Historical Evolution of India's Patent Regime and Its Impact on Innovation in the Indian Pharmaceutical Industry

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Abstract

Article 21 of the Indian Constitution guarantees every person and citizen of India *the right to life and the right to personal liberty*. Further, Article 47 of the Indian Constitution declares that *it is the duty and obligation of the Indian state to improve public health*. In addition, Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) adopted by India asserts that *nations have an obligation to facilitate the right to health*. Thus, the Indian government operates under the premise that *medicines critical to the important healthcare needs of India's population must be both available and affordable. Indeed, this paradigm is the foundational basis for India's vision for the right to health under the Article 21 of the Indian Constitution*. Thus, the Indian policy makers strive to meet India's constitutional obligations for the right to health while promoting its *innovation ecosystem* and safeguarding the legitimate business interests of MNCs. Indeed, this powerful undercurrent has been shaping the evolution of the Indian patent regime since India's independence in 1947, through the 1970s, the economic liberalization era initiated in the 1990s, through the membership of WTO and TRIPs Agreement in 1995, post-TRIPS in 2005 and all the way up to today. In this context, this chapter analyzes how the Indian patent regime has been leveraging the flexibilities afforded under the TRIPS Agreement for the prevention of *evergreening*, award of *compulsory licenses*, retention of *pre-grant opposition*, and introduction of *post-grant opposition* and discusses how these dynamic changes are having a global impact.

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Innovation · Innovation ecosystem · Competitive advantage · Sustainable economic growth · Indian intellectual property rights regime · Indian generic pharmaceutical industry · Available and affordable medicines · TRIPS flexibilities · Evergreening · Compulsory license · Pre-grant opposition · Post-grant opposition

1 Introduction

It has been recognized by industry, academia, and policy makers alike that innovation is pivotal to *value creation*, *competitive advantage*, and *sustainable economic growth*. As knowledge economy became the basis for globalization, innovation opportunities have been incessantly emerging around the world for value-added products, processes, and services to meet the ever-growing needs, wants, challenges, and opportunities of the world. As a result, today we find many individuals, companies, communities, and nations working relentlessly on innovation. Thus, policy makers, both nationally and internationally, have recognized that innovation either flourishes or suffers depending upon the *innovation ecosystem*. However, the *innovation ecosystem* of a nation depends upon three primary factors, namely, technology environment, business environment, and policy environment (Fig. 1).[1]

Consequently, academia, industries, and governments around the world have been focused on strengthening and promoting the *innovation ecosystem* in order to meet the national priorities, as well as achieve *competitive advantage*, *sustainable economic growth*, and *creation of employment* in the global economy.

In this regard, it is important to note that the vision and strategies of a country's *patent regime* play a crucial role in (a) advancing the goals of its *innovation ecosystem* (indigenously or as part of international agreements), (b) protecting its social and economic interests, and (c) safeguarding the legitimate business interests of competition.

Indeed, it is in this light that the historical evolution of the *Indian patent regime* and its impact on innovation in the Indian pharmaceutical industry must be analyzed and understood.

[1] There are other secondary factors as well. *Technology environment* depends upon the quality of education, innovation support, and the training the citizens receive; *business environment* depends upon the investment and policy support for innovative growth of an existing business or new venture creation; *policy environment* depends upon the socioeconomic goals, science and technology vision, and commitment to innovation.

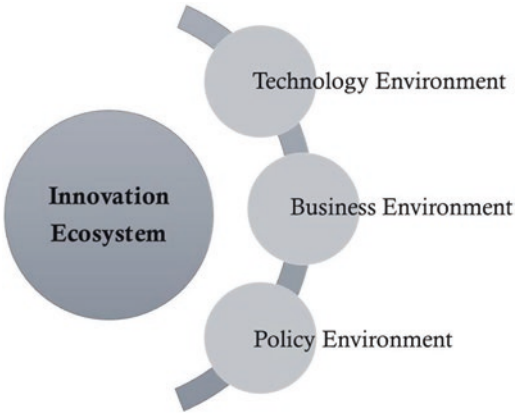

Fig. 1 Innovation ecosystem and the factors governing it

2 Overview of the Indian Pharmaceutical Industry

2.1 Business Achievements

India is a unique global player in the pharmaceuticals business world. To start with, India has a large pool of well-trained scientists and engineers who have the potential to innovate and steer the industry to meet India's vision, national needs, and future goals.

The Indian pharmaceutical industry, valued at US $33 billion in 2017, is currently the *largest global supplier of cost-effective generic drugs*. Thus, the drugs made in India are exported to more than 200 countries around the world, with the United States of America (USA) being India's biggest market. According to *India Brand Equity Foundation* (IBEF), in 2016–2017, around 40.6% of India's pharmaceutical exports (US$ 16.8 billion) were to the American continent, followed by a 19.7% to Europe, 19.1% to Africa, and 18.8% to the Asian continent.[2]

The Indian pharmaceutical companies meet over 50% of the global demand for various vaccines, 40% of the generic demand in the USA, and 25% of demand of all the medicines in the UK. In addition, India supplies over 80% of the antiretroviral drugs needed globally for AIDS (*acquired immunodeficiency syndrome*). In 2017, the Indian pharmaceutical companies received 304 Abbreviated New Drug Application (ANDA) approvals from the US Food and Drug Administration (USFDA).

India is also emerging as a key player in the biotechnology industry. India's biotechnology industry includes biopharmaceuticals, bio-services, bio-agriculture, bio-industry, and bioinformatics. This sub-sector of the Indian pharma industry is expected to grow at an average annual growth rate of around 30% and reach US$ 100 billion by 2025. In fact, the biopharma industry – comprising of vaccines, therapeutics, and diagnostics – contributes US$ 1.89 billion, which is a significant portion of the total industry revenues.

[2] https://www.ibef.org/industry/pharmaceutical-india.aspx

The Indian pharmaceutical market grew at a CAGR[3] of 5.6%, during FY[4] 2011–2016, from US$ 20.95 billion in FY2011 to US$ 27.57 billion in FY2016. In FY2017 alone, the industry's revenues grew by 7.4% and stood at US$ 33 billion. In March 2018, the market grew at 9.5% year-on-year with sales of US$ 1.56 billion. According to the industry analysts, India's pharmaceutical sector is predicted to grow at a CAGR of 22.4% during FYs 2015–2020, to reach US$ 55 billion, as branded drugs worth US$ 55 billion will become off-patent during this period. By FY2020, India is expected to be among the top three pharmaceutical markets in the world by organic growth and sixth largest market in absolute size.

2.2 Investments, Mergers, and Acquisitions

The growing middle-class population in India, increasing demand for better access to healthcare, improving medical facilities, and better penetration of health insurance in the country point to lucrative investment opportunities in the Indian pharmaceutical sector. Not surprisingly, the Government of India amended its *Foreign Direct Investment* (FDI) *policy* in the pharmaceutical sector to automatically allow up to 100% FDI for the manufacture of medical devices subject to, of course, some guidelines.

Thus, according to the data released by the Department of Industrial Policy and Promotion (DIPP), the Indian pharmaceutical sector attracted US$ 15.59 billion worth of FDI in 17 years, between 2000 and 2017. In Q2 2018, the Indian pharmaceutical sector posted private equity and venture capital investments of US$ 396 million. Also, in 2017, India witnessed 46 mergers and acquisitions (M&As) – worth US$ 1.47 billion – in the pharmaceutical sector.[5]

3 Goals and Priorities of the Indian Patent Regime

The Indian pharmaceutical industry is well aware that innovation is critical for *wealth creation, competitive advantage,* and *sustainable growth*. Innovation in the pharmaceutical industry is often a high-risk, high payoff gamble. While companies may deliver *high returns on investment* (ROI) when innovations are successful, innovation failures can threaten company's survival itself.[2] Consequently, Indian pharmaceutical companies rely on successful innovations[6] to make *high profits*, deliver *consistent ROI to shareholders*, and achieve *sustainable growth*. On the

[3] CAGR, compound annual growth rate.

