

Patent Policies and Provisions Relating to Pharmaceuticals in India

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Indian generic pharma industry has established a 'pride of place' as the largest generic manufacturer and supplier of essential and life-saving medicines to UNICEF, WHO, MSF and others. India has the largest number of manufacturing facilities approved by the USFDA and EDRM, etc. While the Patents Act and related IP laws are substantially TRIPS compliant and is reasonably well enforced, there is a need for substantial refinement in other pharma related laws such as Drugs and Cosmetics Act, Biodiversity Act. Need for more uniform and stringent enforcement of quality including upgradation of regulatory agencies is also called for. The Indian Patent Law which provides equitable balance between rights and obligation has also been hailed by all the third world countries and acknowledged, though reluctantly, by developed countries. Such a balanced patent law is essential to provide affordable access to essential medicines to the masses. An analysis of the policies and provisions of (Indian) Patents Act, 1970 and other pharma related laws are provided in this article.

Keywords: Working of patents, patent law, compulsory licence, government use, inventions not patentable, Section 3(d), medicine patent pool

In a recent perspective¹ on Indian patent policies, the patent-related judgment from the Hon'ble Supreme Court of India², it was commented that 'a patent law that treats incremental innovation and significant innovation in the same way, encourages companies to prioritize less important research over the more important ones'. If patent enforcement and infringement suits are the ultimate goal in obtaining grant of a patent, the very objective of encouragement of innovation and progress of science is defeated and gets sidelined. The emergence of 'patent trolls'³ or patent assertion entities (PAEs) globally has even attracted the attention of the President of USA⁴, who has promised action. However, the same is still pending. Persons or companies involved in patent trolls are opportunists, who buy or licence patents with the sole intention of filing infringement suits, often with no intention to manufacture or market the patented invention, but only to collect royalty or licensing fees. It has been reported that 62% of all patent infringement suits filed in USA are by patent trolls and that PAEs might have threatened over 100,000 companies with patent infringement in the year 2012 alone.⁴ Serious challenges posed by the patent trolls have been reviewed extensively in recent times.⁵

Over the last two to three decades, the patent system in developed countries has shifted from incentive for innovation to disputes and expensive litigations. To add to these disturbing trends, there are patent term extensions from within the statute and outside, through extended market and data exclusivities and supplementary protection certificate (SPCs) which add to the life of patent protection. The recent US judgments related to pharmaceuticals and biologicals have leaned away from extending the patent protection vertically and horizontally. The controversial case of *MedImmune v Genentech*⁶ put to test the weaknesses in US Patent Law. The US Supreme Court reversed the Federal Circuit's view supporting the District Court and ruled in a 8 to 1 decision, in favour of *MedImmune*, that disputes for litigation be 'non-hypothetical' and 'non-abstract'.

More recently, the US Supreme Court decided the now famous Myriad Gene patent case⁷ on 13 June 2013. In this case, Myriad sought to claim monopoly on the method of detecting inherited breast and ovarian cancer genes BRCA 1 and BRCA 2. The patent would have given Myriad exclusive rights for isolating an individual's BRCA1 and BRCA2 genes and to synthetically create BRCA composite DNA. In a unanimous opinion, the court held that 'a naturally occurring DNA segment is a product of nature and not patent eligible because it has been isolated, but that

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cDNA is patent eligible because it is not naturally occurring'. The more generic case of '*KSR v Teleflex*'⁸ on obviousness is also well-known and much deliberated. What is the relevance of all these (and much more) cases to the current context is explained herein.

Indian Patent Law has received both accolades as well as brickbats in recent times. The global pharma giants have jointly with US⁹ & EU¹⁰ governments, been putting pressure on India to improve the IP practices and enforcements. The grant of a compulsory licence¹¹ in India has led to extensive criticism from the West. The Gleevec judgment¹² by the Supreme Court has also been extensively criticized by the Big Pharma and US government sources. However, the original inventor of Gleevec, Dr Brian Druker, has justified the Supreme Court ruling on refusal to grant a patent on Imatinib Mesylate (Gleevec®) in India. Dr Druker criticized pharma majors' predatory pricing and the enormous profits they made on many blockbuster drugs.¹³

What might have further added fuel to the 'Gleevec' fire is Indian Pharma company, Sun Pharma's confidence in challenging, based on the US prosecution history of equivalent (to Indian Patent Application of Gleevec) patent, which was initially rejected by the USPTO in 2001, but later reversed on appeal in 2003. It has been reported¹⁴ that Sun Pharma has filed a suit in the District Court of New Jersey seeking declaratory judgment against Novartis, to enable Sun Pharma to launch generic version of Gleevec in US. As commented in SpicyIP¹⁵, if Sun Pharma manages to pull off a Gleevec victory in US itself, it would be a vindication of India's decision and validation of the order of the Hon'ble Supreme Court of India.

