The Indian Journal for Research in Law and Management
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Editor-in-Chief – Dr. Muktai Deb Chavan; Publisher – Alden Vas; ISSN: 2583-9896

PATENT LAW IN INDIA

An Overview of the Statutory Framework, Judicial Interpretation and Emerging Trends

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Abstract

Patent law occupies a pivotal place in India's intellectual property regime, seeking to balance the private incentive to innovate with the larger public interest in access to technology, medicine and knowledge. This article traces the evolution of patent law in India from the colonial-era Patents and Designs Act, 1911 to the present Patents Act, 1970, examines the statutory framework governing patentability, procedure and enforcement, and analyses the manner in which Indian courts have interpreted contentious provisions such as Section 3(d) and the compulsory licensing regime under Section 84. It concludes with a review of the 2024 procedural reforms and the challenges that continue to confront India's patent ecosystem.

I. Introduction

A patent is a statutory monopoly granted by the State to an inventor, conferring upon the patentee the exclusive right, for a limited period, to prevent others from making, using, selling, offering for sale or importing the patented invention without consent[1]. The rationale is essentially utilitarian: by rewarding disclosure of an invention with a time-bound exclusivity, the law encourages research and investment while ensuring that the invention ultimately enriches the public domain. In India,

[1] The Patents Act, 1970 (Act No. 39 of 1970), S.48 (India).

this bargain between the inventor and the State is codified primarily in the Patents Act, 1970, supplemented by the Patents Rules, 2003, as periodically amended.

India's patent regime has undergone a dramatic transformation since independence — from a process-patent-only, pro-generic framework designed to build domestic pharmaceutical and agrochemical capacity, to a TRIPS-compliant product-patent regime that today attempts to reconcile international obligations with constitutional commitments to public health and access to medicine. This article examines that trajectory and the doctrinal architecture that now governs patents in India.

II. Historical Evolution

A. The Colonial and Early Post-Independence Period

Patent protection in India can be traced to Act VI of 1856, modelled on the British patent system, which was subsequently replaced by the Patents and Designs Act, 1911. The 1911 Act permitted both product and process patents across all fields of technology, including food and medicine, a feature that, in the assessment of the Ayyangar Committee constituted in 1957, had allowed foreign multinational corporations to dominate the Indian pharmaceutical market through patent monopolies rather than local manufacture[2]. The recommendations of Justice N. Rajagopala Ayyangar's report formed the direct basis for the Patents Act, 1970, which came into force on 20 April 1972 and repealed the 1911 Act.

The 1970 Act deliberately excluded product patents for substances intended for use as food, medicine or drugs, permitting only process patents in these fields, with a shortened term of seven years from the date of filing (or five years from the date of sealing, whichever was earlier) as against the general term of fourteen years for other inventions. This design choice is widely credited with enabling the rapid growth of India's generic pharmaceutical industry over the following three decades.

[2] Report on the Revision of the Patents Law (Ayyangar Committee Report), Government of India, 1959; see also Statement of Objects and Reasons, Patents Act, 1970.

B. TRIPS and the Amendments of 1999, 2002 and 2005

India's accession to the World Trade Organization and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in 1995 obliged it to extend patent protection to all fields of technology, including pharmaceuticals and agrochemicals, within the transitional period available to developing countries[3]. This obligation was implemented through three successive amendments to the 1970 Act:

the Patents (Amendment) Act, 1999, which introduced a mailbox facility for receiving product patent applications in pharmaceuticals and agrochemicals and provided for Exclusive Marketing Rights pending the transition; the Patents (Amendment) Act, 2002, which extended the patent term uniformly to twenty years, introduced a new definition of 'inventive step', expanded the grounds for compulsory licensing, and reorganised the exclusions under Section 3; and the Patents (Amendment) Act, 2005, which, with effect from 1 January 2005, finally introduced product patents in all fields of technology and inserted the now-celebrated Section 3(d)[4], a provision unique to Indian law that curbs the practice of 'evergreening' by excluding mere new forms of known substances from patentability unless they demonstrate enhanced efficacy .

III. The Statutory Framework

A. Patentable Subject Matter and the Tests of Patentability

Section 2(1)(j) of the Patents Act, 1970 defines an 'invention' as a new product or process involving an inventive step and capable of industrial application. Three cumulative conditions therefore govern patentability in India: novelty (the invention must not form part of the state of the art, i.e., must not have been anticipated by prior publication or prior use anywhere in the world before the date of filing); inventive step, defined under Section 2(1)(ja) as a feature involving technical advance over existing knowledge, or having economic significance, and that makes the invention not obvious to a person skilled in the art; and industrial applicability under Section 2(1)(ac), meaning the invention is capable of being made or used in an industry.

