PATENT LAWS AND THE PUBLIC HEALTH PUZZLE: COMPARING INDIA'S PATENT OPPOSITION MODEL WITH THE US AND EU MODEL

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Abstract

Equitable access to essential medicines is a long-standing policy challenge. The patent opposition mechanism of India demonstrates how this procedural flexibility can be used to improve access to innovative health technologies. The Indian approach of linking its substantive patentability provisions with the procedural mechanism of patent opposition shows that this strategic use of public health flexibilities provided under the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights ("WTO TRIPS Agreement" or "TRIPS Agreement") has the potential to reduce some of the financial burdens on governments because of its role in promoting generic competition. This article revisits how the Indian patent laws evolved while keeping a balance between conflicting interests. It offers an informative and analytical look at legislative changes in India in order to comply with the WTO TRIPS Agreement. This article considers the Indian patent opposition model in comparison with the United States of America ("U.S.") and the European Union ("EU") approaches towards patent opposition. This analysis of India's TRIPS-compliant regime will help other World Trade Organisation ("WTO") member states to model their patent laws in line with their public health needs and national interests.

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INTRODUCTION

Universal health coverage is a formidable challenge for India, a big developing country with a population of more than 1.3 billion.[1] Health for all has been one of the priorities in India. According to the Indian Constitution, the achievement of universal healthcare is an obligation of the State.[2] Several court judgments in India have interpreted the right to health in India as one of the fundamental rights.[3] The Supreme Court of India ("Court") ruled in 1955 that the "*right to health is an essential right for human existence and is, therefore, integral to right to life.*"[4] In 1981, the Court held that the right to life "*includes the right to live with human dignity.*"[5] The Court reaffirmed this finding in 1984,[6] 1996,[7] and again in 1997.[8] These court pronouncements establish that the right to health is essential for the protection of the right to life.

Despite constitutional and international commitments on health, India's progress towards universal healthcare has been slow.[9] The major disease burden of India includes diseases like cancer, diabetes,

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1 Office of the Registrar General & Census Commissioner India, 'Census 2011' <http://www.censusindia.gov.in> accessed 10 December 2022 (Census 2011).

2 The Constitution of India, art 39.

3 'India and Sustainable Development Goals: The Way Forward' (Research and Information System for Developing Countries, 2016) 23 (India and Sustainable Development Goals 2016).

4 *Consumer Education and Resource Centre v Union of India* AIR 1955 SC 636.

5 *Francis Coralie Mullin v The Administrator, Union Territory of Delhi and Ors.* 1981 AIR 746.

6 *Bandhua Mukti Morcha v Union of India*, AIR 1984 SC 802.

7 *Paschim Bagga Khet Mazdoor Samiti v Government of West Bengal* AIR 1996 SC 426 (Pashchim Banga Khet Mazdoorsamity).

8 *State of Punjab v Mahindar Singh Chawla* AIR 1997 SC 1225.

9 India and Sustainable Development Goals (n 3) 23.

cardiovascular diseases, and HIV.[10] In addition to socio-economic factors and the sheer size of the population, an exceptionally high rate of poverty hinders India's pathway to universal health coverage. The officially estimated poverty rate in India is 28.3%.[11] In fact, a study conducted in 2017 criticises the government for keeping the cut-off point unreasonably low in order to achieve a reasonable statistical result. It notes that the "*[t]he low official poverty rates look good only if the cut-off point is an average spending power in villages of Rs. 11.8 per day, per person, and Rs.17.9 in cities.*"[12] It estimates that if this number is slightly increased "*by Rs. 3 for rural areas and Rs. 2 for cities, the proportion of those who are poor goes up to about 38%. Slowly raise the bar by another tiny fraction, say to Rs. 22, and the proportion swells to an amazing 70%.*"[13] Despite the pleasant official claims, the actual situation is alarming for India if 70% of its population finds it hard to purchase even basic commodities. The rate of poverty in some states of India "*is no better than in the poorest African countries.*"[14]

It is important to note that with 89.2% of private expenditure, "*India's out of pocket health spending rate is one of the highest in the world.*"[15] As a result of this private expenditure on health, "*annually 55 million people in India are pushed into poverty just to cover health expenses.*"[16] It has been estimated that medicines form "*around 70% of household expenditure in India.*"[17] Because of extremely low purchasing power, large sections of the Indian population lack access to affordable medicines.[18] A vast

10 Ibid.
11 Nandini Gooptu and Jonathan Parry (eds.), *Persistence of Poverty in India* (1st edn, Routledge 2017) 130.
12 Ibid.
13 Ibid.
14 Ibid.
15 Ibid.
16 Ibid.
17 Ibid.
18 Ibid.

majority of people in India lack the financial resources to buy brand-name drugs protected under patents. Buying patented drugs is not a realistic option for average citizens in India because the annual expenditure on patented drugs exceeds their annual income by over 30 times.[19] Extreme poverty is, therefore, a formidable hurdle for India in terms of achieving universal health coverage.

Before signing up for the TRIPS Agreement in 1995, India had chosen to exclude medicines from patent protection. This approach was aligned with India's public health needs as a developing country with a high poverty rate. After becoming a member of the WTO, India did not have the option to exclude medicines from patent protection because the TRIPS Agreement provides mandatory patent protection for all forms of technology and signing up for the TRIPS Agreement is a requirement to become a WTO member state.[20] India had until January 1, 2005, to comply with the TRIPS Agreement because developing countries were provided with a grace period for TRIPS compliance.[21] The freedom to choose patent opposition procedures is one of the public health flexibilities provided under the TRIPS Agreement. India made good use of this flexibility and provided both pre-grant and post-grant patent opposition procedures to ward off unwarranted patents.

National patent laws or international treaties have not defined the phrase patent opposition. According to the Médecins Sans Frontières' Patent Opposition Database, "*patent opposition is a general term to refer to the ways in which it is possible to challenge the validity of a patent – both during the period when a patent application is being reviewed, and after the patent has been*

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19 Jodie Liu, 'Compulsory Licensing and Anti-Evergreening: interpreting the TRIPS flexibilities in sections 84 and 3 (d) of the Indian Patents Act' (2015) 56 Harv. Int'l LJ 207.

20 Marrakesh Agreement establishing the World Trade Organization (adopted 15 April 1994, entered into force 1 January 1995) 1867 U.N.T.S. 154, art II(2) (Marrakesh Agreement).

21 ibid, art 65(2).

granted."[22] The term 'opposition' has been defined by the World Intellectual Property Organization ("WIPO") as "*a request, presented by the opposing party (a person or entity other than the applicant or the owner of the industrial property right) to the industrial property office [patent office] to refuse the application or to revoke the industrial property rights*."[23] In simple words, it is a low-cost administrative procedure provided to third parties to challenge the validity of questionable patents within a patent office.[24] This procedure is used as a safeguard to make sure that only those inventions make it to grant that meet the requirements of patentability under national patent laws.

In designing its patent opposition model, India enacted a conjunction of two TRIPS flexibilities – the flexibility to decide patentability standards (Article 27.1), and the flexibility to design patent opposition procedures (Article 41.2). India requires higher patentability standards as Section 3(d) of the Indian Patents Act ("Act") introduced the requirement of enhanced efficacy.25 India adopted a robust exclusion for new uses of known drugs. As a result of this provision, patent protection is denied to trivial modifications of known substances unless there is an enhanced efficacy.26 India also raised the bar while defining the inventive step under Section 2(ja) of the Act. The 2005 amendment to the Act defined the phrase 'inventive step' to require technical advance and economic significance of the invention in order to be eligible for patent protection.27 The higher threshold standards

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22 'How to Build an Opposition?' (*Patent Opposition Database*) <https://www.patentoppositions.org/en/how_to_build_an_opposition> accessed 10 December 2022.

23 'WIPO Handbook on Industrial Property Information and Documentation', (World Intellectual Property Organisation 2013) <http://www.wipo.int/standards/en/pdf/08-01-01.pdf.> accessed 10 December 2022).

24 Kimberlee Weatherall et al. 'Patent Oppositions in Australia: The Facts' (2011) 34 (1) U.N.S.W. Law Journal 93.

25 The Patents (Amendment) Act 2005 (India), s 3(d).

26 Ibid.

27 Ibid, s 2(ja).

set out in Sections 3(d) and 2(ja) of the Act mean less burden on India's health system because of the availability of generic alternatives of pharmaceutical drugs. India's legislative choices are in line with its constitutional obligations to provide good healthcare to its citizens as a welfare country.

This article offers an analytical and informative look at India's approach to balancing its treaty obligations with domestic needs. It revisits the legislative history of the Indian patent opposition model with a focus on debates around protecting the national interest. It considers the key developments at the international level which impacted India's legislative choices. It encapsulates parliamentary debates in India about conflicting goals of protecting the right to health, safeguarding the interest of the generic drug industry, and complying with the international obligations under the TRIPS Agreement. These debates are important in terms of understanding the rationale behind India's well-thought-out patent opposition model. It considers India's patent opposition model in comparison with the U.S. and EU approaches towards patent opposition and offers important insights for WTO member states in terms of balancing their conflicting obligations in relation to public health and patent protection.