It is, however, heartening to note that the bulk of the developing countries have applauded these decisions originating in India and paid rich tributes to the equitable balance of rights and obligations provided by Indian Patent Law for enabling affordable access to essential and life-saving medicines, not only to the third world countries, but also to the developed countries through early generic launch. India has been rightly labeled the 'Pharmacy for the Developing World'. India, having been declared as the top contributor of generic medicine for distribution by UNICEF, WHO, MSF and others, India has justified this 'pride of place' in global generic industry.

Indian Patent Policy and Apex Court judgments have attracted global attention. Patenting and litigation

trends in India have been reviewed in a recent article¹⁶ While the sequence of events in the now world famous 'Gleevec case' has been elaborated therein, the Supreme Court of India announced the much awaited judgment², rejecting Novartis's application for beta-crystalline form of Imatinib Mesylate, which has been globally acknowledged as a landmark judgment.

Recent judgments from Delhi High Court and Intellectual Property Appellate Board (IPAB) on blockbuster molecules, such as Erlotinib¹⁷⁻¹⁸ and Sunitinib¹⁹ (at IPAB²⁰, Delhi High Court^{21, 22} and Supreme Court²³) and the interim order on Sitagliptin²⁴ have all made ripples in the global IP Watch community. As per the recent report in the Times of India²⁵, EU, Australia and Canada are also looking at possible changes to the patent laws, in line with India, to deal with the ever greening disease. This is further indicated by the Canadian Supreme Court's refusal to grant a patent for Viagra® due to efficacy considerations. Countries like Argentina, Brazil and many other countries in Latin America as well as South Africa and South Asian countries are following suit to tighten their own patent laws/statutes. South Africa's Treatment Action Campaign (TAC) has strongly supported Indian Patent Law and has openly addressed USA to desist from pressurizing India for amending its patent law.²⁶

The provisions of the Patents Act, 1970 which are subject of debates, disputes and controversial and contradictory views, both criticizing and appreciating, are being dealt with in this context.

Section 83: General Principles Applicable to Working of Patented Inventions

India has incorporated in the Patent Act, Section 83, which is in the form of a preamble to the Chapter on Compulsory Licensing, having the title 'General principles applicable to working of patented inventions'. Section 83 is the over-riding legislative policy and the key to decoding various provisions contained in Chapter XVI of the Act. These 'general considerations' under sub-sections (a) to (g) of Section 83 are very significant to appreciate the philosophy ingrained in the Indian Patent Law. The provisions under Section 83 have been widely acclaimed and are an inherent part of Indian Patent Law ever since 1970 and have continued, as such, post-1995.

Under Section 83(e), there is specific reference to the right of 'Central Government in taking measures to protect public health', which is in line with the

directive principles of state policy under Article 47 of the Constitution of India, which states that it is the, 'duty of the State to raise the level of nutrition and the standard of living and to improve public health'.

The essence of Doha Declaration is also reflected in Section 83(g) which states that the benefit of patented invention should be made available at reasonably affordable prices to the public. The spirit of TRIPS in Article 7, Article 8(1) and Article 8(2) is reflected in Section 83(c), Section 83(d) and Section 83(f), respectively, of the Patents Act, 1970.

The current practice of abuse of patent rights through patent trolls³ is also foreseen and forbidden through Section 83(b) and Section 83(f). While there is no known pharma related patent troll cases in India, probably, the first known and publicized case of patent troll in India is that of Somasundaram Ram Kumar and a second one is that of Bharat Bhogilal Patel. Though these are not pharma related cases, it may be worthwhile to discuss these two cases in brief, to understand the strategies employed by the two.

Somasundaram Ram Kumar who was granted an Indian patent no 214388 for dual sim mobiles sought to obtain royalty of around Rs 35 for every dual sim mobile handset imported into India. Ram Kumar not only registered his patent with the Indian Customs authorities to enforce the Indian patent under Intellectual Property Rights (Imported Goods) Enforcement Rules, 2007, but also filed a suit²⁷ in the Madras High Court for patent infringement and ex-parte injunction, which was granted on 23 March 2009. Thereafter, Ram Kumar served notice around April 2009 on the Central Excise Department, Noida, asking the authorities to cancel manufacturing licence granted to Samsung India Pvt Ltd. These antics were put to end when the patent was revoked²⁸ by the Hon'ble IPAB on separate revocation petitions filed by Spice Mobiles Ltd and Samsung India Electronics Pvt Ltd. In the Bharat Bhogilal Patel case, Bharat Bhogilal Patel was granted two Indian patents nos, namely, IN189027 and IN188787. He too sought to restrain the import of goods into India which infringed his patents. By way of order dated 12 June 2012, the Hon'ble IPAB revoked²⁹ the two patents pursuant to a revocation petition filed by Aditi Manufacturing Co.