[4] FY, fiscal year.

[5] https://www.rdmag.com/article/2016/02/intellectual-property-and-indian-pharmaceutical-industry

[6] Here the word "innovations" encompass not only *new drug discoveries* but also *reverse engineering and remaking of old drugs* for which patent rights have expired (known as *generic drugs*) or *frugal innovation of important drugs for which compulsory licenses have been given – in a highly competitive and cost-effective manner*.

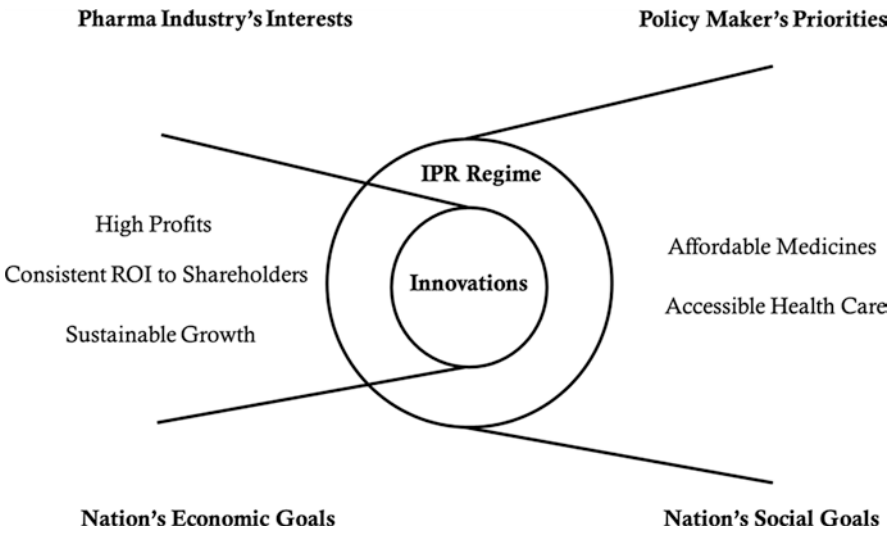

Fig. 2 Dilemma of the Indian policy makers' goals and priorities

other hand, the policy makers of the Indian government *depend on the patent regime to ensure that pharmaceutical innovations deliver affordable medicines and accessible health care to all citizens*. Therefore, successful pharma companies are those that can innovate to solve the healthcare needs, wants, and challenges of millions of people in India while also posting robust revenues, profits, market share, and growth. In other words, nations such as India *aim to balance social goals* (which aim to ensure affordable medicines and accessible healthcare to all citizens) *against the economic goals* (which are aligned with the interests of pharmaceutical companies). Figure 2 summarizes this dilemma of Indian policy makers.

Indeed, it is this powerful undercurrent that has been shaping the policies of the *Indian patent regime* since India's independence in 1947, through the 1970s, the economic liberalization era that started in the 1990s, through the membership of WTO and TRIPS Agreement in 1995, post-TRIPS in 2005, and all the way up to today. Therefore, the historical evolution of the *Indian patent regime*, imperfect as it may seem, makes sense only when one understands how India *tries to continually balance its social goals and priorities against the economic goals*.

4 Brief Overview of the Indian Patent Regime's History

It is important to note that a seminal paper in this area has been published by Janice Mueller.[7] Thus, the Indian patent regime reflects India's journey in three different periods: *colonization*, *post-independence,* and *globalization*. During the

[7] Mueller, J. M. "The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of the Indian Pharmaceutical Innovation," University of Pittsburgh Law Review, 2006, 68, 491–641.

"colonization" phase, the Indian Patents and Designs Act of 1911 – drafted by the British – enacted India's first patent statutes. India gained its independence in 1947. However, during the "post-independence" phase, the British-imposed, foreigner-favoring patent laws stunted the development of the Indian pharmaceutical industry and forced independent India to import even basic medicines at unaffordable prices. Consequently, in 1949, the Indian government constituted a high-powered committee headed by an eminent jurist of the Lahore High Court, Bakshi Tek Chand, and sought an intensive review of the existing patent laws. The most significant finding of the Chand Committee was that the prevailing Indian patent laws offered asymmetrically strong protections to foreign multinational corporations (MNCs) while severely inhibiting the development of the domestic manufacturing sector. Further, according to the Controller General of Patents, Designs, and Trademarks[8]:

> The committee also observed that the Patents Act should contain clear indication *to ensure that food and medicine and surgical and curative devices are made available to the public at the cheapest price commensurate with giving reasonable compensation to the patentee*.

In 1957, the Government of India appointed another committee led by the distinguished retired Justice of the Supreme Court of India, N. Justice Rajagopala Ayyangar, to examine the question of revising the Patents Act and advising government. This committee's recommendations acted as a catalyst for changing the Indian patent law, which eventually led to India Patents Act of 1970. The India Patents Act of 1970 incorporated major provisions to reduce the social costs of the foreigner-owned patents. Thus, the Patents Act of 1970 (a) *prohibited patents on products* useful as medicines and food, (b) *shortened the term* of *chemical process patents*, and (c) significantly *expanded the availability of compulsory licensing*. This led to the birth and growth of the powerful Indian pharmaceutical generic drugs industry. The third "globalization" phase approximately spans the years 1986 up to the present. According to Mueller, during the "globalization" phase:

> India's participation in the debates over the inclusion of intellectual property within the GATT framework and its eventual entry into the World Trade Organization (WTO), along with its accession to the Paris Convention for the Protection of Industrial Property and the Patent Cooperation Treaty, *have compelled significant strengthening of the nation's patent laws*. The implementation of those changes is ongoing, and their anticipated impact remains to be fully seen. Today *India stands as a rising global power with a patent system still very much in flux*.

5 The Historical Evolution of India's Patent Regime and Its Impact

Now we can look at some of the important details in the evolution of India's patent regime and its impact on innovation in the pharmaceutical industry.[9]

[8] http://www.ipindia.nic.in/history-of-indian-patent-system.htm

[9] (a) https://www.rdmag.com/article/2016/02/intellectual-property-and-indian-pharmaceutical-industry; (b) http://icrier.org/pdf/India's_IPR_Regime.pdf; (c) See Reference 7 as well.

5.1 1947–1970

India won its independence in 1947. In its Constitution, India declared itself as *sovereign socialist secular democratic* republic. Thus, from the beginning, Indian policy makers believed in the principle of *distributive justice* and *government's active role in curbing socioeconomic inequalities*.

At the outset, the Indian government had to meet the needs of nearly 400 million people and confront simultaneous challenges such as food and water shortages, inadequate housing, illiteracy, unemployment, infant mortality, epidemics, inaccessible healthcare, and unaffordable medicines. Faced with the staggering healthcare needs and under the burden of British imposed, foreigner-favoring patent laws, India had no choice but to rely on importing even the most basic medicines such as insulin and penicillin manufactured by other nations, at some of the highest prices in the world.

The *Bakshi Tek Chand Committee Report* noted that the existing Indian patent law afforded "inequitably strong IP protection" to MNCs a situation that was blocking the Indian manufacturing industry in its infancy itself.

As reported in the Shodhganga – the digital repository of Indian Electronic Theses and Dissertations – setup by the INFLIBNET Centre[10]:

> The Indian patent system has failed in its main purpose, namely to stimulate invention among Indians and to encourage the development and exploitation of new inventions for industrial purposes in the country so as to secure benefits thereof to the largest sections of the people.[11]

Strong evidence for this had come just a few years afterward, when Hoechst pharmaceutical company won an injunction in Bombay High Court against Unichem Laboratories of India over infringement of its patent for the manufacture of a highly needed antidiabetic drug.[12]

Thus, the *Bakshi Tek Chand Committee Report* recommended[13]:

> The main provisions suggested by the committee among others include *compulsory licensing*, *commercial working of patented inventions in India* barring importations, *setting up of appellate body* in the form of an ad-hoc Special Tribunal nominated by the Central Government consisting of a sitting or retired judge of a High Court (as the President), and *ensuring that food and medicines are available at cheapest rates to the public* commensurate with giving reasonable compensation to the patentee etc.