THE LEGISLATIVE HISTORY OF THE INDIAN PATENT OPPOSITION MODEL

This paper asserts that India designed its patent opposition mechanism keeping in view two objectives. The first objective was to meet India's obligation under the Constitution to provide healthcare to its citizens by improving the availability of cheap generic versions of drugs. This objective can be referred to as the 'consumer welfare objective'. The second objective was to protect a robust generic drug industry in India with huge pharmaceutical export potential. This objective can be

referred to as 'industrial or economic development objective'. A view of the historical evolution of the Indian patent laws supports this assertion.

A. Pre-Independence Period

It is worth noting that, like the evolution of India's patent laws, the growth of the pharmaceutical industry in India also started in the nineteenth century under British rule. In 1888, the Inventions and Designs Act, 1888 was passed by the Governor-General of India in Council as the first consolidated legislation. It superseded the three previous Acts of 1859, 1872, and 1883.[28] In 1907, Britain amended its patent laws.[29] This legislative change in Britain led to the enactment of the Indian Patents and Designs Act, 1911 ("Patents and Designs Act").[30] This new law aligned India's patent laws with the revised British patent laws. It established a patent office in India and replaced all previous legislation on patent rights in India.[31] It was not superseded by any other legislation during British rule in India.

Several pharmaceutical companies were set up in British India. For instance, Bengal Chemicals, Alembic Chemical Works, and Bengal Immunity were set up in 1892, 1907, and 1919 respectively.[32] Modelled on British patent laws, the Indian Patents and Designs Act, 1911 protected the interests of foreign-owned corporations by providing strong patent protection for pharmaceuticals. This legislative scheme

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28 Act No. V of 1888 (India).

29 Patents and Designs Act 1907 (Britain).

30 Act No. II of 1911 (India).

31 Peter Drahos, *The Global Governance of Knowledge: Patent Offices and their Clients* (CUP 2010) 201 (Peter Drahos).

32 Zoee Lynn Turrill, 'Finding the Patent Balance: The Novartis Glivec Case and the TRIPS Compliance of India's Section 3(d) Efficacy Standard' (2013) 44 Georget. J. Int. Law 1558 (Zoee Lynn).

suited multinational drug companies as it did not include special restrictions on patents related to drugs, chemicals, and food.[33]

B. Post-Independence Period

On August 15, 1947, the partition of British India into the Dominion of Pakistan (presently Pakistan and Bangladesh) and Union of India (presently Republic of India) marked an end to British rule in India. In post-independence India, patent reform became a national priority as foreign corporations owned nearly all drug patents in India and had full control of the industry. The local pharmaceutical companies started pressing for a change in the existing patent laws to ensure the effective use of the patent system to protect India's national interest.[34] Keeping in view the significance of patent law for industrial growth and economic development, the government of India took concrete measures to design the Indian patent law in accordance with its national interests and development goals.

On October 1, 1948, the Patents Enquiry Committee ("Tek Chand Committee") under the chairmanship of retired Justice Bakshi Tek Chand was appointed by the Government of India. The Committee reviewed the existing patent laws and made recommendations for law reform in order to bring India's patent laws in line with the national interests.[35] Its key focus was on patents related to drugs, chemicals, and food. It referred to the changes made in the patent law of the United Kingdom ("UK") in 1919 to introduce special restrictions for

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33 Shri Justice N. Rajagopala Ayyangar, 'Report on the Revision of the Patent Laws' (1959) <https://ipindia.gov.in/writereaddata/Portal/Images/pdf/1959-_Justice_N_R_Ayyangar_committee_report.pdf> accessed 10 December 2022 (Report on Revision of Patent Laws).

34 Jae Sundaram, 'India's Trade-Related Aspects of Intellectual Property Rights Compliant Pharmaceutical Patent Laws: What Lessons for India and Other Developing Countries?' (2014) 23(1) Info. and Comm. Tech. L. 2 (Jae Sundaram).

35 Ministry of Industry and Supply, 'Report of the Patents Enquiry Committee' (1948-50) https://indianculture.gov.in/reports-proceedings/report-patents-enquiry-committee-1948-50 accessed 10 December 2022 (Report of the Patents Enquiry Committee).

patents related to drugs, chemicals, and food.[36] Section 38(A)(1), introduced in the UK patent law, limited patent protection to special chemical processes and the substances resulting therefrom. Under this provision, a new process of manufacturing that produced a new substance by its own chemical reaction was considered a special chemical process.[37] This provision, denying patent protection to chemical substances themselves, made it legal for competitors to use non-infringing processes to manufacture the same substance.[38]

The Tek Chand Committee found that foreign corporations had been making use of the favourable product patent regime to their advantage against India's national interests in several ways, for instance,

> "*by importing the patented product rather than manufacturing it here [in India],*[39] *fixing the prices at high levels, not allowing others to manufacture the product even when it was not itself engaged in manufacturing.*"[40] It noted that "*[t]he absence of these provisions [like s 38(A)(1) in the UK patent law] undoubtedly favoured the foreigner and enabled him to abuse his patent rights in India to the detriment of the people of this country.*"[41]

The final report ("Report") of the Tek Chand Committee, submitted in April 1950, suggested a series of changes in India's patent laws to align them with national interests.[42] It recommended denying patent protection to food and medicines, improving the stability of the legal

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36 Ibid.

37 Report on Revision of Patent Laws (n 33) 30.

38 Ibid, 31.

39 *Bayer Corporation v Natco Pharma Ltd.*, Order No. 45/2013 (Intellectual Property Appellate Board, Chennai).

40 Sudip Chaudhuri, 'TRIPS and Changes in Pharmaceutical Patent Regime in India' (2005) Indian Institute of Management 29.

41 Report on Revision of Patent Laws (n 33).

42 Manoj Pillai et al., *Patent Procurement in India* (Intellectual Property Owners Association 2007) 3.

framework, and using compulsory licenses to override patents.[43] By using a language similar to the language of Section 38(A)(1) in the UK patent law, the Tek Chand Committee recommended that "*[s]ubstances prepared or produced by chemical processes or intended for food or medicine should not be patentable except when made by the invented processes or their obvious equivalent.*"[44] Many recommendations of the Tek Chand Committee were quite similar to those made by the British Swan Committee in 1949.[45]

It is worth noting that the Patents and Designs Act included pre-grant opposition procedures. Any person could oppose the grant of a patent within three months after the publication of a patent application on any of the four grounds provided in the Act.[46] The Report recommended that patent opposition proceedings should be deleted from the Indian patent law because they cause a delay in the grant of patents.[47]

In 1953, a Patents Bill was tabled in the Lok Sabha to give effect to the Tek Chand Committee's suggestions.[48] The Bill was modelled on the UK Patents Act of 1949. It required the deletion of opposition proceedings in line with the recommendations of the Tek Chand Committee. The Bill sought to replace the existing patent law in India with a completely new law. The reasons for introducing this Bill were provided as under:

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43 Jae Sundaram (n 34).

44 Report on Revision of Patent Laws (n 33).

45 In England, in 1944, the Labor Government appointed a Committee to examine the Patents and Designs Act and make recommendations for changes in the law. The Committee was headed by Sir Kenneth R. Swan, a distinguished patent attorney, and it submitted its report in 1947. The United Kingdom Patents Act of 1949 was passed in the light of recommendations made by the Committee in its report.

46 Indian Patents and Designs Act 1911 (India), s 9.

47 Report on Revision of Patent Laws (n 33).

48 Bill No. 59 of 1953 (India).

> "*The Indian Patents and Designs Act, 1911 was enacted at a time when India had not developed industrially. The experience of the working of this Act coupled with the progress of industrial development in the country indicated clearly the need for a more comprehensive legislation so as to ensure that patent rights are not abused to the detriment of the consumer or to the prejudice of the trade or of the industrial development of the country … the final report of the Patent Enquiry Committee [Tek Chand Committee] was submitted in 1950. The object of this Bill is to give effect to the recommendations of the final report of the Patents Enquiry Committee as have been accepted by Government.*"[49]

However, the Lok Sabha was dissolved, and the Bill could not be enacted into law.[50] This first post-independence attempt to change the patent law in India failed, but it triggered a constructive debate and led to a further government study of the Patents and Designs Act and its compatibility with India's national interests.

In 1957, another committee was appointed by the Government of India to review the existing patent regime and its alignment with socio-economic conditions.[51] Headed by Shri Justice N. Rajagopala Ayyangar, this committee ("Ayyangar Committee") was constituted to make recommendations for aligning the patent regime with India's goal of becoming a self-sufficient and self-reliant nation.[52] Along with other factors, public health concerns resulting from low life expectancy, high death rate, and unaffordability of essential medicines

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49 Prashant Reddy T. and Sumathi Chandrashekaran, *Create, Copy, Disrupt: India's Intellectual Property Dilemmas* (OUP 2017) 6 (Prashant Reddy and Sumathi Chandrashekharan).

50 Paul Goldstein and Joseph Straus, *Intellectual Property in Asia: Law, Economic History and Politics* (Springer, 2009) 59.