There are a large number of on-going pharma related frivolous litigations in various High Courts in India. Even though, these cannot be typically classified as litigations initiated by PAEs, the subject

matter such as Patent-Regulatory Linkage, potential threat of infringement and data exclusivity, which are already decided in earlier cases at the Single Bench of Delhi High Court³⁰, the Division Bench of Delhi High Court³¹ as well as Supreme Court³², these protracted litigations appear to have the same intention like PAEs, especially since the plaintiffs in these cases are not 'working' their patents in India.

Section 146: Working of Patents and Form 27

Section 146 of the Patents Act, 1970 provides power to the Controller to call for information from patentees regarding working of the patent and to provide a statement as to the extent to which the patented invention has been worked on a commercial scale in India. This section is further supported by Rule 131 which prescribes filing of information about working of patents in prescribed Form 27, in every calendar year within three months of the end of each year.

It is to be noted that 'not working the invention' in India is not a punishable offence. Not filing a return under Section 146(2) and Rule 131 in Form 27 is a punishable offence with fine under Section 122(1)(b). Moreover, furnishing information or statement which is false, and which the patentee either knows or has reason to believe to be false or does not believe to be true, the patentee is liable to be punished with imprisonment which may extend to six months, or with fine, or with both under Section 122(2).

Section 146 is in line with Section 83(a) of the Patents Act which states 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'

Further, Section 83(b) states that

'Patents are not granted merely to enable patentees to enjoy a monopoly for importation of the patented article'.

Section 146 is also in line with Article 31 of TRIPS titled 'Other use without Authorization of the Right Holder' and Article 5(A) of the Paris Convention titled 'Patents: Importation of Articles; Failure to Work or Insufficient Working; Compulsory Licenses'. Specifically, Article 5(A)(2) of the Paris Convention states that,

‘Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work’.

The Hon’ble Controller General of Patents, Designs and Trademarks (CGPDTM) in the order³³ granting compulsory licence for Sorafenib in Paragraph 12 titled ‘Patented invention not worked in the territory of India’ has expounded that mere importation cannot amount to working of a patented invention. The Hon’ble CGPDTM further explained that a patentee can achieve the balance of rights with the obligations when the patented invention is either manufactured in India or a licence is granted to any other person for manufacturing in India. The Hon’ble CGPDTM was of the view that ‘worked in the territory of India’ implies manufactured in India to a reasonable extent so that the principles enumerated in Section 83 can be brought into effect. In the absence of manufacturing in India, Section 83 will be a dead letter’. The Hon’ble CGPDTM concluded by stating that ‘worked in the territory of India’ means ‘manufactured to a reasonable extent in India’.

In *Franz Xaver Huemer v New Yash Engineers*³⁴, an Austrian citizen sought to enforce his five patents, despite not working the same in India, thereby seriously affecting India’s market and economy. In the order, while dismissing the appeal filed by Franz Xaver Huemer, the Hon’ble High Court of Delhi relied on fundamental principles and precedents in England and the USA, wherein it was accepted that a patentee who does not put his patent for use by the public is not entitled to temporary injunction. The Court held that the plaintiff who has registered patents in India, but has not used them in India cannot, in equity, seek temporary injunction.

Recently, proposals have been mooted to get the Form 27 amended. Paris Convention and Article 27(1) of TRIPS have been quoted to even seek deletion of Section 146 and Rule 131. The patent trolls and PAEs are working overtime to get rid of the ‘working’ provision so that the condition of ‘patents not worked in India’ is not available for revocation under Section 85 of the Patents Act, 1970, as well as for not meeting the grounds of compulsory licence under Section 84 of the Patents Act, 1970. Amendments to Patents Act, 1970 with regard to Form 27 appears to be not warranted.

The need for these provisions is extremely high for pharmaceutical patents, to enable continued affordable access to essential medicines in India.