This is the first instance where the Indian policy makers unequivocally articulated the need to balance India's social goals against its economic goals.

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[10] http://shodhganga.inflibnet.ac.in/bitstream/10603/128146/14/07_chapter%202.pdf

[11] Venkataramiah, E.S. *Supra Note*, **2**, pp. 23.

[12] https://indiankanoon.org/doc/865758/

[13] Draft Manual 2008. *Supra Note*, **1**, pp. 8 and 9.

In 1957, yet another committee was constituted under Rajagopala Ayyangar, for the purpose of building on the recommendations of *Bakshi Tek Chand Committee Report* and sculpting policies that will ensure India's national goals and interests and kick-start the Indian industry. Thus, the new committee once again carefully examined the patent laws of India, in light of the successful public welfare models of several other nations.

Accordingly, the *1959 Ayyangar Committee Report*[14a] noted the following:

> It would be convenient to consider the two matters dealt with by this provision separately –
>
> (1) The precise degree and extent of *patentability to be permitted in regard to inventions of chemical products in general*; and
> (2) the law determining the *patentability of inventions relating to food and medicine*.

In continuation, the *Ayyangar Committee Report*[14a] recommended:

> As regards inventions relating to chemical products, or products produced by chemical processes, I am clearly of the view that the interests of the country would be best served *by confining patentability to the processes* by which the products are obtained and *to deny patents to the products either per se or in the qualified manner suggested in the Bill*. The reasons for this recommendation are based on (1) the history of the law relating to patents regarding chemical inventions in Europe during the past nearly 100 years and the lessons to be derived therefrom; (2) the experience of other countries somewhat similarly situated like India; and (3) *the disadvantages to an underdeveloped country of permitting product claims for such inventions*.

Also notable are the arguments advanced in the *Ayyangar Committee Report*[14b] on patent grant vis-à-vis *economic benefits* and *social costs*:

> Where *the patentee has no intention of working the invention in this country* either because he considers that this is *not profitable* or because he *prefers to expand the production in his home country* so as to achieve there greater efficiency and more production or is otherwise not interested in working the invention in India, *the grant of the Indian patent might tend to improve the economy of the patentee's home country but offers little advantage to us*. Unless therefore the law provides for *measures to be taken to compel the patentees to work the invention within the country*, and these measures are effective to achieve their purpose, *the social cost involved in the grant of the patent is not offset by any benefit to the community* [*by way of an increase of technical skill or of national wealth*].

Next, a joint select committee of the parliament and the parliament itself debated the findings and recommendations of the *Bakshi Tek Chand Committee Report* and the *Ayyangar Committee Report*. This resulted in the Patent Bill of 1965 which incorporated changes relating to patents for food, drug, and medicines. This bill was introduced first in the lower house of the Parliament on September 21, 1965. The bill was reintroduced with some changes in the Parliament in 1966 but could not be passed. The bill eventually lapsed with the dissolution of the Lok Sabha (the lower

[14] a) https://spicyip.com/wp-content/uploads/2013/10/ayyangar_committee_report.pdf, page 23. (b) https://spicyip.com/wp-content/uploads/2013/10/ayyangar_committee_report.pdf, page 18.

house of Parliament) in March 1967. However, the bill was finally passed by the Parliament, and the *Patents Act 1970*[15a] came into force on April 20, 1972 along with Patent Rules 1972. Thus, the *Patents Act 1970* repealed and replaced the 1911 Act while incorporating the recommendations of both the committees. The 1911 Act however continued to apply to designs.

5.2 1970–1995

In the Patents Act 1970, the following *four articles* and *their intended purpose* are noteworthy[15b]:

Chapter II (***Inventions not Patentable***), **Article 5** clarifies that *only processes are patentable*:

> In the case of inventions –
>
> (a) claim.ing *substances intended for use, or capable of being used, as food or as medicine or drug*, or
>
> (b) relating to substances prepared or produced by chemical processes (including alloys, optical glass, semi- conductors and inter-metallic compounds), ***no patent shall be granted in respect of claims for the substances themselves***, ***but claims for the methods or processes of manufacture shall be patentable***.

Chapter VIII (*Grant and Sealing of Patents and Rights Conferred Thereby*), **Article 53** states:

> (1) Subject to the provisions of this Act, the term of every patent granted under this Act shall –
>
> (a) in respect of an *invention claiming the method or process of manufacture of a substance*, where the substance is intended for use, or is capable of being used, as food or as a medicine or drug, be ***five years from the date of sealing of the patent***, or ***seven years from the date of the patent whichever period is shorter***; and
>
> (b) *in respect of any other invention*, be ***fourteen years from the date of the patent***.

Finally, XVI (*Working of Patents, Compulsory Licences, Licences of Right and Revocation*), **Article 83** clarifies the *economic goals* of the Indian policy makers:

> Without prejudice to the other provisions contained in this Act, in exercising the powers conferred by this Chapter, regard shall be had to the following general considerations, namely;
>
> (a) that ***patents are granted to encourage inventions and to secure that the inventions are worked in India on a commercial scale*** and to the fullest extent that is reasonably practicable without undue delay;
>
> (b) that they are ***not granted merely to enable patentees to enjoy a monopoly for the importation*** of the patented article;
>
> (c) that the protection and enforcement of patent rights ***contribute to the promotion of technological innovation and to the transfer and dissemination of technology***, to the mutual advantage of producers and users of technological knowledge and ***in a manner***

[15] (a) http://www.ipindia.nic.in/writereaddata/Portal/IPOAct/1_113_1_The_Patents_Act_1970_-_Updated_till_23_June_2017.pdf. (b) http://www.wipo.int/wipolex/en/text.jsp?file_id=128091

conducive to social and economic welfare, and to a balance of rights and obligations;

(d) that patents granted ***do not impede protection of public health and nutrition*** and should ***act as instrument to promote public interest*** specially in sectors ***of vital importance for socio-economic and technological development of India***;

(e) that patents granted ***do not in any way prohibit Central Government in taking measures to protect public health***;

(f) that the patent right ***is not abused by the patentee*** or person deriving title or interest on patent from the patentee, and the patentee or a person deriving title or interest on patent from ***the patentee does not resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology***; and

(g) that patents ***are granted to make the benefit of the patented invention available at reasonably affordable prices to the public***.

Chapter XVI (***Working of Patents, Compulsory Licences, Licences of Right and Revocation***), **Article 97** clarifies when *compulsory licenses* will be given:

(1) If the Central Government is satisfied in respect of any patent or class of patents in force ***that it is necessary or expedient in the public interest that compulsory licences should be granted*** at any time after the sealing thereof to work the invention or inventions, ***it may make a declaration to that effect in the Official Gazette***, and thereupon the following provisions shall have effect, that is to say –

(i) the Controller shall on application made at any time after the notification ***by any person interested grant to the applicant a licence*** under the patent on such terms as he thinks fit;

(ii) (in settling the terms of a licence granted under this section, the Controller shall endeavour to secure that ***the articles manufactured under the patent shall be available to the public at the lowest prices consistent with the patentees deriving a reasonable advantage from their patent rights***. …

Thus, the Patents Act 1970 (a) *prohibited patenting of products* and *allowed patenting only on the methods/processes of manufacture useful as medicines and food* (see Article 5), (b) *shortened the term of chemical process patents* (see Article 53), and (c) *significantly expanded the grant of compulsory licenses* (see Articles 83 and 97).

Indeed, the India Patents Act, 1970, was *momentous* in the history of the Indian pharmaceutical industry as it enabled domestic firms to replicate the drugs patented by MNCs, creating a booming generic pharmaceutical industry. As MNCs began to exit the Indian market due to significantly diminished IP protection, the Indian pharmaceutical companies began to fill the void and dominate the global business *of reverse-engineered highly cost-efficient generics* that sold at *exceptionally cheaper prices compared to the counterparts marketed by* MNCs. This is how the generic pharmaceutical industry of India was able to become *one of the most prolific drug manufacturing industries in the world*, ranking third globally in annual volume.