51 Jae Sundaram (n 34).

52 Report on Revision of Patent Laws (n 33).

led to this initiative by the Indian government.[53] According to the report ("Ayyangar Report") submitted by the Ayyangar Committee in 1959, the ratio of patents granted to indigenous patentees was extremely disproportionate to those granted to foreign patentees because foreigners owned around 90% of patents in India.[54] Further, the non-working of many of those foreign-owned patents was detrimental to the national interests of India.[55]

The Ayyangar Report highlighted numerous implications of the patent system for under-developed countries but recommended that the patent system was necessary for India's industrial growth.[56] In doing so, it also recommended certain safeguards such as the granting of compulsory licences to override patents, revoking patents if not worked or inadequately worked in India,[57] authorising government use of inventions,[58] and adoption of opposition procedures in the Indian patent laws. The Ayyangar Committee found that foreign-owned patents resulted in the high cost of pharmaceutical drugs in India, and suggested that the public interest requires prohibiting product patents for food and medicines.[59] Thus, it proposed the adoption of the following draft provision:

> *"(2) No patent shall after the commencement of this Act be granted in respect of inventions claiming – (a) substances intended for or are capable of being used as food or beverage or as medicine (for men or animals) including sera, vaccines, antibiotics and biological*

53 Santanu Mukherjee, 'The Journey of Indian Patent Law towards TRIPS Compliance' (2004) 2 IIC Int. Rev. Intellect. Prop. Compet. Law 125.
54 Report on Revision of Patent Laws (n 33) 108.
55 Ibid, 72.
56 Ibid, 19-20.
57 Ibid, 47.
58 Ibid, 66.
59 Ibid, 39.

> *preparations, insecticide, germicide, or fungicide, and (b) substances produced by chemical processes including alloys but excluding glass.*
>
> *(3) Notwithstanding anything in sub-section (2) inventions of chemical processes for the manufacture or production of the substances mentioned in that subsection shall be patentable."*[60]

The Committee's findings were informed by a detailed analysis of patent laws and policy recommendations not only in India but also in other jurisdictions like the UK, Canada, and Australia. The findings of Ayyangar Committee on patent opposition proceedings were exactly opposite to that of the Tek Chand Committee. Justice Ayyangar supported the retention of opposition proceedings in the Indian patent law as a measure to balance the interests of the patent applicant and the public at large.[61] He asserted that patent opposition proceedings were not abused in India to cause unnecessary delay in the grant of patents and supported his assertion with statistics of oppositions filed in India from 1950 to 1957.[62]

In 1957, a U.S. Senate Committee started investigating the effects of drug patents on domestic consumers in the U.S. In May 1961, it submitted its detailed report to the U.S. Senate with proposed reform legislation. Though this reform legislation was rejected by the U.S. Congress, it significantly influenced drug patent policy in India. The following extract from the report was repeatedly used by the opponents of pharmaceutical patents in India as a propaganda coup:

> *"India which does grant patents on drug products, provides an interesting case example. The prices in India for the broad-spectrum antibiotics, Aureomycin, are among the highest in the world. As a*

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60 Ibid, 121.
61 Ibid, 82.
62 Ibid, 82-83.

> *matter of fact, in drugs generally, India ranks among the highest priced nations of the world – a case of inverse relationship between per capita income and the level of drug prices."*[63]

In 1965, the Patents Bill ("Bill"), drafted in the light of the Ayyangar Committee's recommendations, was sent to the Joint Committee of the Parliament. Although the Bill lapsed as the Lok Sabha was dissolved in 1967,[64] It came to be passed by both, the Lok Sabha and the Rajya Sabha, post the elections. In September 1970, the Bill became an Act of Parliament after receiving assent from the President of India, and finally came into force in April 1972, as the Patents Act, 1970 ("Patents Act"),[65] 22 years after the submission of Tek Chand Committee's report.

Most of the Ayyangar Committee recommendations were reflected in the Patents Act, making it clear that the legislature gave more importance to the suggestions made by this committee. The Patents Act provided only process patents for food and medicines to allow freedom for generic competition. The definition of the patentable invention provided under the Patents Act covered both processes and products,[66] but an exception was made for food and medicines under Section 5(a) of the legislation, which specifically excluded from patent protection the "*substances intended for the use, or capable of being used, as food or as medicine or drug.*"[67]

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63 United on the Judiciary, States Senate, 'Study of Administered Prices in the Drug Industry' (27 June 1961) <https://ipmall.law.unh.edu/sites/default/files/BAYHDOLE/4_PREPPED_FILES/1961.05.08_Senate_Report_on_Administered_Prices_Drugs.pdf> accessed 10 December 2022 (United States Senate Report on Administered Prices).

64 Sheetal Thakur, *Patenting in India* (L.B.P. 2014) 68.

65 The Patents Act 1970 (India).

66 Ibid, s 2(ja).

67 Ibid, s 5(a).

Section 3(d) further narrowed down the scope of patentable invention defined in Section 2(ja). It stipulated that: "*The following are not inventions within the meaning of the Act… (d) the mere discovery of any new property or new use for a known substance or of the mere use of the known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.*"[68] It is worth noting that the original Section 3(d) did not impose the additional requirement of enhanced efficacy for patent eligibility. Moreover, there was no mention of "*new forms of a known substance*" in the original Section 3(d) of the Act. The Patents Act, likewise the Patents and Designs Act, provided for a pre-grant opposition procedure and added more grounds for invoking the procedure.[69]

Before the adoption of The Patents Act, drug prices in India were significantly high mainly because of product patents.[70] The Patents Act arguably aimed at changing this situation. Its objectives were aligned with India's policy goals stated under Article 39 of the Constitution, which reads as follows:

> "*State shall, in particular, direct its policy towards securing (a)…(b) that the ownership and control of the material resources of the community are so distributed as best to serve the common good; (c) that the operation of the economic system does not result in the concentration of wealth and means of production to the common detriment; (d)…(e) that the health and strength of workers, men, and women, and the tender age of children are not abused and that citizens are not forced by economic necessity to enter avocations unsuited to their age or strength; (f) that children are given opportunities and facilities to develop in a healthy manner and in conditions of freedom*

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68 Ibid, s 3(d).
69 Ibid, s 25(1).
70 United States Senate Report on Administered Prices (n 63).

> *and dignity and that childhood and youth are protected against exploitation and against moral and material abandonment (Emphasis added).*"[71]

The commitment to public health is included in India's public policy objectives because the government of India has a primary constitutional duty to provide the right to health to its population under Article 47 of the Constitution.[72] The judiciary in India has interpreted relevant provisions of the Constitution in a manner to create an enforceable right to health.[73] For instance, in *Paschim Banga Khet Mazdoor Society v State of West Bengal,* the Indian Supreme Court ruled that it is a fundamental right to have access to medical treatment in a public hospital.[74]

India's legislative choice of providing only process patents for medicines was well-thought-out, keeping in view domestic needs and constitutional obligations of a big developing country with a growing population. This approach was compatible with consumer welfare objectives and public health goals of India. It demonstrated the importance of a robust generic drug industry to promote equitable access to cheaper medicines.[75]

C. Inclusion of Trade-Related IP in the Uruguay Round of Negotiations

India was among the nations that negotiated the General Agreement on Tariffs and Trade ("GATT") in 1947.[76] This multilateral agreement was aimed at progressively reducing trade barriers and tariffs. Problems for India's revised patent law regime started with the eighth

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71 The Constitution of India, art 39.
72 Ibid, art 47.
73 Zoee Lynn (n 32).
74 Paschim Banga Khet Mazdoorsamity (n 7).
75 Jae Sundaram (n 34).
76 Antony Taubman et al., *A Handbook on the WTO TRIPS Agreement* (CUP 2012) 4-5.

round of GATT talks. These talks among 123 countries are called the Uruguay Round, as they were initiated at Uruguay in 1986.[77] Intellectual property was put on the agenda in the form of the TRIPS Agreement.[78]

Prior to these negotiations, India was not the only country to deny product patents for drugs. Medicines were exempt from patent protection in more than 50 countries, including some of the developed countries of today's world.[79] India's patent regime, resulting in the rapid development of India's generic drug industry, was of particular concern for foreign innovator companies because they were not allowed to compete with the Indian companies in India while the Indian generic companies were able to have a significant market share in lucrative markets. Pharmaceutical Research and Manufacturers of America ("PhRMA") stated that "*the Indian patent system was the most direct motivation for the U.S. efforts in the Uruguay Round negotiations relating to patents.*"[80] India strongly opposed the U.S. idea of including intellectual property in the negotiations in Uruguay. India clearly communicated its opposing views to the Negotiating Group on TRIPS:

> "*The protection of intellectual property rights has no direct or significant relationship to international trade. It is because substantive issues of intellectual property rights are not germane to international trade that GATT itself has played a peripheral role in this area and*

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77 Ibid.

78 Agreement on Trade Related Aspects of Intellectual Property Rights (adopted 15 August 1994, entered into force 1 January 1995) 1869 U.N.T.S. 299 (TRIPS Agreement 1994).

79 C.M. Correa and AA Yusuf (eds.), *Intellectual Property and International Trade: The TRIPS Agreement* (Kluwer 2008) 227- 229.

80 Special 301 Report on Intellectual Property Barriers, 'Submission of the Pharmaceutical Research and Manufacturers of America' (16 February 1999).