Section 84: Compulsory Licence to Person Interested

Section 84 of the Patents Act, 1970 is a laudable element in administering a balance of rights and obligations, especially relating to pharmaceuticals. The Hon’ble IPAB³⁵ in the order upholding the decision of the Hon’ble Controller General in the matter of compulsory licence granted for Sorafenib has observed in the introductory paragraph of the order that,

‘Compulsory licence’ is not an unmentionable word. Under a different name, it was there in the TRIPS too where it is called, ‘Other use without authorization of the right holder’. It has been there even in the Paris Convention of 1883 ‘to prevent abuse which might result from the exercise of exclusive rights’.

In paragraph 2 of the order, the Hon’ble IPAB furthers observes the perspective from which the Chapter of compulsory licence was introduced in the Indian Patents Act. The Ayyangar Report was relied on, which says that,

‘There is no uniformity in the economic problems which confront different countries at any time or even the same country at different periods of its history and account has therefore to be taken of the actual conditions in the matter of devising the precise adjustments which are needed to rectify the imbalance which the patent system is apt to produce if left uncontrolled’.

The intention of the lawmaker is clearly brought out by the Hon’ble IPAB³⁵ in the order upholding the decision of the Hon’ble Controller General in the matter of compulsory licence. The Hon’ble the IPAB has observed in paragraph 2,

‘Patent rights were created ‘not in the interest of the inventor, but in the interest of the national economy’, says the Report on the Revision of Patents Law by Shri Justice N Rajagopala Ayyangar (‘Ayyangar Report’), quoting from Michel on Principal National Patent Systems. The report also quotes from Patents and Designs Amendment Bill which says that the monopoly is granted to the benefit of trade and industry to enlist the cooperation of the capitalist in this endeavour to bring in new invention’.

Indian Patents Act provides the following important sections for compulsory licence to interested third party

qualifying for receiving the grant of compulsory licence. The grant of compulsory licence is based on fulfillment of the following three conditions:

Section 84(a): That the reasonable requirements of the public with respect to the patented invention have not been satisfied, or

Section 84(b): That the patented invention is not available to the public at a reasonably affordable price, or

Section 84(c): That the patented invention is not worked in the territory of India.

Section 84 further exemplifies the condition for validating the grounds including efforts to obtain voluntary licence. The first compulsory licence was granted in India for Nexavar (Sorafenib) to Natco Pharma Ltd in March 2012 under the provision of Section 84. The 2012 grant of compulsory licence to Natco for Nexavar (Sorafenib) has also been widely discussed and debated globally.

While there have been efforts for qualifying under Section 84(6) to be eligible for receiving compulsory licence, consequent to new strategies adopted by the patentee through protracted correspondence with no definitive rejection or grant of voluntary licence, no new compulsory licence has yet been granted. There are news reports stating that a second application for Dasatinib (Sprycel®) has been made by an Indian company, BDR Pharmaceuticals International Pvt Ltd at the Indian Patent Office.³⁶

The language of the provision of Section 84(6) also causes confusion when it is subjected to analysis minutely. The explanation to Section 84(6) (iv) has departed from the intention of the law makers. The wording of Section 84(6)(iv) is as follows, followed by the explanation.

Section 84(6)(iv) – ‘as to whether the applicant has made efforts to obtain a licence from the patentee on reasonable terms and conditions and such efforts have not been successful within a reasonable period as the Controller may deem fit’.

Explanation – For the purpose of clause (iv) ‘reasonable period’ shall be construed as a period not ordinarily exceeding a period of six months.

The intention of law-makers was not to restrict ‘such efforts’ to be done within six months of the completion of three years from the date of grant of patent. The intention of the law-maker was to give sufficient time to work the invention by patentee after grant of patent.

A third party who is interested in compulsory licence should be free to approach patentee for

voluntary licence after grant of patent and within the validity of patent. Restricting reasonable period’ to ‘not ordinarily exceeding a period of six months’ was not the intention of law-makers. However, the law-makers have clearly provided flexibility. This inbuilt flexibility was probably intended to be used by the Controller to grant compulsory licence within a reasonable period. More on ‘reasonable period’ and ‘reasonably’ is dealt with elsewhere.

Section 92: Compulsory Licence on notification by Central Government

Section 92 provides special provision for compulsory licences (CLs) on notifications by Central Government under a circumstance of national emergency or extreme urgency or public non-commercial use. There have been extensive reports that the Commerce Ministry (DIPP) proposed to grant a CL under this provision to molecules such as Trastuzumab, Ixabepilone and Dasatinib. However, considering the very restrictive nature for qualifying under this provision, the Government appears to have developed cold feet for continuation with their proclamation of grant of CL.