Thus, the Indian government was able to meet its *social goals* as well as *economic goals* (Fig. 2). Interestingly, however, there were advantages as well as disadvantages to the unexpected nearly complete exit of the western pharmaceutical companies from India. Thus, while the generics industry saw a rapid growth, creativity and new drug discovery took a hit.

In 1990s, the Indian government led by Prime Minister P. V. Narasimha Rao *initiated the economic reforms and opened up the Indian economy to foreign*

investment.[16] While this created many opportunities for rapid growth of the economy, it also necessitated India to become a member of the international trade agreements. Indeed, this exposed the limitations of the Indian patent regime on investment, imports, as well as exports of medicines.

As the USA succeeded *in the inclusion of patent rights* in particular and *intellectual property rights* (IPRs) in general, in the *General Agreement on Tariffs and Trade* (GATT) negotiations, India faced new challenges.

Thus, India needed to figure out how to leverage the trade benefits of globalization against its obligation to afford stronger patent protections to MNCs under the TRIPS *Agreement*, which could threaten its high priority social goals and the interests of the domestic pharmaceutical industry. India feared that the stronger IP protection mechanisms under TRIPS could once again unduly favor the MNCs and may unravel the benefits achieved under the Patents Act of 1970.

Initially, India opposed the strong IP protections which are part of the TRIPS Agreement, leading a group of developing countries with similar reservations. However, India signed the Uruguay Round Agreements (along with 116 other nations) on April 15, 1994, and became a member of the WTO effective January 1, 1995, while continuing advocacy of more equitable provisions. Thus, India became obligated to modify its domestic intellectual property laws in order to comply with the TRIPS Agreement.

The TRIPS Agreement afforded *a 10-year grace period* to developing countries for configuring their judicial systems and economies, to fully comply with the TRIPS provisions.

5.3 1995–2005

To start with, the Indian government enacted the Patents (Amendments) Ordinance of 1994 to buy time, while statutory changes to the law were pursued in Parliament.[17] However, this ordinance expired on March 26, 1995, before a permanent legislative solution from the Indian Parliament was put in place for compliance of the TRIPS requirements. Unfortunately, the tenth Lok Sabha was itself dissolved later in 1995, throwing the Indian IPR regime into uncertainty. During this period of political chaos, India was taken to the dispute settlement panel of the WTO by the USA and EU separately that resulted in pronouncements against India. Under the impending threat of trade sanctions, the Indian Parliament then acted rapidly to pass the necessary laws.

Thus, changing the IP Laws for TRIPS Compliance was a big challenge for India once TRIPS Agreement came into force on January 1, 1995. To meet its obligations, India embarked on a substantive overhaul of its patent laws but chose to do so

[16] https://qz.com/india/799883/how-narasimha-rao-fixed-the-indian-economy-and-the-congress-party-only-to-be-forgotten/

[17] See Reference 10.

gradually and stagewise. This resulted in three separate patent amendment Acts in 1999, 2002, and 2005 that incrementally modify the Patents Act of 1970 to make it fully TRIPS compliant.

In this context, it is important to note that the *Doha Declaration of November 2001 took into consideration the concerns expressed by several emerging and less-developed nations and strengthened the cause of flexibilities* under TRIPS. Thus, these flexibilities enabled some WTO member states to alleviate hardships resulting from the need to modify patent laws to TRIPS standards.

The DOHA Declaration (2001): Key Articles

The DOHA Declaration recognized the serious concerns of the least developed countries.[18a,b] Some of the articles shown below exemplify this:

Ministerial Declaration

(3) We ***recognize the particular vulnerability of the least-developed countries and the special structural difficulties they face in the global economy***. We are committed to addressing the marginalization of least-developed countries in international trade and to improving their effective participation in the multilateral trading system. We recall the commitments made by ministers at our meetings in Marrakesh, Singapore and Geneva, and by the international community at the Third UN Conference on Least-Developed Countries in Brussels, to help least-developed countries secure beneficial and meaningful integration into the multilateral trading system and the global economy. We are determined that the WTO will play its part in building effectively on these commitments under the Work Programme we are establishing.

(5) We ***are aware that the challenges Members face in a rapidly changing international environment cannot be addressed through measures taken in the trade field alone***. We shall continue to work with the Bretton Woods institutions for greater coherence in global economic policy-making.

Trade-Related Aspects of IPRs

(17) We stress the importance we attach to implementation and interpretation of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) ***in a manner supportive of public health, by promoting both access to existing medicines and research and development into new medicines*** *and, in this connection*, ***are adopting a separate declaration***.

[18] (a) https://www.wto.org/english/tratop_e/dda_e/dohaexplained_e.htm; (b) https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.pdf

(continued)

Special and Differential Treatment

(44) We *reaffirm that provisions for special and differential treatment* are an integral part of the WTO Agreements. We *note the concerns expressed regarding their operation in addressing specific constraints faced by developing countries, particularly least-developed countries*. In that connection, we also note that some Members have proposed a Framework Agreement on Special and Differential Treatment (WT/GC/W/442). We ***therefore agree that all special and differential treatment provisions shall be reviewed with a view to strengthening them and making them more precise, effective and operational***. In this connection, we endorse the work programme on special and differential treatment set out in the Decision on Implementation-Related Issues and Concerns.

Finally, the India Patents Act 1970 was amended in 2005, so as to[19]:

(a) Include *products* in the *patentable subject matter* category.
(b) Make *reverse-engineering or copying of patented drugs without requisite licensing* from the patent holder *illegal* after January 1, 1995. One exception was that the Act did allow the manufacture of generic versions of drugs patented prior to 1995.
(c) Provide a *20-year guaranteed term of protection to patents* under Article 32 of TRIPS.

5.4 The Key Provisions That Gained Prominence After 2005

However, the India Patents Act, 1970 (2005), also needed to ensure that (Fig. 2):

(a) The *new policies did not adversely impact India's social goals to provide affordable medicines and accessible healthcare to all its citizens*; that means preventing abuse by MNCs.
(b) The *interests of India's generic pharmaceutical industry are considered, while India meets its social goals*; that means FDI and ensuring access to new markets outside India.
(c) The *innovation ecosystem is supported by the Indian government* to facilitate the Indian pharma industry achieve long-term competitive advantage.

Accordingly, the Indian policy makers decided to (i) invoke 3(d) to *prevent* Evergreening by MNCs[20] and (ii) *retain* certain articles to *allow* Compulsory

[19] For "Post-TRIPS experience of the generic pharmaceutical industry in India," see next chapter by B. Dhar.

[20] http://www.ipindia.nic.in/writereaddata/Portal/IPOAct/1_113_1_The_Patents_Act_1970_-_Updated_till_23_June_2017.pdf, page 8

Licensing,[21] so as to ensure its social goals. In addition, India decided to (iii) *retain* pre-grant opposition and (iv) *introduce* post-grant opposition. The details are described below.

Prevent Evergreening

Simply stated, "Ever-greening" refers to *the different means a pharmaceutical patent holder employs to exploit the legal loopholes of patenting to extend/fortify monopoly typically over blockbuster drugs*[22] by either filing disguised or artful patents on previously patented invention just before the end of the term of the parent patent or employing other related regulatory policies.

According to Kumar and Nanda[22]:

> *Ever-greening* is a *strategy employed by the innovator companies to recover high costs* incurred by them in Research and Development and as a means to legally protect any minor modifications that are intentionally made to the parent patent just to obtain multiple patents on the same drug and hence extend the overall term of the patent *to enjoy monopoly for extended periods of time.*
>
> In simple words, a company launches a drug product and obtains patent protection for it and just before the end of the term of that patent; the company files a new patent for a minor modification in the original molecule that extends the overall term of patent protection which ultimately contributes to their monopoly. Hence, extending the patent protection period *delays or prevents the entry of the generic versions of the drug* which can affect the budget for public health and finally the patient.