> *the international community has established other specialized agencies to deal with them.*"[81]

Later, however, India reversed this stance due to an economic slowdown, and the fear of trade barriers to its exports, suspension of economic aid, and withdrawal of textile tariff concessions. In April 1989, India fundamentally changed its stance during negotiations at Geneva and agreed to the idea of including intellectual property in the negotiations for TRIPS.[82] India's domestic industry, scientists and public health activists were aggrieved by India's decision. They formed an anti-TRIPS alliance called the National Working Group on Patent Laws. In December 1989, this alliance organized a full-day conference to highlight the implications of TRIPS for India and suggested to the government to issue:

> "*an unequivocal policy statement that there will not be any change in the law and policy relating to Patents and Intellectual Property Rights and this position would be maintained in GATT and other national, international and bilateral fora.*"[83]

In the early 1990s, India was facing not only the threat of trade sanctions under the United States Trade Representative ("USTR") Special 301 mechanism but also a full-fledged economic crisis. In the given circumstances, India decided to accept the proposal on TRIPS despite public criticism and without even issuing a white paper.[84] The first department-related parliamentary standing committee on commerce tried to intervene by using its mandate on the issue of

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81 Group of Negotiations on Goods (GATT), 'Standards and Principles Concerning the Availability, Scope and Use of Trade-Related Intellectual Property Rights (Communications from India)' (10 July 1989) MTN-GNG/NG11/W/37, p.19.

82 'Intellectual Property Rights: The Geneva Surrender' (1989) 24 Econ. Political Wkly.1201.

83 B.K. Keayla, 'Resolution Adopted at the National Conference of Scientists on Science, Technology and Patents' (4 December 1989).

84 Rajya Sabha, 'Written Answers to Government's Reaction on Dunkel's Proposals' (25 February 1992) 90.

TRIPS.[85] It recommended that India should provide protection to only process patents and not product patents. The Indian government, not bound by the the same, decided not to adhere to the recommendation.[86]

When India was close to signing the TRIPS Agreement, four petitioners moved the High Court of Delhi on April 7, 1994:

> "*seeking a writ of mandamus restraining the Union of India from signing/ ratifying the existing version of the GATT treaty, or to restrain the Union of India from, agreeing to sign and signing Article 27(3)(b) of the TRIPS Agreement.*"[87]

The petitioners contended that the fundamental rights of Indian citizens would be violated if India signed the TRIPS Agreement. This last attempt to stop India from signing TRIPS failed as the Court dismissed the petition.[88] India then became a member of the WTO after signing the Marrakesh Agreement in April 1994.[89]

D. Legislative Changes for TRIPS Compliance

India's policy of staying out of the international patent framework was aimed at maximizing its sovereignty over its national patent laws.[90] However, India had to change its policy to attain membership of the WTO, for which signing up for TRIPS was a necessity.[91] After signing

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85 Rajya Sabha, 'Parliamentary Standing Committee on Commerce Draft Dunkel Proposals' <https://parliamentofindia.nic.in/ls/lsdeb/ls10/ses5/1923129209.htm> accessed 10 December 2022.

86 Ibid.

87 *Vandana Shiva and Ors. v Union of India* 1995 (32) DRJ 447.

88 Ibid.

89 Rudiger Wolfrum and Peter-Tobias Stoll, 'Agreement Establishing the World Trade Organization' in Rudiger Wolfrum and others (eds), *WTO-Institutions and Dispute Settlement* (Brill Nijhoff 2006)1-192.

90 Peter Drahos (n 31).

91 Marrakesh Agreement (n 20) art II(2).

up for TRIPS in 1995, India subsequently joined both the Paris Convention,[92] and the Patent Cooperation Treaty,[93] in 1998.

The TRIPS Agreement was unprecedented because it not only provided for 20 years patent protection for innovations across all technological fields,[94] but also brought in enforcement[95] and dispute settlement[96] provisions for the effective implementation of the agreed minimum standards.[97]

The TRIPS Agreement had serious implications for countries like India because it was no longer possible to exempt medicines. Yet, India, as a developing country, had until January 1, 2005, to comply with TRIPS.[98] As a legislative measure to comply with TRIPS, India introduced the Patents (Third Amendment) Bill 2003, which lapsed with the dissolution of the Indian Parliament.[99]

On March 17, 2005, a day before the Patents (Amendment) Bill, 2005 ("Amendment Bill of 2005") was tabled in the Lok Sabha, the Secretary of the Legislative Department received a letter, with a note appended to it, from a Director at the Department for Promotion of Industry and Internal Trade ("DIPP"). The note included provisions on the strengthening of the pre-grant opposition procedure, compulsory licensing, and the scope of patentability. In fact, the present wording of Section 3(d), the most prominent anti-evergreening provision in Indian patent laws, comes from that last-minute amendment to the

92 Paris Convention for the Protection of Industrial Property 1883 (adopted 20 March 1983, entered into force 7 July 1984) 828 U.N.T.S. 305.
93 Patent Cooperation Treaty 1970 (adopted 19 June 1970, entered into force 24 January 1978) 1160 U.N.T.S 231.
94 TRIPS Agreement 1994 (n 78), art 27(1).
95 Ibid, arts 41 – 61.
96 Ibid, arts 63 – 64.
97 J.H. Reichman, 'Enforcing the Enforcement Procedures of the TRIPS Agreement' (1997) 37 Va. J. Int'l L. 339.
98 TRIPS Agreement 1994 (n 78), art 65(2).
99 Ibid, art 65.

pending legislation.[100] While drafting Section 3(d), the DIPP tried to keep a balance between the obligations under TRIPS and the domestic demands to restrict patent protection to new chemical entities ("NCEs").

The Amendment Bill of 2005 was passed by the Lok Sabha,[101] followed by the Rajya Sabha, and assented to by the President whereafter it came to be enacted as the Patents (Amendment) Act, 2005.[102] This marked the return of product patents for medicines after a gap of 35 years.

The issue of TRIPS compliance put India in a very difficult situation because India had excluded drugs from patent protection after intensive public debate and an extensive government study supporting this move keeping in view India's constitutional obligations and ground realities. The Indian Government was being pressurized from within India and abroad as public health non-governmental organizations and the World Health Organization were fully aware of the long-lasting impact of pharmaceutical patent protection in India on millions of patients across the globe, especially in low-income countries.[103]

The TRIPS Agreement, however, provided a number of public health flexibilities, such as compulsory licensing of patents (under Article 31), parallel importation of patented products (under Article 6), freedom to decide patentability criteria (under Article 27(1)), and patent opposition procedures (under Articles 62(2) and 41(2)). These flexibilities provided member states with policy space to craft patent laws at national levels according to their domestic needs.

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100 Prashant Reddy and Sumathi Chandrashekharan (n 50).

101 Ibid.

102 'Indian Parliament Approves Drug Patents Bill' (*ABC NEWS*, 24 March 2005) <https://www.abc.net.au/news/2005-03-24/indian-parliament-approves-drug-patents-bill/1538902.> accessed 11 December 2022.

103 Jae Sundaram (n 34).

India made good use of public health flexibilities while making legislative changes to comply with the TRIPS Agreement, by crafting detailed compulsory licensing provisions (under Sections 84, 92, and 92A), embraced international exhaustion of rights (under Section 107A), raised patentability threshold standards (under Sections 3(d) and 2(ja)),[104] and provided both pre-grant and post-grant patent opposition as a procedural safeguard to challenge the validity of questionable patents (under Sections 25(1) and 25(2)). This procedural safeguard was also linked to substantive provisions, such as Sections 2(ja) and 3(d), which raised the bar for patentability.[105] Under Sections 25(1)(e) and 25(2)(e), the lack of inventive step is a ground of patent opposition, which makes Section 2(ja) a key provision to oppose questionable patents.[106] Moreover, Section 3(d) raised the bar by imposing a condition of enhanced efficacy.[107] Under Sections 25(1)(f) and 25(2)(f), one of the grounds of patent opposition is that "*the subject of any claim of the complete specification is not an invention within the meaning of this Act, or is not patentable under this Act*."[108] In this way, Section 3(d) is linked to the Indian opposition proceedings. This approach of the Indian legislature has helped opponents in mounting successful patent oppositions based on Sections 3(d) and 2(ja).[109]

The legislative history of the Indian patent regime shows that the patent opposition model was designed to achieve two objectives. The first objective was to fulfil the constitutional duty of India to provide

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104 Omar Serrano and Mira Burri, 'TRIPS Implementation in Developing Countries' in Manfred Elsig, Michael Hahn, and Gabriele Spilker (eds), *The Shifting Landscape of Global Trade Governance* (CUP 2019) 227.

105 The Patents (Amendment) Act 2005 (India), ss 2(ja) and 3(d).

106 Ibid, ss 25(1)(e) and 25(2)(e).

107 Ibid, s 3(d).

108 Ibid, ss 25(1)(f) and 25(2)(f).

109 Sandeep K. Rathod, 'Patent Oppositions in India' in Carlos M. Correa and Reto M. Hilty (eds), *Access to Medicines and Vaccines: Implementing Flexibilities Under Intellectual Property Law* (Springer Nature 2022) 154.

good healthcare to its population by promoting price-reducing generic competition, and the second objective was to protect a robust generic drug industry in India with huge pharmaceutical export potential.