In the midst of plethora of injunctions, infringement suits and counterclaim for revocations, Roche appears to have the last laugh on Herceptin® (Trastuzumab). While India was planning to grant a compulsory licence based on Section 92, Roche strategically opted not to renew the Indian patent no 205534 granted for Trastuzumab in India. Since the patent has ceased on 3 May 2013, anyone is free to launch a generic version of Herceptin® (Trastuzumab) in India. However, considering the complex nature of the molecule and the biological process of synthesis involved as well as the limitations of the regulatory agencies in approving biosimilars, an Indian manufacturer of generic Trastuzumab appears not to be in sight, in the immediate future. Indian biosimilar manufacturers must get together and jointly work to bring a biosimilar version of Herceptin® (Trastuzumab) to the market by meeting the regulatory yardsticks and by seeking fast track approvals.

Section 92A: Compulsory Licence

Section 92A of the Patents Act, 1970 finds its origin in the Millennium Development Goals (MDGs).³⁷ Under MDGs, it has been acknowledged that special provisions will have to be made for combating HIV/AIDS, malaria, and other diseases in developing and least developing countries. This leads to Doha Declaration, where it has

been unanimously acknowledged that every country is free to establish its own regime/statute for facilitating affordable access to essential medicines. However, Para 6 of Doha Declaration has authorized WIPO to frame procedures for grant of CL for manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector. However, very stringent procedures proposed in the subsequent WIPO forum proved to be incapable of meeting the objectives of Doha Declaration. This was a case in Canada, where despite no opposition from the patentee (Apotex) there was procedural delay of 2 years for export of Apo-TriAvir (a triple combination of Zidovudine, Lamivudine & Nevirapine used to treat HIV/AIDS) to Rwanda in 2008 under CAMR (Canada's Access to Medicines Regime). However, under Section 92A, India has made a relatively simpler procedure for granting CL for manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector to address public health problems.

Section 47, Section 100 and Section 101: Government Use

The Indian Patents Act provides sovereign immunity against infringement of patent, when the patents are worked for 'government use'.

Section 47 of the Patents Act states that patent process, patented medicine, drug, machine, apparatus or other article may be imported or made by or on behalf of the Government for the purpose 'merely of its own use'.

While Section 100 gives power to Central Government to use inventions for 'purposes of government', Section 101 states the rights of third parties in respect of use of invention for purposes of government.

The provisions of Section 47 and Section 99 to Section 100 for government use of patented inventions were put to test in India in *Garware Wall Ropes Ltd v A I Chopra and Konkan Railway Corp Ltd*.³⁸ It was held that under Section 99 and Section 100 even a third person i.e. contractor can be allowed to use the patent for the purposes of government or government undertakings. However, the use of patented invention was subject to an agreement or licence given by the patentee or payment of royalty, etc. In deciding this issue, the Hon'ble Bombay High Court made it clear that the Central Government or State Government are not entitled to use a patent free of cost for any other purposes than 'merely of its own use' i.e. for performing

the governmental functions by the government servants or government departments in performance of their duties or in the discharge of their duties.

A similar provision, under 28 USC 1498, exists in USA wherein 'the use or manufacture of an invention described in and covered by a patent of the United States by a contractor, a subcontractor, or any person, firm, or corporation for the government and with the authorization or consent of the government, shall be construed as use or manufacture for the United States'. In cases where a patented invention is used or manufactured by or for the United States without licence from the owner thereof or the third party has no lawful right to use or manufacture the same, the patentee can seek remedy by action against the US in the US Court of Federal Claims. This US provision basically insulates third parties who act as government contractors from liability.

Where does the 'government use' provision find its legal sanctity? Article 44(2) read with Article 31(h) of TRIPS provides for such government use of patented inventions.

However, Government of India has not invoked Section 100 and 101 of Patents Act, 1970 for making available generic versions of patented medicines economically and affordably for distribution through government owned cancer hospitals, defence hospitals, Employees' State Insurance Corporation of India (ESIC) and other government sponsored health projects.

Section 3: Inventions not Patentable

India has explicitly put down specific grounds to unambiguously clarify 'What are not inventions' under Section 3 of the Patents Act. Whether Section 3 comes after Section 2(1)(j) and 2(1)(j)(a) (patentability criteria – what are inventions and what is inventive step) or before, during examination, is not the question. Section 3 provides the needful and just (natural justice) exceptions to patentability. It is indeed surprising that Section 3 of the Patents Act, 1970 is now subject of renewed criticism. The crescendo has reached a new high pitch after the Gleevec judgment by the Supreme Court of India.

It is an acknowledged fact that sovereign states like India are free to determine the threshold for patentability, territorially. Member states signatory to TRIPS have been allowed to retain flexibilities and important policy options, and are free to determine the appropriate method of implementing provisions of TRIPS Agreement within their own legal system and practice in order to safeguard interest of the country.