Companies *often seek protection of the following for the purpose of evergreening*:

- Combinations of two or more drugs
- Dosing regimen, dosing rate, and dosing route
- Biological targets for a known compound
- Delivery profiles, mechanisms of action
- Isomeric forms and derivatives
- Screening methods
- Packaging
- Different treatment methods

Thus, the *rationale and tactics for evergreening of blockbuster drugs* by MNCs are the following[22]:

> Pharmaceutical research and development is an expensive, time consuming and uncertain process that may take 8–10 years to complete. Patent clock starts much before a new drug is approved for marketing and significant amount of time may be lost in the review and

[21] http://www.ipindia.nic.in/writereaddata/Portal/IPOAct/1_113_1_The_Patents_Act_1970_-_Updated_till_23_June_2017.pdf, pages 64–73.

[22] Kumar, A.; Nanda, A. "Ever-greening in Pharmaceuticals: Strategies, Consequences and Provisions for Prevention in USA, EU, India and Other Countries", *Pharmaceutical Regulatory Affairs: Open Access.* 6(1), DOI: https://doi.org/10.4172/2167-7689.1000185 (2017).

> approval process by regulatory bodies. So, *in order to recoup the considerable time and resources invested in the drug development* and *approval process*, *the pharmaceutical companies depend on exclusivity provisions granted by the regulatory bodies*. *There are several official and unofficial methods to extend term of a patent beyond 20 years*. Official methods include provisions by some regulatory bodies such as *data exclusivity*, *orphan drug exclusivity*, *pediatric exclusivity*, *the 180-day exclusivity* (Hatch Waxman Act, U.S. Food and Drug Administration),[23] and *supplementary protection certificate* (European Medical Agency), whereas unofficial methods include *altering or reformulating the existing compound to obtain a new patent by utilising polymorphism, creating combinations, stereo-selective/chiral switches, conversion to NDDS, OTC switching, authorised generics*, etc.

Evergreening, if unchecked, *blocks* the generic drugs market, *undermines* innovation, and *prevents access* to *affordable medicines and accessible healthcare* to citizens. Not surprisingly, this would be detrimental to India's social goals as well as economic goals. Consequently, *the following was substituted for clause (d) in Section 3 in the Patents (Amendment) Act, 2005,* to discourage or prevent *evergreening*. Thus, the new Section 3(d) states[24]:

> The mere discovery of a new form of a known substance ***which does not result in the enhancement of the known efficacy of that substance*** or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus ***unless such known process results in a new product or employs at least one new reactant***.
>
> ***Explanation***. For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance ***shall be considered to be the same substance***, ***unless they differ significantly in properties with regard to efficacy***.

Aleksandar Ristanić nicely articulated how India leveraged the flexibility afforded by Article 27(1) TRIPS to design 3(d)[25a]:

> First and foremost, Article 27(1) TRIPS requires member states to make patents "*available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application*". TRIPS thus ***simply enunciates these essential patent law concepts*** such as *invention*, *novelty*, *inventiveness* and *industrial applicability* ***without defining them***, ***which leaves a***

[23] The "Drug Price Competition and Patent Term Restoration Act of 1984," also known as *the Hatch-Waxman Amendments*, established the approval pathway for generic drug products, under which applicants can submit an ANDA under section 505(j) of the *Federal Food, Drug, and Cosmetic Act (FD&C Act)* (see https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ucm613498.htm).

[24] http://www.ipindia.nic.in/writereaddata/Portal/IPOAct/1_113_1_The_Patents_Act_1970_-_Updated_till_23_June_2017.pdf

[25] (a) http://lup.lub.lu.se/luur/download?func=downloadFile&recordOId=8894039&fileOId=8894040, page 18. (b) Ho, Cynthia M., Access to Medicine in the Global Economy: International Agreements on Patents and Related Rights, (Oxford University Press, 2011), page 92.

> ***considerable discretion to states with how to apply those requirements in their national laws***. The way these key terms are defined, however, can be of the utmost importance for both innovation and access to medicine. If a drug is unpatented it is in the public domain and anyone can produce it.[25b] ***An example of taking advantage of freedom and flexibilities under TRIPS is to be found in India's 2005 amendment to its Patents Act 1970***. While finally allowing the patent protection for pharmaceutical products, India's patent law, Section 3(d), in particular, limits the number of patents that can protect a drug, providing two important exclusions from the scope of that protection. It excludes from the scope of inventions mere discoveries of (1) new forms of known substances – unless there is an enhancement of the known efficacy of that substance, and (2) new uses for known substances. In addition, ***the amendment provides a list of substances that would be considered a new form of the same substance unless they differ significantly in properties with regard to efficacy***.

Indeed, the US and the EU strongly oppose Section 3(d) of the Patents (Amendment) Act, 2005. However, many other countries – like Argentina, Brazil, China, Indonesia, Malaysia, the Philippines, South Africa, and Thailand – either emulate India's patent reforms or strongly support them.

Thus, in 2008, the Philippines amended Section 22 of the Republic Act 8293, exactly along the lines of Section 3(d). Argentina revised and restricted the patentability of derivatives of pharmaceutical products, following the example set by 3(d), and going even tougher in certain respects. Mexico revised its patent law precisely adopting the language of 3(d). The same is true of many other countries mentioned. The *Novartis* vs. *Union of India Case Study* is instructive of how 3(d) set a precedent in India.[26a]

5.5 The Novartis vs. Union of India Case Study

Soon after Section 3(d) in the *Patents (Amendment) Act, 2005,* came into force, the statute was tested. Thus, in 2006, Novartis applied for an Indian patent on the *beta crystalline form of imatinib mesylate*.[27] The Madras Patent Office rejected the patent application, citing that *imatinib mesylate* was a *known compound* (a pre1990s molecule) and the *beta crystalline form was merely a derivative of imatinib mesylate*.

Novartis then appealed the Madras Patent Office's decision to the Intellectual Property Appellate Board (IPAB). IPAB modified the decision of the Patent Office stating that ingredients for grant of patent novelty and nonobviousness may be present in the application but rejected the application on the ground that the drug is not a new substance but an amended version of a known compound. Novartis mounted a separate and concurrent litigation before the Madras High Court arguing that Section 3(d) has violated Article 14 of the Indian Constitution because the

[26] (a) https://www.omicsonline.org/open-access/evergreening-in-pharmaceuticals-strategies-consequences-and-provisions-for-prevention-in-usa-eu-india-and-other-countries-2167-7689-1000185.pdf. (b) High Court of Judicature at Madras for W.P., Novartis AG and another v. Union of India and others, nos. 24759 and 24760 of 2006, 6 August 2007.

[27] *Imatinib mesylate* is used to treat chronic myeloid leukemia and is marketed by Novartis as "Glivec" or "Gleevec."

definition of "enhanced efficacy" was too vague and was in violation of India's obligations under the TRIPs Agreement. The High Court ruled that the law was not vague and that the law complied with TRIPS. In upholding the constitutionality of Section 3(d), the Madras High Court noted that[26b]: "India, being a welfare and a developing country, which is predominantly occupied by people below poverty line, has a constitutional duty to provide good health care to its citizens by giving them easy access to life saving drugs. In so doing, the Union of India would be right, it is argued, to take into account the various factual aspects prevailing in this big country and prevent 'evergreening' by allowing generic medicine to be available in the market." Thus, it was evident that Novartis could not back up its claim of "enhanced efficacy" for *imatinib mesylate over the parent molecule*, according to the patentability standards laid down by Section 3(d).