Table 1: Notable Successful Pharmaceutical Patent Oppositions in India[110]

Drug	Thera-peutic area	Patent Application Number	Opponent(s)	Date of Decision(s)
Imatinib (Gleevec)	Anti-cancer	1602/MAS/1998	Cancer Patients Aid Association (CPAA), Hetero, Cipla, Natco	2006
Combivir	HIV	2044/CAL/1997	INP+ and Manipur Network of Positive People	2007 (Patent application abandoned)
Abacavir Sulphate	HIV	872/CAL/98	INP+	2007 (Patent application abandoned)
Tenofovir	HIV	2076/DEL/1997	INP+, DNP+, Cipla	2009
Valganciclovir	Anti-viral	959/MAS/1995	Indian Network of People Living with HIV/AIDS (INP+), Delhi Network of People Living with HIV/AIDS (DNP+), Matrix, Ranbaxy, Cipla, and Bakul Pharma	2010
Ritonavir and Lopinavir (Kaletra)	HIV	339/MUMNP/2006	Matrix, Initiative for Medicines, Access and Knowledge (I-MAK), Cipla, and Okasa	2010 (Patent application abandoned)
Atazanavir Sulphate	HIV	6425/DELNP/2006	Matrix and Cipla	2010
Raltgravir Potassium	HIV	4187/DELNP/2007	INP+, DNP+, and Mylan	2020

[110] Ibid.

Table 1 shows that there are several examples of successful pharmaceutical patent oppositions in India. These examples highlight the significance of these procedures in terms of achieving the objectives not only in relation to public health but also to protect the generic drug industry in India.

Table 2: Rate of Pre-Grant Opposition in India (2005-2020)[111]

Year	Number of Pre-Grant Oppositions Filed	Number of Applications Published	Patent Opposition Rate	Number of Patents Granted	Patent Opposition Rate
2005-06	155	23,398	0.66%	4,320	3.59%
2006-07	44	19,310	0.23%	7,539	0.58%
2007-08	64	60,506	0.11%	15,261	0.42%
2008-09	153	40,749	0.38%	16,061	0.95%
2009-10	160	34,305	0.47%	6,168	2.59%
2010-11	154	32,213	0.48%	7,509	2.05%
2011-12	193	27,753	0.70%	4,381	4.41%
2012-13	279	26,159	1.07%	4,126	6.76%
2013-14	309	31,413	0.98%	4,227	7.31%
2014-15	247	26,934	0.92%	5,978	4.13%
2015-16	290	41,752	0.69%	6,326	4.58%
2016-17	206	86,766	0.24%	9,847	2.09%
2017-18	260	46,899	0.55%	13,045	1.99%
2018-19	426	46,345	0.92%	15,283	2.79%
2019-20	800	50823	1.57%	24,936	3.21%
Total	3,740	595,325	0.63%	145,007	2.58%

Table 2 shows that the rate of patent opposition in India is too low to make a significant impact in terms of achieving its intended objectives. India's well-thought-out patent opposition model is seriously under-utilised. The average opposition rate from 2005-2020 in relation to the number of patent applications published is just 0.63%, which is not encouraging. Civil society organizations and patient groups could use

[111] Office of the Controller General of Patents, Designs & Trademarks, 'Annual Report' (2005-2020) <https://ipindia.gov.in/annual-reports-ipo.htm≥ accessed 11 December 2022.

these procedures to challenge unwarranted pharmaceutical patents, but they are often under-resourced in terms of legal aid professionals.[112]

PATENT OPPOSITION MODEL OF THE EUROPEAN UNION

The European post-grant opposition system is the most well-known and tried system, as it has been around for decades since the formation of the European Patent Office ("EPO").[113] On October 5, 1973, The European Patent Convention ("EPC") provided a procedure for post-grant patent opposition.[114] By using this procedure, third parties can oppose a European patent within 9 months of its publication of the grant.[115] An opposition can be filed by a natural or legal person after the prescribed fee is paid.[116] The grounds of opposition include a lack of industrial application, non-obviousness, a lack of novelty, unpatentable subject matter, and insufficient disclosure.[117] The real party in interest may shield their identity by using a straw man filing on their behalf.[118] This provision is petitioner-friendly because it safeguards the petitioners against a counter-attack in the form of patent infringement litigation.

The Opposition Division of the EPO deals with opposition notices filed by third parties. It comprises of three experienced and technically qualified members, including the primary examiner who examined the

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112 Jagjit Kaur Plahe and Don McArthur, 'After TRIPS: Can India Remain the Pharmacy of the Developing World?' (2021) 44(6) South Asia: J. of South Asian Stud. 1178.

113 Karen E. Sandrik, 'The Post-Grant Life: Coordinating & Strategizing Challenges of Issued Patents in Multiple Continents' (2018) 17(2) Chi.-Kent J. Intell. Prop. 456.

114 European Patent Convention 1973 (EU), art 99.

115 Ibid.

116 'Schedule of Fees and Expenses Applicable as from 1 April 2023' (European Patent Office, 31 March 2023) <https://new.epo.org/xx/legal/official-journal/2023/etc/se2/p0/2023-se2-p0.pdf> accessed 10 July 2023 (Schedule of Fees and Expenses).

117 European Patent Convention 1973 (EU), arts 100, 52 – 57.

118 *Automobiles Peugeot and Automobiles Citroen v Idem*, G9/93 (OJ 1994, 891); *Indupack AG v Hartdegen, Emmerich Ing.*, G3/97; and *Genetech, Inc. v Delta Biotechnology Ltd., Riatal GmbH and Naohito Oohashi*, G4/97 (OJ 1999, 245, 270).

patent application.[119] The Opposition Division has a quasi-judicial role in this *inter partes* proceeding. The Opposition Division invites the parties to make observations.[120] The EPO procedure is primarily a written procedure during which a written exchange of communications takes place.[121] The Opposition Division may also conduct oral proceedings at the instance of the EPO or if requested by at least one party.[122]

Withdrawal of patent opposition or settlement between the patent owner and the opponent is not forbidden. If the opposition is withdrawn or the opponent is legally incapacitated, the opposition is not necessarily terminated. The Opposition Division can still proceed with the opposition of its own motion and issue a decision.[123] The Opposition Division may even consider other grounds not invoked by the opponent.[124] The EPO's right to pursue opposition on its own motion is a powerful tool to ensure patent quality and to deter settlements between the patent owner and the opponent, as such settlements normally undermine the public interest. This provision may, however, discourage the use of the opposition proceedings by opponents who seek to force patent holders to license their patents.[125]

Before taking a decision, the opposition division ensures that its opinion is communicated to the patentee and the opponent.[126] In

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119 European Patent Convention (EU), art 19.

120 ibid, art 101.

121 Fiona Rotstein and Chris Dent, 'Third-Party Patent Challenges in Europe, the United States and Australia: A Comparative Analysis' (2009) 12(5) J. World Intellect. Prop. 475.

122 European Patent Convention 1973 (EU), arts 116 and 117.

123 Ibid, art. 114; Implementing Regulations to the Convention on the Grant of European Patents (Oct. 5, 1973), rules 60(2) and 84(2).

124 Implementing Regulations to the Convention on the Grant of European Patents (Oct. 5, 1973), rule 8.

125 Bronwyn H. Hall et al., 'Prospects for Improving US Patent Quality via Postgrant Opposition' (2004) 4 Innov. Policy Econ. 125 (Bronwyn Hall et al).

126 Colleen Chien et al., 'Inter Partes Review and the Design of Post-Grant Patent Reviews' (2018) 33(3) Berkeley Tech. L.J.831 (Colleen Chien).

response to this communication, the patent owner is allowed to make changes to the patent after seeking approval from the Opposition Division.[127] Within two months after the Opposition Division's decision, an appeal can be made to the EPO Technical Boards of Appeal by either party or by both parties,[128] after paying the prescribed fee.[129] If the appellant decides to withdraw the appeal, the appeal proceedings are terminated, and the Technical Board of Appeal does not pursue the appeal proceedings of its own motion.[130]

According to a 2004 study by Hall and Harhoff, the opposition rate (in relation to granted patents) between 1980 and 1995 was approximately 8%.[131] The opposition rate (in relation to granted patents) between 1981 and 1998 was 8.3%, according to a study by Graham.[132] The EPO reported in 2009 an opposition rate of 5.2% in relation to granted patents.[133] A 2009 study by Harhoff also confirmed an opposition rate of around 5%.[134] The opposition rate declined over time, and the current rate, though much better as compared to other jurisdictions, is not very encouraging. The success rate of EPO opposition proceedings is, however, quite high. It has been estimated that 35% of the opposed patents are revoked, and another 33% patents are amended or narrowed down.[135] The combined success rate of 68% in the EPO proceedings is remarkable.

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127 Ibid.

128 European Patent Convention 1973 (EU), art 21(4), 106(1) and 107.

129 Schedule of Fees and Expenses (n 116).

130 Bardehle Pagenberg, *European Patent Opposition Proceedings* 11, https://www.bardehle.com/uploads/files/European_Patent_Opposition_en.pdf. (Accessed December 6, 2022).

131 Bronwyn Hall et al (n 125).

132 Wesley M. Cohen and Stephen A. Merrill (ed.), *Patents in the Knowledge-Based Economy* (National Academies Press 2003) 91 (Cohen and Merrill).

133 WHO, WIPO and WTO, *Promoting Access to Medical Technologies and Innovation: Intersections Between Public Health, Intellectual Property and Trade* (World Health Organization, World Intellectual Property Organization and World Trade Organization, 2012) 173.

134 Dietmar Harhoff, 'Economic Cost-Benefit Analysis of a Unified and Integrated European Patent Litigation System' (2009) *Final Report to the European Commission* 49.