Article 27 of TRIPS states what is ‘patentable subject matter’, while at the same time providing flexibility to member countries to exclude from patentability inventions which are necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health to avoid serious prejudice to the environment. Patentability criteria, as such, are not dictated by TRIPS. Indian Parliament has, in the best public interest, not only retained the subsections of Section 3(a) to Section 3(o) but also introduced Section 3(p) to protect traditional knowledge.

With regard to Section 3(d), the Parliament deemed it essential to amend Section 3(d) to incorporate an explanation of a ‘known substance’ under this section as follows.

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.

It is worthwhile to note that Section 3(d) finds its origin in Article 10(2)(b) of European Drug Regulatory Directive, 2004 wherein a ‘generic medicinal product’ is defined as:

‘a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies. *The different salts, esters, isomers, mixtures of isomers, complexes or derivatives of an active substance*

shall be considered to be the same active substance, unless they differ significantly in properties with regard to safety and/or efficacy. In such cases, additional information providing proof of the safety and/or efficacy of the various salts, esters or derivatives of an authorized active substance must be supplied by the applicant.’

As per the definition of ‘generic medicinal product’ under Article 10(2)(b) of European Drug Regulatory Directive, 2004, different salts, esters, isomers, mixtures of isomers, complexes or derivatives of an active substance are considered to be the same active substance, unless they differ significantly in properties with regard to safety and/or efficacy.

Introducing this Explanation to Section 3(d) in the Parliament, the lawmakers made their intention abundantly clear, that is, to curb ever greening. However, it is pertinent to note that Section 3(d) does not entirely prohibit the grant of patents which seek to claim/protect new form of a ‘known substance’. Patents have been granted in India for new form of a ‘known substance’ when ‘efficacy’ is proved. Few examples of patents which have overcome the objection under Section 3(d) are listed in Table I.

The need for ‘enhanced efficacy’ interpreted as ‘therapeutic efficacy’ in a known substance to qualify for patentability as provided in the Section 3(d) of the Patents Act, 1970 has not only been upheld at the Hon’ble IPAB³⁹ but also by the Hon’ble Madras High Court⁴⁰ as well as the Hon’ble Supreme Court. The Hon’ble Supreme Court’s Order⁴¹ on Gleevec between Novartis and Cipla & others created global impact equaling or even surpassing the recent Myriad Gene case. The important element of the Supreme Court judgment needs to be highlighted to appreciate the order. In paragraph 156, their Lordships observed as follows,

Table I—Patents which have overcome the objection under Section 3(d)

Indian Patent No	Title of the invention	Patentee
223589	A crystalline polymorph of an Epothilone analog of Formula I	Bristol-Meyers Squibb Co
223767	Indolylakylamine derivatives	Wyeth
223849	8-Azabicyclo [3.2.1.] Octane-3-Methanamine derivatives compounds	Sanofi-Synthelabo
224394	Amorphous ammonium salt of Eprosartan	Smithkline Beecham Corporation
225283	Crystal of Diuridine Tetraphosphate or salt thereof and method for preparing the same, and method for producing said compound	Yamasa Corporation
239408	Novel Tyrosine derivatives	Orchid Research Laboratories Ltd
242111	Crystalline Clopidogrel Besylate and process for preparation thereof	Cadila Healthcare Limited
254576	Morpholine derivatives as Norepinephrine Reuptake inhibitors	Eli Lilly and Company Limited
254839	Polymorphic forms of Rifaximin, processes for their production and use thereof in medicinal preparations	Alfa Wassermann S P A
254845	Prodrugs containing novel bio-cleavable linkers	Piramal Enterprises Limited
254845	Prodrugs containing novel bio-cleavable linkers	Piramal Enterprises Limited
255388	Novel crystalline polymorphic form of a Camptothecin analogue	Cipla Limited

‘We certainly do not wish the law of patent in this country to develop on lines where there may be a vast gap between the coverage and the disclosure under the patent; where the scope of the patent is determined not on the intrinsic worth of the invention but by the artful drafting of its claims by skillful lawyers, and where patents are traded as a commodity not for production and marketing of the patented products but to search for someone who may be sued for infringement of the patent.’

Obviously, the observation was that India ‘should not be converted into a patent battlefield’ like USA & Europe, with never-ending litigations to seek perennial patenting or better known as ‘evergreening’ of patents. The court further observed that holding Section 3(d) valid, or rejecting patents for new form of known substances without enhanced efficacy, does not mean that incremental innovations are not patentable. An analysis of pharmaceutical patents granted in India post-2005, clearly indicates that 90% of all pharma patents granted in India are for incremental innovations.