Next, Novartis appealed IPAB's decision to the Supreme Court of India.[28] However, the Indian Supreme Court agreed with the IPAB ruling that Novartis *had not established the "enhanced therapeutic efficacy" over the parent compound*, *and thus failed to meet the requirements laid down by* Section 3(d). In addition, the Indian Supreme Court opined that *the constitutional validity of* Section 3(d) *was as per the flexibilities offered by* TRIPS framework.[29]

Analyzing the *Novartis* vs. *Union of India case*, Lukose[30] noted that the patented drug "Gleevec" by Novartis costed the patients Rs. 4115/per tablet, while its generic version was available at Rs. 30/per tablet, at 99% cost savings to the patient. The differential is even greater in annual costs. Thus, while the annual cost of the Gleevec to patients in India is Rs. 1,500,000, its generic versions costed just Rs. 10,000 annually, a whopping savings of Rs. 1,490,000. Typically, when a patent for a blockbuster drug expires, the price falls up to 95%.[31]

Thus, the *Novartis* vs. *Union of India case* makes clear that India will not permit the *evergreening* of patents, risking its social and economic goals. Indian patent regime also sends a strong message to the world that an extended monopoly to salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures

[28] After IPAB rejected the patent application in 2009, Novartis appealed directly to the Supreme Court through a Special Leave Petition under Article 136 of the Indian Constitution. Under normal circumstances, an appeal from IPAB should have been before one of the High Courts before it could proceed to the Supreme Court. However, the patent if granted on appeal would expire by 2018 and thus any further appeal at that stage would be pointless. Considering this urgency and the need for an authoritative decision on Section 3(d), the Supreme Court granted special leave to bypass the High Court appeals process.

[29] Banerjee R. "The Success of, and Response to, India's Law against Patent Layering." *Harvard Int Law J.* 2013, *54*: 205–232.

[30] (a) Lukose, L. "Patent Evergreening and Ethics," *7th International Conference on Information Law and Ethics*, University of Pretoria, South Africa (2016). (b) Proceedings of the 7th International Conference on Information Law and Ethics ICIL, Bottis M. and Alexandropoulos E. (Eds) (2016), ISBN: 978-618-5196-25-7.

[31] https://theconversation.com/explainer-evergreening-and-how-big-pharma-keeps-drug-prices-high-33623

of isomers, complexes, combinations, and other derivatives of a known substance *will not be possible unless they exhibit demonstrably high therapeutic efficacy over the known substance*.

Allow Compulsory Licensing
The flexibilities afforded by the TRIPS Agreement (see Articles 30 and 31 below)[32] allow "compulsory licensing" – *in the case of a national emergency, other circumstances of extreme urgency or public health use* etc. Thus, *compulsory licensing enables other companies to produce a patented product without the permission of the patent holder, under certain conditions*.

Article 30
Exceptions to Rights Conferred

Members ***may provide limited exceptions to the exclusive rights conferred by a patent***, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

Article 31
Other Use Without Authorization of the Right Holder

Where the law of a Member ***allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government***, the following provisions shall be respected:

(a) authorization of such use *shall be considered on its individual merits*;
(b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. ***This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public noncommercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable.*** In the case of public noncommercial use, where the government or contractor, without making a

(continued)

[32] https://www.wto.org/english/docs_e/legal_e/27-trips.pdf

patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;

(c) the *scope and duration of such use shall be limited to the purpose for which it was authorized*, and in the case of semi-conductor technology shall only be for public noncommercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;

(d) such use shall be *non-exclusive*;

(e) such use shall be *non-assignable*, except with that part of the enterprise or goodwill which enjoys such use;

(f) any such use shall be *authorized predominantly for the supply of the domestic market of the Member authorizing such use*; …. (continued)

TRIPS Agreement empowers individual nations to rightfully exercise the option of *compultsory licensing* under *justifiable socioeconomic circumstances and legitimate needs*. Therefore, a *compulsory license* would ensure much needed access to affordable medicines to all citizens, shielding them from the negative effects of the monopoly of patents. *The Natco Pharma* vs. *Bayer Corporation case* exemplifies how India awarded its first *compulsory license* in 2012.[33]

5.6 The Natco Pharma vs. Bayer Corporation (*Nexavar* Compulsory License) Case

Bayer first obtained a US patent (US8609854B2) on the drug *sorafenib tosylate* in 1999. Following further development, it launched *sorafenib tosylate* internationally in 2005, under the brand name "Nexavar," an oncology drug useful for the treatment of advanced stage liver and kidney cancers (Fig. 3).

In 2008, Bayer obtained the Indian patent (Patent No. 215758) on *sorafenib tosylate* and launched the drug into the Indian market under the same trade name, "Nexavar," selling it at Rs. 275,000 (US$ 5500) per patient per month in India. In 2010, Cipla, a well-known Indian generic drug manufacturer, which held one of the largest market shares in India, started selling the generic version of Nexavar at about Rs. 29,000 (US$ 580) per month, a price that is 90% cheaper. In 2011, Bayer sued *Cipla* for patent infringement. On a different front, the Indian generic drug manufacturer Natco Pharma Limited ("Natco") applied for *compulsory license* in India on the *sorafenib tosylate patent*.

In 2012, *the Controller General of Patents Designs and Trademarks of India* granted the Indian generic drug manufacturer, Natco Pharma Limited, a *compulsory*

[33] http://lup.lub.lu.se/luur/download?func=downloadFile&recordOId=8894039&fileOId=8894040, page 33

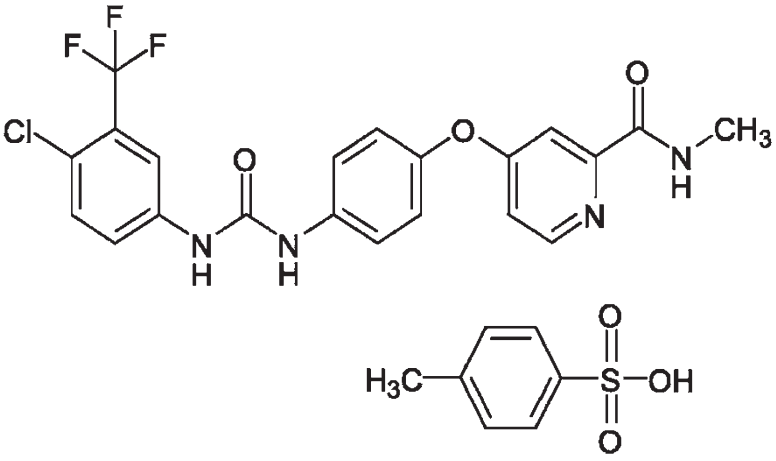

Fig. 3 Sorafenib tosylate ("Nexavar")

license for Bayer AG's drug, *sorafenib tosylate* ("Nexavar"), an oncology drug useful for the treatment of advanced stage liver and kidney cancers.

The *compulsory license application* of Natco was based on the grounds stated in Section 84(1) of the Indian Patents Act 1970, as amended by Act 15 (2005),[34] which reads as follows:

> 84. Compulsory licenses. – (1) At ***any time after the expiration of three years from the date of the grant of a patent***, any person interested may make an application to the Controller for grant of *compulsory license* on patent on any of the following grounds, namely:
>
> (a) ***that the "reasonable requirements of the public" with respect to the patented invention have not been satisfied***, or
> (b) ***that the patented invention is "not available to the public at a reasonably affordable price"***, or
> (c) ***that the patented invention is "not worked in the territory of India***.

In a landmark decision on 9 March 2012, the Controller *granted the compulsory license* to Natco and stripped Bayer of its exclusive right to the medicine in India, citing that *the grounds (a)–(c) in Section 84(1) of the Indian Patents Act 1970 (2005) were individually met, though any one of them would have been sufficient for the grant of a compulsory license*.

[34] http://www.wipo.int/edocs/lexdocs/laws/en/in/in065en.pdf

Further, the Controller reasoned that[35]:

- Bayer's drug was *available only to a small percentage of eligible patients* (slightly above 2%), *which failed to meet the "reasonable requirements of the public."*
- The 2012 price of Rs. 280,000 per month (approximately US$5600) to the patient *does not meet the condition that the drug must be available to the public at a "reasonably affordable price."* This is based on the purchasing power of patients in India.
- Bayer's *patented invention was "not being worked in India"* as Nexavar *was not manufactured within India and imported from the manufacturing facilities outside India.* This did not satisfy the third mandatory requirement.
- Natco may sell the drug to patients within India at a price of no more than Rs. 8800 (approximately US$176) per month, which is 97% cheaper than the Bayer's price.
- Natco was required to pay a 6% royalty to Bayer.