135 Cohen and Merrill (n 132).

One of the reasons for a comparatively higher rate of opposition in the EU might be the fact that the decision of the EPO in relation to a notice of opposition binds all EPC signatory countries.[136] The single centralized action saves time, cost and effort, and an enhanced scope of effect provides greater incentive to potential opponents as the rewards of a successful opposition are comparatively much higher. A single action at the EPO can potentially knock out a patent for all EU countries. Unlike the U.S. procedures, the EPO has not provided a second window to challenge a patent. After the expiration of the first window of 9 months, the relevant national authorities hear patent validity challenges. Challenging questionable patents at the EPO within the first 9 months is a more fruitful option for third parties in terms of the impact of successful oppositions.

Another reason for a higher rate of opposition might be the fact that patent opposition proceedings at the EPO do not generate any legal estoppel.[137] The opponent is allowed to initiate national invalidation proceedings. The petitioner may argue the same issues in national revocation proceedings and may even use the same facts, evidence, and arguments.[138] The lack of legal estoppel adds to the attractiveness of the opposition proceedings for potential challengers. The potential opponents are not faced with the risk of losing opportunities for further actions on the same issues if the opposition fails. Moreover, the EPO opposition proceedings provide a relatively less costly opportunity to challenge questionable patents.

Civil society organizations ("CSOs") and non-governmental organizations ("NGOs") have opposed patents at the EPO. For instance, in April 2013, the EPO's Opposition Division, in the 'Brüstle'

136 European Patent Convention 1973 (EU), art 2.
137 Ibid, art 138.
138 *Glaxo Group Ltd. v Genentech Inc. and Anor* (2008) EWCA (Civ.) 23.

case, revoked the stem cell patent (1040185 B1).[139] In 2015, Gilead's Sofosbuvir patent was successfully challenged by European CSOs.[140] The Myriad Genetics' BRCA1 and BRCA2 patents were challenged by CSOs in Europe.[141] Moreover, CSOs opposed certain contentious animal and plant patents.[142] For instance, in 2018, as a result of opposition by CSOs supported by 75,000 signatures, the EPO revoked Bayer's broccoli patent (1.597.965).[143] In 2019, Novartis abandoned one of its Kymriah patents when Médicins du Monde and Public Eye filed a patent opposition at the EPO.[144]

Despite its numerous merits and achievements, the application of the European patent opposition suggests that the mechanism is not perfect or exemplary. Alfred Spigarelli, Director Quality Support, EPO, estimated in 2012 that on average, the EPO takes 34 months to decide an opposition.[145] In some cases, the EPO opposition proceedings take up to 6 years.[146] Another 2 years are generally taken by the Technical Boards of Appeal to hear the case.[147] Nearly 3 years

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139 'EPO Revokes Patent in the Brüstle Case' European Patent Office (11 April 2013) <https://www.epo.org/news-issues/news/2013/20130411a.html.> accessed 6 December 2022.

140 Caitlin H. Douglass et al., 'Pathways to Ensure Universal and Affordable Access to Hepatitis C Treatment' (2018) 16 BMC Medicine 5.

141 Aurora Plomer, *Patents, Human Rights and Access to Science* (Edward Elgar 2015) 3.

142 Charles Lawson and Jay Sanderson (eds), *The Intellectual Property and Food Project: From Rewarding Innovation and Creation to Feeding the World* (Routledge 2016) 249.

143 'EPO Revokes Bayer Broccoli Patent' Kluwer Patent Blog (16 November 2018) <http://patentblog.kluweriplaw.com/2018/11/16/epo-revokes-bayer-broccoli-patent/≥ accessed 10 December 2022.

144 Oliver Classen, 'Novartis Cancer Treatment for CHF 370,000?! Public Eye Opposes Kymriah Patent' Public Eye (2019) < https://www.publiceye.ch/en/media-corner/press-releases/detail/novartis-cancer-treatment-for-chf-370000-public-eye-opposes-kymriah-patent≥ accessed 11 December 2022).

145 Alfred Spigarelli, 'The Opposition Procedure at the EPO' European Patent Office 10 (Spigarelli).

146 Kevin Greenleaf, Chris Benson and David Cheng, 'Beyond Our Borders: Comparing the Opposition Proceedings of Europe, China, and the United States' (2013) 5(6) Landslide 40.

147 'European Patent Opposition Proceedings' (Bardehle Pagenberg, 2022) 10 <https://www.bardehle.com/uploads/files/European_Patent_Opposition_en.pdf.> accessed 6 December 2022.

average time, possibly resulting from timeline flexibility in the EPO proceedings, is a cause of serious concern for both the patentee and petitioners. The thoroughness of the European opposition proceedings, which allow for amendments in the opposed patents to protect the interests of patent owners, contributes to delay in the proceedings.[148] As opposition proceedings in Europe take place after the grant of a patent, the delay in proceedings does not negatively impact patentees in terms of reducing the period of exclusivity. The delay in proceedings, however, impacts the public interest. As stated in the report of the European Commission Pharmaceutical Sector Inquiry,

> "*[t]he duration of the [opposition] procedure considerably limits the generic companies' ability to clarify the patent situation of potential generic products in a timely manner*."[149] Normally, generic manufacturers are "*afraid to enter at risk without a final determination that the patent is invalid or not infringed, just as people are afraid to build houses on land they don't own*."[150]

The EU's petitioner-friendly opposition proceedings are better as compared to the U.S. but still not exemplary. The EPO needs to fix the problem of delay in opposition proceedings. Even the slightest delay can have substantial social costs. This is particularly important for European patents as patenting decisions of the EPO impact more than 450 million people across 28 countries.[151]

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148 Colleen Chien et. Al (n 126).

149 European Commission, 'Pharmaceutical Sector Inquiry Report' (*European Commission*, 2008) 12 <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/communication_en.pdf.> accessed 6 December 2022 (Pharmaceutical Sector Inquiry Report).

150 Dan L. Burk and Mark A. Lemley, *The Patent Crisis and How the Courts Can Solve It* (UCP 2009) 32.

151 Fabian Gaessler et al., 'Patents and Cumulative Innovation–Evidence from Post-Grant Patent Oppositions' (2017) 1 A.O.M Journals 4.

More importantly, the EU provided limited opportunities for challenging patent applications pending before the EPO. Instead of providing full-fledged pre-grant opposition procedures, the EU provided the 'Third Party Observation Procedure' to challenge pending patent applications only in relation to substantive requirements. This mechanism can be used by 'any person' without paying any fee.[152] These third-party observations may be filed anonymously.[153] By allowing 'any person' to make straw-man observations, the EU keeps this mechanism open for anyone, even for those who do not want to disclose their identity.

The 'Third Party Observation Procedure', despite allowing straw-man observations from any person, provides a limited opportunity to challenge questionable patent applications. As the third party making such an observation is not a party to the proceedings before the EPO, they will not be directly informed or involved in the further proceedings. The European CSOs could have more effectively challenged pending patent applications to ward off questionable patents if they were provided with full-fledged pre-grant opposition procedures. The Indian opposition model, which provides third parties with administrative invalidation procedures both before and after the grant of a patent, is a comparatively better model.

In terms of substantive requirements for patentability, there are four basic requirements under the EPC: (1) an invention in any field of technology; (2) industrial application; (3) novelty; and (4) inventive step. Substantive requirements are provided in Articles 52 to 57 of the EPC. Unlike India, the EU patent laws are lenient and do not provide

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152 European Patent Convention 1973 (EU), arts 114 and 115.

153 European Patent Office, 'Notice EPO OJ2011, 420 from the European Patent Office dated 10 May 2011 concerning the filing of third party observations under Article 115 EPC by means of an online form' (XEPC.eu, 2011) <https://xepc.eu/node/oj2011-420> accessed 10 July 2023.

anti-evergreening provisions such as Section 3(d). As compared to India, the EU regime is lenient towards patents directed to new polymorphs of known compounds. Patents protecting polymorphs are vital in blocking generic competition and life-cycle management of drug patents.[154]

In 2011, the Board of Appeal of the European Patent Office held in *Warner-Lambert Company LLC v Teva Pharmaceutical Industries* that "*in the absence of any unexpected property, the mere provision of a crystalline form of a known pharmaceutically active compound cannot be regarded as involving an inventive step*."[155] The Board further noted that "*the arbitrary selection of a specific polymorph from a group of equally suitable candidates cannot be viewed as involving an inventive step*."[156] The Board established that the mere provision of a polymorph does not meet patentability criteria in the EU. However, in 2013, the Board held that an inventive step threshold is met if an unanticipated advantage is observed for even a single polymorph when compared with the amorphous form.[157] New polymorphs of a known compound can be patented in the EU if an unexpected advantage is observed.

PATENT OPPOSITION MODEL OF THE UNITED STATES

Expensive and lengthy drug patent infringement and patent validity litigation has been a serious issue in the U.S. since the adoption of the modern system of drug regulation under the 1962 Kefauver-Harris

154 Guy Brain et al., 'Patenting Polymorphs at the European Patent Office' (*J A Kemp*, 2021) <https://jakemp.com/en/briefings/patenting-polymorphs-at-the-european-patent-office/> accessed 10 July 10 2023 (Guy Brain et al).

155 *Warner-Lambert Company LLC v Teva Pharmaceutical Industries Ltd.* T 0777/08 – 3.3.01, (2011) 2.

156 ibid.

157 *Teva Pharmaceutical Industries Ltd. v Gallagher, Kirk James* T 1422/12 – 3.3.10 (2013) 10; Guy Brain et al (n 154).