Evergreening

The Hon’ble Supreme Court has, further, rightly criticized ‘evergreening’. Evergreening is the art of extending the life of a parent patent by introducing minor physical improvements or label claims in the guise of incremental (often frivolous) innovations. In USA, when the evergreened patents are used to extend the life of an OB (Orange Book) listed Reference List Drug (RLD), the innovator or his licensee is able to sue a generic applicant for a much longer period, delaying the generic launch and adding to the litigation woes and costs.

The Hon’ble Madras High Court⁴⁰, in the Gleevec case, had observed,

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

In a recent article⁴², the impact of evergreening has been highlighted. The Table 2 compiled, from patent information available from the Australian Patent Office has been used to show the extent to which evergreening extends the patent protection to a blockbuster molecule.

This extension is at an enormous cost to the patient population who are denied affordable access to the generic versions of these molecules for almost double the time-period prescribed under the patent statute. It is further reported that a recent European Commission study demonstrated that evergreening patents interfere and hinder fair competition in the pharmaceutical market. The Federal Trade Commission (FTC) of USA has also been fighting to prevent unfair deals to delay generic launches.

In fact, while, Mr Gopal Subramaniam, the senior advocate appearing for the Novartis in the Gleevec case stated that ‘Section 3(d) is *ex majore cautela*’, it can be summarized and interpreted that the explanation in Section 3(d) introduced on the floor of the House in the Indian Parliament prior to passing the Third Amendment Bill (leading to the third amendment effective 1 January 2005 to the Patents Act, 1970), was itself a ‘*ex majore cautela*’ (by way of abundant caution) to prevent ‘evergreening’.

Medicine Patent Pool

As against patent troll, Medicine Patent Pool (MPP) is taking slow but steady strides. A patent pool

Table 2— List of blockbuster molecules with extended patent protection by evergreening

Case study	Rank	Generic name	Proprietary trademark	Maximum period of patent protection
1	8	Clopidogrel	Plavix, Coplavix, Dualplavix, Duocover	38 yrs 7 months 11 days
2	6	Venlafaxine, Desvenlafaxine	Efexor, Efexor-XR, Pristiq	39 yrs 8 months 13 days
3	13	Atorvastatin	Lipitor, Caduet	33 yrs 7 months 1 day
4	12	Alendronate	Fosamax, Fosamax Plus D-Cal	36 yrs 5 months 17 days
5	4	Cefuroxime	Fortum, Zinnat	43 yrs 7 months 16 days
6	11	Zoledronic Acid	Zometa, Aclasta	36 yrs 9 months 29 days
7	3	Citalopram, Escitalopram	Cipramil, Lexapro	46 yrs 7 months 8 days
8	1	Omeprazole, Esomeprazole	Losec, Prilosec, Nexium	48 yrs 27 days
9	15	Rosuvastatin	Crestor	27 yrs 10 months
10	7	Risedronate	Actonel, Actonel E.A.T. Combi	39 yrs 3 months 26 days
11	9	Nevirapine	Viramune, Viramune XR	37 yrs 11 months 8 days
12	2	Fexofenadine	Telfast	46 yrs 8 months 18 days
13	5	Lansoprazole	Zoton	40 yrs 4 months 14 days
14	10	Meloxicam	Mobic	36 yrs 11 months 3 days
15	14	Olanzapine	Zyprexa	31 yrs 3 months 2 days

is a way of facilitating access to intellectual property.⁴³ Patent pool enables two or more entities to voluntarily share their intellectual property and to licence their technologies.

MPP endeavors to increase access of affordable HIV medicines. The well balanced MPP takes care of the inventor's and assignee's interest as well as potential licensee's interest including that of public interest.

One of the earliest patentee-licensor in the MPP was Gilead. However, Gilead's offer under MPP was restrictive in nature, since (i) the manufacturing was restricted only to India, (ii) APIs had to be bought from Gilead or licensees of Gilead and (iii) the agreement excluded HIV patients living in middle and lower-income countries.

Recently, it has been reported that Roche will execute an agreement with MPP to make Valganciclovir (Valcyte®) affordable. However, it is pertinent to note here that the product claims in Indian patent for Valganciclovir were revoked⁴⁴ pursuant to a post-grant opposition.

There is potential for Indian companies to contribute to patent pools for overseas licensing. However, the licensing agreement will need to ensure that they are not in violation of Section 140 of the Patents Act, 1970.

