect:

Early working (Bolar exception),

Parallel imports and

Research and experimental use.

The "early working" provision is popularly referred to the "Bolar provision or exception in USA", Patent provide a monopoly to the innovator companies for a specified period of time. After the expiry of the term, others can also produce and market the products. But before 1984, the entry of generic products was very slow in USA. Food and Drug Administration (FDA) estimated by 1984, about 150 off-patent brand name drugs had not generic equivalents in the market.[19]

Under the Bolar provision of the Patent Act, non patentees could start using the parented product for regulatory purposes even before the expiration of the patents. The Bolar provision is very important for generic entry. It permits generic entry soon after the patent expires and allows consumer to benefit from completion and lower prices without delay. Thus in the new patent regime, an innovator companies introduce new drugs in India and enjoy exclusive patent rights, such Bolar provisions can be used to introduce generics after the expiry of patents.

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Conclusions and Suggestions

Benefits and obligation of compulsory license should be a reality in developing and least developed countries. In accordance with TRIPS, 'compulsory provisions should be available and easy procedures for granting a compulsory license should be adopted. The grounds for granting compulsory licenses include: abusive pricing making the product inaccessible for the majority of the population, patent owner's refusal to deal; non-commercial use by the

[19] Before the 1984 the discussion on the problems of...ric entry in USA was based on federal Trade commission.

government; and for public interest (such as public health emergency).

Fullest use of the transition period by the least developed countries. The least developed countries should make the fullest use of the transition period they have been granted to prepare themselves for the consequences of the implementation of the Agreement.

Permit parallel imports of pharmaceutical product which are essential.

National drugs policies and regulations should include the right to shop globally for the best prices. Parallel imports are particularly important for the East African countries with their smaller economies that suffer from inadequate competition. Where allowed, parallel imports have shown to be effective in lowering drug prices.

Government should create a framework for pharmaceutical patenting.

patent laws are to be amended in a better manner so as to give different kind of legal treatment to life saving medicines

There is a Need of better regulation for International Institutions which create a balance between pharma patenting and health issues.

These debates did not end with the Glivec litigation. India and South Africa jointly proposed a temporary waiver of TRIPS obligations relating to COVID-19 vaccines, diagnostics and therapeutics before the WTO in October 2020, arguing that intellectual property protections were constraining the global pandemic response. Although the decision eventually adopted by WTO members in June 2022 was confined to patents on vaccines and fell short of the original proposal, the episode demonstrated that the tension between patent protection and public health identified throughout this paper continues to shape international trade negotiations today.[20]

International consensus for amending TRIPS proviso to pharma patents may be obtained periodically.

[20] 'India for Early Outcome of TRIPS Waiver for Covid Vaccines, Diagnostics' Deccan Herald (New Delhi, 2022) <https://www.deccanherald.com/india/india-for-early-outcome-of-trips-waiver-for-covid-vaccines-diagnotics-1027036.html> accessed 17 September 2026.