Drug Amendments.[158] After several unsuccessful legislative efforts,[159] the Leahy-Smith America Invents Act, 2011 ("Leahy-Smith Act") was introduced as an important statutory reform of the U.S. patent laws.[160] Aimed at reducing the amount of patent validity litigation in the U.S., the Leahy-Smith Act replaced *inter partes* re-examination with a procedure that looked more like opposition proceedings in terms of active participation of third-party challengers and producing evidence.[161] The Act provided two new procedures to challenge patent validity after its grant: post-grant review ("PGR") and *inter partes* review ("IPR"). These proceedings were provided as faster and less expensive administrative alternatives to court litigation.[162] One of the key objectives of these substantial changes in the law was to improve patent quality in America.[163]

Any third party, excluding an owner of the patent, may use either of the two procedures to raise questions about patent validity.[164] Grounds for challenging patents in PGR proceedings[165] are slightly broader as compared to *inter partes* review.[166] Available grounds for challenging patents through PGR proceedings include novelty, non-obviousness, subject-matter eligibility, and written description.[167] The Patent Trial

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158 Henry Grabowski et al., 'Updated Trends in U.S. Brand-name and Generic Drug Competition' (2016) 19(9) Journal of Medical Economics 836-844.

159 An *ex parte* re-examination procedure created under the 1980 Bayh-Dole Act failed to provide an attractive mechanism for potential challengers as the participation of third-party challengers was extremely limited. An optional *inter partes* re-examination procedure created in 1999 also failed because it was too restrictive and too risky to achieve the desired objective of reducing patent litigation.

160 Leahy-Smith America Invents Act of 2011 (U.S.).

161 *Ex parte* re-examination proceedings still remain available. The Leahy-Smith America Invents Act did not eliminate these proceedings. See *35 U.S.C.* (U.S.), s 302.

162 House Judiciary Committee, House of Representatives, 'Report on America Invents Act' (2012) 78 <https://www.congress.gov/congressional-report/112th-congress/house-report/98/1> accessed 10 July 2023 (Report on America Invents Act).

163 Ibid, 39 – 40.

164 35 U.S.C. (U.S.), ss 302 and 321.

165 Ibid, ss 101, 102, 103, and 112.

166 Ibid, ss 321(b) and 324(b).

167 Ibid, s 321(b).

and Appeal Board ("PTAB") of the U.S. Patent and Trademark Office ("PTO")[168] conducts quasi-judicial PGR proceedings.[169] The PTAB comprises Administrative Patent Judges and does not involve the participation of patent examiners.[170] Unlike that of the European opposition, the challengers are required to disclose the real party behind the petition.[171] This requirement makes the procedure less attractive for petitioners because the petitioners are vulnerable to a counter-attack in the form of patent infringement litigation.

Within 9 months of the patent grant, third-party challengers may file petitions for PGR.[172] No extension to this 9-month period is admissible.[173] The fee for PGR of up to twenty claims is USD 20,000.[174] An additional fee needs to be paid for each additional claim beyond the sum.[175] There is no discounted fee for small entities, community organizations or individuals. This high fee makes the procedure less attractive for resource-constrained civil society organizations and public-spirited individual opponents who challenge patents without financial incentives.

The U.S. outperforms the EPO on timing. The PTAB is required to complete the review proceedings within one year of the institution.[176] An extension of up to 6 months is possible upon a showing of good cause.[177] PGR proceedings are different from European opposition

168 Ibid, s 326(c).
169 Ibid, s 6(a).
170 Ibid, s 6(a).
171 Ibid, s 322(b).
172 Ibid, ss 6(f) and 311(c).
173 Ibid, s 321.
174 Rules of Practice for Trials Before the Patent Trial and Appeal Board and Judicial Review of Patent Trial and Appeal Board Decisions' (Federal Register, 2012) <https://www.federalregister.gov/documents/2012/08/14/2012-17900/rules-of-practice-for-trials-before-the-patent-trial-and-appeal-board-and-judicial-review-of-patent> accessed 10 July 2023 (Rules of Practice).
175 Ibid.
176 Ibid, ss 316(a) and 326(a).
177 Ibid.

proceedings, where the timeline is much more flexible in the absence of a statutory time limit. PTAB's decision in the PGR proceedings can be appealed by either party to the Court of Appeals for the Federal Circuit.[178]

Unlike the time-tested European opposition procedures, the PGR is a recent development. The PGR proceedings are not perfect or exemplary. As compared to the petitioner-friendly European opposition procedure, the PGR generates troublesome legal estoppel. The challenger is not allowed to bring a future action on any issues that were actually raised in the review proceedings or could potentially be raised during such proceedings.[179] Moreover, facts determined during these proceedings cannot be challenged in a future action.[180] These harsh estoppel provisions make the procedure less attractive to potential challengers as they have to choose this procedure to the exclusion of other invalidity mechanisms.

To renounce the ability to a later challenge by surrendering the right to sue in court is always a difficult decision for any challenger. As noted by David Kappos, then-Director of the USPTO, the estoppel statutes relating to PGR "*mean that your patent is largely unchallengeable by the same party*."[181] The U.S. needs to reconsider the harsh estoppel provisions. The estoppel provisions were aimed at reducing redundant filings and abusive use of PGR. The European opposition lacks this safeguard, and there is no evidence to suggest that a lack of estoppel provisions resulted in abuse of opposition proceedings in Europe. Moreover, the

178 Ibid, s 141(c).
179 Ibid, s 315(c).
180 Ibid.
181 Karen E. Sandrik, 'The Post-Grant Life: Coordinating & Strategizing Challenges of Issued Patents in Multiple Continents' (2018) 17(2) Chi.-Kent J. Intell. Prop. 454.

prescribed fee[182] to invoke PGR proceedings is considerably higher as compared to other jurisdictions.

The PGR has not been a preferred procedure to invalidate questionable patents, and it is unlikely to be invoked at a significant rate in future. Still, the most common form of challenging patent validity in the U.S. is court litigation. Court litigation in the U.S. has serious disincentives for potential challengers, which include "*the lack of financial reward for invalidating patents and the risk of triggering countersuits for infringement*."[183] Moreover, "*patent litigation is notoriously expensive, prolonged, and unpredictable*."[184] Patent litigation is currently the primary gatekeeper of patent quality in the U.S., but it does not ideally address the problem of low-quality patents. Patent litigation is unattractive for resource-constrained CSOs to challenge the validity of low-quality patents.

Though the U.S. Congress recognized that "*questionable patents are easily obtained*" and are "*too difficult to challenge*,"[185] currently, the U.S. does not provide third parties with a pre-grant opposition procedure to challenge patent applications pending before the USPTO. In the absence of pre-grant opposition procedures, a large number of patents with low or minimal inventive step are granted in the U.S.[186] As compared to revoking questionable patents after grant, preventing the grant of such patents in the first place is a superior policy option to avoid negative social and economic consequences associated with unwarranted exclusive rights.

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182 Rules of Practice (n 174).

183 Megan M. La Belle, 'Patent Law as Public Law' (2012) 20(1) Geo. Mason L. Rev. 44.

184 Ibid.

185 Report on America Invents Act (n 162).

186 World Health Organization, *Intellectual property and access to medicines: papers and perspective* (World Health Organization Regional Office for South-East Asia 2010) 45.

The U.S. should consider providing simpler and less risky pre-grant opposition procedures as it is the home base for a number of active and capable non-profit organizations willing to bring patent validity challenges with an aim to protect the public interest. For instance, non-profit organizations Patients Not Patents ("PNP") and the I-MAK have been active challengers of patents related to drugs and medical products.[187] Another non-profit organization Electronic Frontier Foundation ("EFF") targets questionable internet technology and software patents.[188] These and many other organizations in the U.S., if provided with a more attractive and less risky invalidity mechanism, can contribute significantly towards warding off unwarranted patents in the U.S.

In terms of substantive requirements for patentability, there are five requirements under the U.S. Patent Act: (1) patentable subject matter; (2) utility; (3) novelty; (4) non-obviousness; and (5) enablement.[189]

Unlike India, the U.S. Patent Act does not provide any specific safeguards against the ever-greening of pharmaceutical patents. Patents on polymorphs are allowed in the U.S. Polymorphic patenting allows patentee corporations to block generic competition by extending their market exclusivity. For instance, Pfizer Inc. extended market exclusivity for its blockbuster drug Lipitor through the strategy of polymorphic patenting.[190] Similarly, Vertex Pharmaceuticals extended the market lifetime for Lumacaftor through a polymorph patent.[191] On the contrary, India's Section 3(d) expressly excluded

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187 Christopher J. Worrel, 'Improving the Patent System: Community Sourcing and Pre-grant Opposition' (2011) 42 U. Tol. L. Rev. 844.

188 'Patent Busting Project' (Electronic Frontier Foundation, 2004) <https://www.eff.org/issues/patent-busting-project> accessed 12 December 2022.

189 35 U.S.C. (U.S.), ss 101 - 103 and 112.

190 Runjhun Tandon et al., 'Patenting of polymorphs' (2018) 7(2) Pharmaceutical Patent Analyst 60.

191 Ibid.

polymorphs from patent protection unless they exhibit enhanced efficacy. India's approach of confining patent protection to only true polymorphs with enhanced efficacy is a better policy to check the ever-greening of drug patents.