Pharma R&D and Patenting in India post 2005

The trend of pharmaceutical patent filings and grant which is indicative of the increasing interest and investment in pharmaceutical R&D in India has been dealt with in an earlier article by the present authors.¹⁶ The R&D trends and patenting trends described in the article continues with New Drug Delivery System (NDDS), synergistic combinations, new processes for API's & formulations and herbal research.

According to Thompson Reuters the '2013 State of Innovation India Report'⁴⁵ reveals that pharmaceuticals are on the top of the chart⁴⁶ of patent filings. As per Bob Stemberge, senior patent analyst, Thompson Reuters, 'This year's report confirms the powerhouse India has become in the pharmaceutical sector, as more drug manufacturing, especially for generics, occurs here. There were more than 1,000 inventions related to organic pharmaceuticals in the year 2012, and this pace is expected to continue in the future.'⁴⁷

Ranbaxy has been granted a fixed dose combination (FDC) for arterolane maleate (150 mg) and piperazine phosphate (750 mg) drug, marketed as Synriam. Biocon has come up with a new drug,

Alzumab which is the first in its class globally developed through biological process for the treatment of psoriasis. Cadila Pharmaceuticals has recently launched a new lung cancer drug, Mycidac-C injection for treatment of Non Small Cell Lung Cancer (NSCLC). Biocon has come up with a new drug, Alzumab which is the first in its class globally developed through biological process for the treatment of psoriasis. Another Indian company, Zydus Cadila has launched a new class of anti-diabetic drug, Saroglitazar branded as Lipaglyn in India. The transition from a purely generic pharma industry to innovative NCE/NME research based pharmaceutical manufacturers is visibly in progress though in its infancy. In spite, of the much debated Section 3(d) and other provisions for maintaining a higher TRIPS+ benchmark for patentability, patents granted for incremental innovations form a large percentage of patents granted in India.

Pharmaceutical Trademarks

A cursory glance at the data on trademarks indicate that pharmaceuticals comprise the largest class (14.1) along with multiple classes (7.2) amounting to about 22.3% of all the trademarks filed.

Quality of Indian Generic Medicines

The quality of Indian pharma has made great strides during the last 50 years. In the early stages of growth of Indian pharma, the criticism has been validly intensive on quality and bio-availability. Bioavailability has been a new concept in the 70's in India. By early 80's India not only managed to improve the quality but also commenced complying with bio-availability requirement especially with anti-biotics and other essential medicines. Most of the Indian multi-national pharma corporations commenced working with India on loan licences⁴⁸ and contract manufacturing. By early 90's many Indian generic pharma manufacturers commenced exports to regulated markets in preference to Third World Countries. The quality standards of Indian pharma benefited from their entrepreneurial initiatives to file increasing number of DMF's and ANDA's, and consequent inspections and advisories from agencies such as US-FDA, UK-MHRA, TGA and others. Over the years, the Indian DMF and ANDA filings as well as approvals of manufacturing facilities in India by US FDA and MHRA have substantially gone up. In Europe as well as in USA, every pharmaceutical company which is within the regulatory framework,

periodically receives notices, cautions and de-registrations till the concerned unit rectifies the deficiencies and convinces the regulatory authorities, once again. Such alerts and bans have been issued by US FDA lately against a few leading Indian pharma companies and more importantly against specific manufacturing sites. While the Indian pharma industry needs to gear up to improve their quality and cGMP diligence it may be noted that such actions are common, though not frequent against large pharma companies and manufacturing sites in USA and Europe also. A matter of serious concern however, is the standard and human resource infrastructure and regulatory expertise of Indian regulatory authorities, which needs extensive upgradation and calls for improved investment in infrastructure and logistics.

Conclusion

Having stood the test of time, with equitable balance of rights and obligations, the Indian Patent Law (Patents Act, 1970 and Patents Rules, 2003 as amended), provides a model for the rest of the world, especially post the Doha Declaration. The threshold for patentability for innovations in pharmaceutical and biotech field has been raised to prevent frivolous patenting as well as evergreening.

The additional patentability filters in Section 3 and more particularly, Section 3(d) has also contributed to restricting patentability to genuine inventions and to prevent 'evergreening' which is being globally recognized as an abuse of the monopoly in the patent statute. India has put to test the compulsory licensing provisions, which has drawn global attention with mixed responses. Judgments on patentability, patent validity and infringement status from the Supreme Court of India and High Courts as well as IPAB have been well received and acknowledged as world-class. The research and patenting trends as well as recent launches in India are showing the early signs of transition from a purely generic pharma to an innovative research based pharmaceutical industry.

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