Next, Bayer then appealed the decision of the Controller to the IPAB. Pending appeal, Bayer also petitioned for stay of the Controller's order, which was denied. About a year later, the IPAB upheld the Controller's decision of granting the *compulsory license* to Natco with certain changes. Though both the Controller and the IPAB arrived at the same conclusion in the *Natco Pharma* vs. *Bayer Corporation Case*, their approaches differed from each other. Thus, while the Controller relied on the *statistical data submitted by the parties* for analyzing the substantive issues of the case, the IPAB analyzed the issues from the *public health perspective in the context of the right to life* under Article 21 of the Indian Constitution.[36]

Then, Bayer tried to appeal the IPAB's decision to the Bombay High Court, which simply refused to take up the case. On 12 December 2014, the Indian Supreme Court finally dismissed Bayer's petition against the Bombay High Court and ruled in favor of the *compulsory license* of Nexavar to Natco. The Supreme Court's judgment *fits the established opinion that all the three grounds for compulsory license had been fully met*. Once again, being the first of its kind in the history of the Indian patent regime, the *Bayer vs. Natco ruling* has set a clear precedence for seeking *compulsory licenses* by other generic pharmaceutical companies in India, as well as by the policy makers and patent regimes of other countries.

Naturally, MNCs strongly opposed *the judgment in the Natco Pharma* vs. *Bayer Corporation* and expressed many concerns.[37] On the other hand, the judgment was

[35] https://www.whitecase.com/sites/whitecase/files/files/download/publications/alerts-indian-patent-office-grants-compulsory-license.pdf; See 84(1) above.

[36] Sood, M. "Natco Pharma Ltd. v. Bayer Corporation and the Compulsory Licensing Regime in India," *NUJS Law Review*, 99 (2013), p. 104.

[37] http://lup.lub.lu.se/luur/download?func=downloadFile&recordOId=8894039&fileOId=8894040

hailed by the *champions for affordable access to drugs*. The case is also notable because it is only the second time in the world that a nation issued a *compulsory license* for a drug used for treatment of a *chronic* rather than an *infectious* disease. Prior to this case, only Thailand awarded *compulsory licenses* to four drugs between 2006 and 2008.[38]

Retain Pre-grant Opposition

Pre-grant opposition[39a] was already there in the India Patents Act 1911,[39b] and it was retained in the India Patents Act, 1970 (2005).[39c] India's *pre-grant opposition procedures* in 1911 were modeled similar to the British patent laws in force.[40] However, during that time, the British patent system was not the only patent system that relied *on pre-grant opposition*; many other countries also used a *novelty-only examination system* coupled with *pre-grant opposition*[41] to supplement the resources of the patent examiner.

Thus, Section 25(1) of the India Patents Act, 1970 (2005), provides for *pre-grant opposition* of pending patent applications. The *pre-grant opposition* may be based on any number of grounds,[42] including *anticipation, lack of inventive step, non-invention under Section 3 of the Patents Act (including the anti-evergreening provisions of Section 3(d)), insufficient or unclear description of the invention in the specification, failure to disclose the source of biological material used for the invention, and inventions which are considered traditional knowledge*.

Notably, Section 25(1) of the India Patents Act, 1970 (2005), *does not impose any estoppel limitations on a party* who first files a *pre-grant opposition* and later tries to challenge the patent's validity in a court proceeding. The Act even mandates that the party filing the *pre-grant opposition* receive a hearing before the Controller if requested, which will delay the process even if patentability was affirmed over all objections.

The Indian patent regime views that *pre-grant opposition* is actually helpful to get all the prior art before the patent examiner. Hence, the same patent examiner who examines the initial patent application will also examine the *pre-grant opponent's submission*. The Indian Patent Office does not agree that *pre-grant opposition* would delay the process of patent grants. It is important to note that the

[38] https://www.reuters.com/article/us-india-drugs/analysis-india-cancer-ruling-opens-door-for-cheaper-drugs-idUSBRE82C0IN20120313

[39] (a) See Reference 3. This author describes the *pre- and post-grant opposition to patents* in great detail. (b) Indian Patents and Designs Act, 1911. http://theindianlawyer.in/statutesnbareacts/acts/d42.html, Section 9. (c) See Reference 20, Chapter V, Section 25, page 25.

[40] Janis, M. D. "Patent Abolitionism", *Berkeley Tech. L. J*. 899, 903 (2002).

[41] Vojacek, J. *A Survey of the Principal National Patent Systems*, 28 (1936).

[42] See Section 25(1)(k) for details.

Indian generic pharmaceutical companies and the MNCs are on opposite sides of the *pre-grant opposition* debate. Thus, while the former *favor pre-grant opposition*, the latter *strongly oppose* it.[43]

Mueller observes[44] that according to press reports in March 2006, approximately 100 *pre-grant oppositions* were pending in the four Indian Patent Office branches, including challenges filed by Indian generic firms against pending patent applications on Astra Zeneca's cholesterol drug *Rosuvastatin*, Pfizer's antifungal drug *Voriconazole*, Wockhardt's antibacterial drug *Nadifloxacin*, Gilead-Roche's bird-flu drug *Oseltamivir*, and Astra Aktiebolag's formulation of ulcer drug *Omeprazole*. In addition, nongovernmental organizations and healthcare advocacy groups in India have also been using the *pre-grant opposition* as a powerful tool to challenge the grant of patents on essential medicines.

Introduce Post-grant Opposition

Unlike *pre-grant opposition* "which already existed" in the Indian patent law in one form or another, *post-grant opposition* is a "new addition" to the Patents (Amendment) Act, No. 15 of 2005. The grounds for *post-grant opposition* are very similar to those of *pre-grant opposition*, including virtually all patentability criteria. Therefore, to understand the "new" grounds for *post-grant opposition*, see Section 25 (2) (a)–(k) below of the India Patents Act 1970 (2005)[45]:

25. **Opposition to the patent**.
(2) At ***any time after the grant of patent but before the expiry of a period of one year from the date of publication of grant of a patent***, ***any person interested may give notice of opposition*** to the Controller in the prescribed manner on any of the following grounds, namely –
  (a) that the patentee or the person under or through whom he claims, *wrongfully obtained the invention or any part thereof* from him or from a person under or through whom he claims;
  (b) that the invention so far as claimed in any claim of the complete specification *has been published before the priority date of the claim* – (i) in any specification filed in pursuance of an application for a patent made in India on or after the 1st day of January, 1912; or (ii) in India or elsewhere, in any other document: Provided that the ground specified in sub-clause (ii) shall not be available where such publication *does not constitute an anticipation of the invention* by virtue of sub-section (2) or sub-section (3) of section 29;

(continued)

[43] https://economictimes.indiatimes.com/news/economy/policy/what-is-patents-amendment-bill/articleshow/971708.cms (December 27, 2004).

[44] https://core.ac.uk/download/pdf/129759353.pdf

[45] http://www.ipindia.nic.in/writereaddata/Portal/IPOAct/1_113_1_The_Patents_Act_1970_-_Updated_till_23_June_2017.pdf, page 26.

(c) that the invention so far as claimed in any claim of the complete specification is *claimed in a claim of a complete specification published on or after the priority date of the claim of the patentee* and filed in pursuance of an application for a patent in India, being a claim of which the priority date is earlier than that of the claim of the patentee;
(d) that the invention so far as claimed in any claim of the complete specification *was publicly known or publicly used in India* before the priority date of that claim.