The U.S. patent regime, with expansive approach on patentability and no procedures to challenge pending patent applications, favours large pharmaceutical corporations with financial might and experienced patent lawyers to exploit the relaxed patentability standards. Patentee corporations benefit from slower and more expensive judicial procedures to challenge questionable patents because, during pendency of proceedings, the patent remains in force to block generic competition.

RECENT DEVELOPMENTS IN INDIA

In August 2022, the Economic Advisory Council to the Prime Minister of India ("EAC-PM") proposed reforms to patent law in India aimed at fast-tracking the process of granting patents. The key proposal in relation to pre-grant opposition is to put a timeline of 6 months from the date of issuance of the First Examination Report ("FER") in order to streamline the process.[192] Currently, no specific timeline is provided to file pre-grant opposition. Without paying any fee,[193] a representation for opposition can be filed at any time after an application for a patent has been published,[194] but a patent has not been granted.[195] The proposal to reduce the pre-grant opposition time to 6 months does not consider the public interest in scrutinising the grant of patents. Grant

192 Sanjeev Sanyal and Aakanksha Arora, 'Why India Needs to Urgently Invest In Its Patent Ecosystem?' (2022) Economic Advisory Council to the Prime Minister 14.

193 No fee has been stipulated for instituting pre-grant opposition proceedings under the Patents Act and the Patents Rules.

194 The Patents Act 1970 (India), s 11A.

195 Ibid, s 25(1). Prior to 2005 amendment, pre-grant opposition was allowed within four months from publication of the acceptance of a complete specification.

of undeserved patents is a real-world issue.[196] Any restrictions on rigorous scrutiny of patents will lead to the further proliferation of undeserved patents resulting in societal losses.

The approaches taken by EAC-PM to reach its conclusions are murky because neither all details of its working nor all data used by it is publicly available. The proposals made by EAC-PM are overly protective of patentee corporations' private interests at the expense of overlooking the larger public interest. Brand-name pharmaceutical corporations will be notable beneficiaries of the change if the EAC-PM proposal to provide a 6-month timeline for pre-grant opposition is accepted. Opposing pharmaceutical patents is particularly time-consuming. As noted by Menghaney and Joseph,

> "*The information in patent applications does not permit the public to rapidly identify the claimed medical product. The identification and further analysis are time-consuming as several applications are pending on the same medicine, vaccine or technology.*"[197]

In January 2023, the Centre for Intellectual Property, Innovation and Technology at Hidayatullah National Law University ("HNLU") published a report that made recommendations to streamline the process of pre-grant opposition. A key recommendation of the report is to provide a limited timeframe of 6-12 months from the date of issuance of FER to oppose pending patent applications.[198]

Another recommendation of the HNLU report is to allow only interested persons to file pre-grant opposition.[199] Section 25(1) allows

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196 Dean Baker et al., 'Innovation, intellectual property, and development: A better set of approaches for the 21st century' (2017) Shuttleworth Foundation 63.

197 Leena Menghaney and Roshan Joseph, 'India's patent law safeguards under fire' (*The Hindu*, 3 July 2021) <https://www.thehindu.com/sci-tech/science/indias-patent-law-safeguards-under-fire/article65592176.ece> accessed 11 July 2023.

198 Vivekanandan et al., *A study of patent opposition system* (Centre for Intellectual Property, Innovation and Technology 2023) 28.

199 Ibid.

'any person' to file a pre-grant opposition.[200] The phrase 'any person' is not defined under the Act. The judicial interpretation of 'any person' in some recent decisions is narrowing down the scope of pre-grant oppositions. In November 2020, the Bombay High Court narrowly interpreted the clause to mean a person having certain qualifications. It noted:

> "*We have not been informed about the educational background of the Petitioner. The Petitioner has made no statements on oath. It is argued that the Petitioner has employed a team of researchers. Particulars of these researchers and who pays the team are not given.*"[201]

Calling into question the credentials of a patent opponent is against the very purpose of pre-grant opposition. One of the key purposes of this mechanism is to bring forward any additional information that can be helpful in making a novelty or obviousness determination. As noted by Beth Noveck,

> "*often 'ordinary' people possess extraordinary knowledge that they are willing to share when it is easy to do so … Patent examination is well-suited to pre-grant community participation because it depends on scientific expertise to make the correct determination.*"[202]

Keeping in view this rationale of pre-grant opposition, it is not logical to consider the qualifications of a person bringing forward any additional prior art information. This is the reason why the EU allows third parties to bring in any valuable information, even anonymously. Even if an individual does not have a personal interest in opposing a patent, the society at large has a collective interest if an undeserving

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200 The Patents Act 1970 (India), s 25(1).

201 *Dhaval Diyora v Union of India and Ors,* No.3718 of 2020 (India) 14.

202 Beth Simone Noveck, 'Peer to Patent: Collective Intelligence, Open Review, and Patent Reform' (2006) 20(1) Harv. J.L. & Tech. 144.

patent is successfully opposed. It is unfortunate if Indian courts ignore this public interest dimension of pre-grant opposition and narrow down its scope to only persons with certain qualifications. This is particularly concerning in relation to pharmaceutical patents because of the far-reaching negative impacts of undeserved patents on public health.

The effectiveness of this round of opposition will be curtailed if this procedure is confined to only 'persons interested'. The narrow interpretation of 'any person' is not in line with the legislative intent of making pre-grant opposition as an expansive safeguard against undeserved patents. It is important to note that prior to the 2005 amendment, pre-grant oppositions could be filed only by an 'interested person'. In the amended Act, the Indian Parliament purposefully expanded the scope of pre-grant opposition by allowing 'any person' to oppose pending patent applications. The possibility of frivolous oppositions is too small to eclipse the overall benefit of allowing 'any person' to oppose patents. Only a very small percentage (less than 1%) of patent applications are opposed.[203] The number of frivolous oppositions within this small tally of overall oppositions can be negligible.

The research methods used for preparing the HNLU report are not explained. The report relies on data collected by a leading law firm in India, but there is a lack of public information about the empirical data. As noted by the Executive Director of the law firm, "*the restructuring recommended by this report will improve the patent landscape in India and make it more inventor and/or investor friendly, thereby helping in ease of doing business in India*."[204]

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[203] See Table 2 above.

[204] 'Report on Patent Opposition System provides recommendations on enabling ease of doing business in India' (*Press Trust of India*, 1 September 2023) <https://www.ptinews.com/pti/report-on-patent-opposition-system-provides-

In January 2023, soon after the release of the HNLU report, the Delhi High Court noted in *Natco v Assistant Controller of Patents*, "*The right to oppose the grant of a patent is just as sacrosanct as the right to seek a grant of a patent.*"[205] It acknowledged the public interest dimension of patent opposition proceedings:

> "*The public interest involved in ensuring that patentable inventions are patented, cannot be accorded a greater degree of sanctity than the public interest involved in ensuring that the non-patentable inventions are not allowed to be patented.*"[206]

Pre-grant oppositions have an important role in making sure that undeserved patents are not easily granted. Because of India's global role as a 'pharmacy of the developing world', pre-grant oppositions in India have a significant impact on access to affordable medicines not only for Indian citizens but also for marginalised populations in many other countries.

CONCLUSION

India made efficient use of both substantive and procedural flexibilities to provide an exemplary patent opposition model. India's approach to raising substantive threshold standards for patent eligibility is in line with its national interest. The higher threshold standards mean less burden on India's health system because of the availability of generic alternatives of pharmaceutical drugs. India's legislative approach is also aligned with its constitutional obligations to provide good healthcare to its citizens as a welfare country.

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recommendations-on-enabling-ease-of-doing-business-in-india/59349.html> accessed 10 July 2023.

205 *Natco Pharma Limited v Assistant Controller of Patents & Designs A*NR., 2023/DHC/000268, (India) 28.

206 Ibid.

India's approach to reinforcing its heightened patentability requirements with procedural mechanisms of patent opposition is well-thought-out, as it provides third parties with an opportunity to oppose questionable patents by leveraging higher substantive requirements for patentability in India. The legislative history of India's patent laws supports the assertion that the Indian patent opposition model is informed by public health objectives and national interest considerations. This model was designed to promote price-reducing generic competition keeping in view India's constitutional obligation, under Article 47 of the Constitution of India, of providing good healthcare to citizens.

Compared to India, the U.S. approach is to limit patent opposition. The U.S. procedure is not only costly, but it also generates troublesome legal estoppels. The U.S. does not provide third parties with a pre-grant opposition procedure to question pending patent applications. The EU also provides only post-grant opposition proceedings, but the EU's petitioner-friendly proceedings are better as compared to the U.S. model. The EU, however, does not provide a model strategy. EU proceedings lack speed efficiency. On average, the EPO takes around 3 years to decide on an opposition.[207] This inordinate delay is a cause of serious concern as it negatively impacts the public interest.[208]

India made better policy choices in terms of designing its patent opposition model. India's approach of providing third parties with procedures to challenge the validity of patents both before and after their grant and linking these procedures with substantive threshold standards is well-thought-out. This approach is exemplary for the WTO member states in terms of keeping a balance between their obligations under TRIPS and domestic needs.

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[207] Spigarelli (n 145).
[208] Pharmaceutical Sector Inquiry Report (n 149).

Recent developments in India indicate that India's TRIPS-compliant pre-grant opposition procedures are under pressure. India will need to sustain this pressure and resist any changes that undermine the public interest. India's patent regime must remain sensitive to public health needs if India wants to remain a hub of generic medicines not only for its citizens but also for poorer patients in many other countries.