[3] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, art. 27, 33.

[4] The Patents (Amendment) Act, 2005 (Act No. 15 of 2005), inserting § 3(d), Patents Act, 1970.

Even where these three conditions are satisfied, Section 3 excludes an extensive list of subject matter from patentability, including frivolous inventions, inventions contrary to public order or morality, mere discoveries of scientific principles or abstract theories, mere discoveries of new properties or new uses of known substances, methods of agriculture or horticulture, methods of medical, surgical, diagnostic or therapeutic treatment of human beings or animals, plants and animals in whole or in part other than micro-organisms, mathematical or business methods, computer programmes per se and algorithms, and traditional knowledge. Section 4 additionally bars the patenting of inventions relating to atomic energy.

B. Section 3(d) and the Novartis Litigation

Section 3(d), as it stands after the 2005 amendment, excludes from patentability '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', and deems salts, esters, ethers, polymorphs, metabolites, particle size, isomers and other derivatives of a known substance to be the same substance unless they differ significantly in properties with regard to efficacy[5]. The provision was inserted specifically to prevent the practice of 'evergreening', whereby pharmaceutical companies seek fresh, extended patent protection for trivial or incremental modifications of existing molecules.

The constitutional validity and interpretation of Section 3(d) were tested in Novartis AG v. Union of India, where the Madras High Court had earlier upheld the provision against a challenge of vagueness and inconsistency with Article 14 of the Constitution and the TRIPS Agreement[6]. The dispute reached the Supreme Court after the Intellectual Property Appellate Board rejected Novartis's patent application for the beta-crystalline form of imatinib mesylate, marketed as Glivec, an anti-leukaemia drug, on the ground that it was merely a new form of a known substance without demonstrated enhanced therapeutic efficacy. The Supreme Court, in its 2013 judgment, held that the appellant had failed to establish increased therapeutic efficacy over the known substance and affirmed that physicochemical properties such as improved bioavailability, flow characteristics or thermodynamic stability, without more, do not satisfy the enhanced-efficacy standard under Section 3(d) . The decision has since been treated as the definitive judicial statement

[5] The Patents Act, 1970, § 3(d) and Explanation thereto, as amended by Act No. 15 of 2005.
[6] Novartis AG v. Union of India, (2007) 4 MLJ 1153 (Madras HC, Division Bench).

on Section 3(d) and has been cited internationally as an example of a developing country calibrating its patent standards to safeguard public health while remaining compliant with TRIPS.

IV. Procedure for Grant of a Patent

The procedural pathway to the grant of a patent in India, governed by Chapters III to VI of the Act read with the Patents Rules, 2003, may be summarised as follows:

1. Filing of application. An application may be filed under Section 7 either as a provisional specification, to be followed by a complete specification within twelve months, or directly as a complete specification, accompanied by Form 1 and the prescribed fee, before the appropriate patent office having jurisdiction (Chennai, Delhi, Mumbai or Kolkata).

2. Publication. Under Section 11A, the application is ordinarily published in the Official Journal eighteen months after the priority date, or earlier on request, disclosing the invention to the public and opening the door to pre-grant opposition.

3. Examination. Substantive examination begins only upon a request for examination under Section 11B, which, following the Patents (Amendment) Rules, 2024, must now be filed within thirty-one months from the date of priority or filing, a reduction from the earlier forty-eight-month window intended to accelerate prosecution[7] . The Controller, assisted by an Examiner, issues a First Examination Report noting objections as to novelty, inventive step, sufficiency of disclosure, clarity of claims or the applicability of Sections 3 and 4.

4. Opposition. The Act uniquely provides for both pre-grant opposition under Section 25(1), which may be filed by any person at any time after publication and before grant, and post-grant opposition under Section 25(2), which may be filed by a person interested within twelve months of the date of publication of grant. The grounds available under both provisions substantially overlap and include lack of novelty, obviousness, insufficient disclosure, wrongful obtaining and non-patentability under Sections 3 and 4.

5. Grant and term. Once objections are resolved, the Controller grants the patent under Section 43, and it is thereafter entered in the Register of Patents maintained under Section 67. Under

[7] Patents (Amendment) Rules, 2024, G.S.R. 195(E), amending Rule 24B, Patents Rules, 2003 (reducing the period for filing a Request for Examination from 48 to 31 months).