Explanation. For the purposes of this clause, an invention relating to a process for which ***a patent is granted shall be deemed to have been publicly known or publicly used in India before the priority date of the claim*** if a product made by that process *had already been imported into India* before that date except where such importation has been for the purpose of reasonable trial or experiment only;

(e) that the invention so far as claimed in any claim of the complete specification *is obvious and clearly does not involve any inventive step*, having regard to the matter published as mentioned in clause (b) or having regard to what was used in India before the priority date of the claim;
(f) 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*;
(g) that the complete specification *does not sufficiently and clearly describe the invention* or *the method* by which it is to be performed;
(h) that the patentee has *failed to disclose* to the Controller the information required by section 8 or has furnished the information which in any material particular was false to his knowledge;
(i) that in the case of a patent granted on a convention application, *the application for patent was not made within twelve months from the date of the first application* for protection for the invention made in a convention country or in India by the patentee or a person from whom he derives title;
(j) that the complete specification *does not disclose or wrongly mentions the source and geographical origin of biological material* used for the invention;
(k) that the invention so far as claimed in any claim of the complete specification *was anticipated having regard to the knowledge, oral or otherwise*, available within any local or indigenous community in India or elsewhere, but on no other ground.

Unlike *pre-grant oppositions,* the *post-grant oppositions* will be heard by a *three-person Opposition Board* that *does not include* the original patent examiner. *Post-grant opposition* is a very important aspect of European Patent Convention (not yet part of the US patent law). In 2017, of all the patents granted under the European Patent Convention, approximately 3.7% were subjected to *post-grant oppositions*.[46]

It is important to mention that neither the Patents Act nor any other rules require the Controller to (a) *notify* (in the Official Journal) that a *post-grant opposition* has been initiated or (b) *announce* the decision taken and *provide* the underlying reasons. At this time, it is yet unclear how much the *post-grant opposition procedure* will be used in India.

[46] https://www.epo.org/about-us/annual-reports-statistics/annual-report/2017/statistics/searches.html#tab4

6 Conclusion

India is a dominant player in the global generics market, with the largest number of USFDA-approved labs outside the USA, and holding a 30% share (by volume) of the US generics market. However, India has been witnessing increasing competition from other nations such as South Korea and China, who are also trying to establish themselves in the global generics market. Indeed, competition is always better for the patients seeking cheaper medicines and better access to healthcare.[47] In response to these dynamic market changes, the Indian generic pharmaceutical industry has been *strategically repositioning* itself. Some highlights are:

(a) **Gaining Proficiency in Complex Generics**. According to Vijayaraghavan,[48] complex generics include, "*Complex injectable formulations* (liposomal, microsphere-based depot formulations et al), *inhalation drugs*, *topical products and transdermals*." Case and point: Sun Pharma could commence selling *Lipodox*, a pegylated liposomal doxorubicin formulation (generic of Janssen's *Doxil*), even prior to the patent expiry in the USA due to drug shortage and be the only generic on the market even after the *Doxil* patent expired.

(b) **Focusing on Specialty Portfolios**. *Indian pharma companies are increasingly focusing on specialty portfolios in specific therapeutic categories. In other words, Indian pharmaceutical companies are actively pursuing the Section 505(b)(2) of USFDA specialty drugs*.[49] *This is evident from industry examples such as*:
- *Glenmark's targeted focus on dermatology, oncology, and respiratory*
- *Dr. Reddy's focus on Dermatology – through its US subsidiary Promius Pharma*
- *Lupin Pharma's focus on pediatrics – proprietary portfolio of branded drugs such as Alinia® and Locoid® Lotion*

(c) **Capitalizing on the Abuse Deterrent Opioids[50] Market**. The USFDA's *Opioids Action Plan* laid down the new draft guidance in March 2016, for regulation of *the generic versions of approved opioids with abuse-deterrent formulations*.[51] Indeed, this attracted the Indian pharmaceutical companies to

[47] https://www.sathguru.com/news/2017/05/03/innovation-in-indian-pharma-empowering-stronger-global-presence-but-fraught-with-challenges-for-serving-indian-market/

[48] https://www.sathguru.com/Publication/download/Medcon-2017-Whitepaper.pdf, page 80. See full details in this reference.

[49] For drugs approved under section 505(b)(2) of USFDA, an NDA must be filed but for which approval can be based in part on the safety and effectiveness of an already-approved drug.

[50] *Abuse deterrence* is an emerging market segment in the global pharmaceutical industry for *extended release* and *rapid release prescription control substances (opioids)*.

[51] See Reference 47, page 17.

do business in this space. Further, as the USA is a key market for Indian-made drugs, Indian pharma companies have been innovating to gain a strong foothold in this new market segment. This is evident in Zydus Cadila's recent acquisition of Sentynl Therapeutics (USA) for $171 million. Currently, Sentynl holds the US market rights for "Abstral," *a unique sublingual abuse deterrent formulation of Fentanyl* for cancer pain – a product that has no direct market competition.

(d) **Fortifying Domestic R&D and Fostering Innovation**. The Indian pharmaceutical companies as well as the policy makers of India have long recognized the absolute need to strengthen domestic R&D and *nurture innovation opportunities for creating sustainable competitive advantage*. Significant *innovation opportunities* for India include[52] 3D printing in medical applications across product development and commercial manufacturing, increasing pursuit of drug device combinations for life cycle management and competitive advantage, innovations in biomaterials expanding possibilities, pervasive use of robotics, artificial intelligence and machine learning for developing smart devices, and leveraging Internet of Things (IoT) to progress toward a more connected continuum of care.

Not surprisingly, therefore, India's policy makers know that they have a critical role to play in fortifying the *innovation ecosystem* of India. Accordingly, the Government of India declared 2010–2020 as the "Decade of Innovation." In 2013, *the Ministry of Science and Technology* unveiled a coherent vision for bringing the different pieces of the Indian *innovation ecosystem* together, which states[53]:

> The guiding vision of aspiring Indian STI [Science, Technology, and Innovation] enterprise is to accelerate the pace of discovery and delivery of science-led solutions for faster, sustainable and inclusive growth. A strong and viable Science, Research and Innovation System for High Technology-led path for India (SRISHTI) is the goal of the new STI policy.

Therefore, India is embracing many important initiatives such as *Make in India*[54] and *Startup India*[55] and many others[56] shown below to meet its socioeconomic goals:

- ***The National Health Protection Scheme (Ayushman Bharat, 2018)***. This is the largest government funded healthcare program in the world, expected *to benefit*

[52] See Reference 47, page 7.

[53] https://timreview.ca/article/818

[54] http://www.makeinindia.com/home

[55] https://up.startupindia.gov.in/content/sih/en/home-page.html

[56] http://www.nbr.org/downloads/pdfs/ETA/IIP_kapoor_sharma_workingpaper_070815.pdf

100 million poor families in the country for secondary and tertiary care hospitalization – by providing a cover of up to US$ 7720 per family per year.

- ***Single-window facility to provide consents, approvals, and other information***. In March 2018, the Drug Controller General of India announced this *to boost the Make in India initiative*.
- ***Electronic platform to regulate online pharmacies***. The Government of India announced this initiative *to stop any misuse of online pharmacies*.
- ***Drug Price Control Order and the National Pharmaceutical Pricing Authority***. The Government of India introduced these initiatives *to ensure the affordability and availability of medicines*.
- ***The Government of India's "Pharma Vision 2020."*** This is aimed *at making India a global leader in end-to-end drug manufacture* with reduced approval time for new facilities.

In support of this vision, the Government of India is striving *to create a robust IPR regime* that can serve as the bedrock of innovative and competitive India. Indeed, many countries are closely observing *the evolution of Indian IPR regime* to see how it further leverages the flexibilities offered by TRIPS *to advance its own socioeconomic goals* while simultaneously *promoting its innovation ecosystem* and *protecting the legitimate business interests of* MNCs. Thus, India's patent reforms are having a global impact.[57]

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[57] For understanding (a) how China's patent legislation has impacted the patent protection for pharmaceuticals in China and (b) what China is interested in learning from the Indian example, see the previous chapter on "Indian Patent Law and Its Impact on Pharmaceutical Industry: What China can learn from India?" by Juan HE.

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