Section 53, the term of every patent, whether granted for a product or a process, is twenty years from the date of filing of the application (or, for applications entering the national phase under the Patent Cooperation Treaty, twenty years from the international filing date).

6. Post-grant obligations. Section 146 obliges every patentee and licensee to furnish periodic statements of the commercial working of the patented invention in India through Form 27. Following the Patents (Second Amendment) Rules, 2024, this statement is now required only once for every block of three financial years rather than annually, easing what had become a significant compliance burden on patentees [8].

V. Rights of the Patentee and Compulsory Licensing

Section 48 confers on the patentee the exclusive right to prevent third parties from making, using, offering for sale, selling or importing the patented product, or, in the case of a process patent, from using the process or dealing in the product directly obtained by that process, without the patentee's consent. These are negative rights of exclusion rather than a positive right to work the invention, and they are subject to statutory limitations, including the research and experimental-use exemption under Section 47, the Bolar-type exemption for regulatory submissions under Section 107A, and provisions for parallel importation.

The most significant limitation on patent exclusivity is the compulsory licensing regime under Sections 84 to 92, which reflects the constitutional and TRIPS-consistent recognition that patent rights must yield to public interest in defined circumstances. Under Section 84(1), any person interested may, after three years from the date of grant, apply for a compulsory licence on the ground that the reasonable requirements of the public with respect to the patented invention have not been satisfied, or that the patented invention is not available to the public at a reasonably affordable price, or that the patented invention is not worked in the territory of India.

India's first, and to date most significant, compulsory licence was granted in *Natco Pharma Ltd. v. Bayer Corporation,* concerning Bayer's patented anti-cancer drug sorafenib tosylate, marketed as Nexavar. The Controller of Patents, in an order dated 9 March 2012, granted Natco a compulsory licence on the ground that Bayer had failed to make the drug available to the public at a reasonably

[8] Patents (Second Amendment) Rules, 2024, amending Rule 131(2), Patents Rules, 2003; The Patents Act, 1970, § 146.

affordable price and had not worked the invention in India to an adequate extent[9] . The order was upheld by the Intellectual Property Appellate Board and, subsequently, by the Bombay High Court, which held that the requirement of 'working' the invention in India under Section 84(1)(c) is to be assessed case-by-case and is not to be read as an inflexible requirement of local manufacture in every instance[10]. The decision remains the principal precedent on the compulsory licensing provisions and is frequently cited in debates on balancing pharmaceutical patent rights against access to affordable healthcare.

VI. Infringement, Remedies and Judicial Approach

A suit for infringement lies under Section 104 before a district court or, where the value of the suit exceeds the pecuniary threshold, before the High Court exercising ordinary original civil jurisdiction, subject to the 2021 transfer of jurisdiction from the erstwhile Intellectual Property Appellate Board to the High Courts following the Tribunals Reforms Act, 2021. Reliefs available under Section 108 include a permanent injunction, damages or an account of profits, and delivery-up or destruction of infringing goods. A defendant may raise, by way of counter-claim, the invalidity of the patent under Section 64, and revocation may equally be sought as an independent proceeding.

The Supreme Court's decision in *Bajaj Auto Ltd. v. TVS Motor Co. Ltd*., arising from a dispute over twin-spark-plug engine technology used in motorcycles, is notable less for its substantive findings on infringement than for the procedural directions it issued: expressing concern at the prolonged pendency of patent, trademark and copyright disputes in Indian courts, the Court directed that all such suits be disposed of on a priority, day-to-day basis, and that interlocutory matters not be allowed to substitute for a final trial on the merits [11]. The judgment continues to be cited for its emphasis on the need for expeditious adjudication of intellectual property disputes in India, an area in which delay has historically undermined the practical value of patent rights.

In assessing infringement, Indian courts have generally applied the doctrine of pith and marrow together with a purposive construction of claims, examining whether the essential or novel features

[9] Natco Pharma Ltd. v. Bayer Corporation, Compulsory Licence Application No. 1 of 2011, Order of the Controller of Patents dated Mar. 9, 2012.
[10] Bayer Corporation v. Union of India, Writ Petition No. 1323 of 2013, Bombay High Court, decided Jul. 15, 2014; affirming the order of the Intellectual Property Appellate Board dated Mar. 4, 2013.
[11] Bajaj Auto Ltd. v. TVS Motor Co. Ltd., (2009) 9 SCC 797.

of the patented invention have been taken by the defendant, rather than confining the enquiry to a textual or literal comparison of claim language[12]. Interim injunctions in patent suits are granted applying the conventional triple test of prima facie case, balance of convenience and irreparable injury, tempered in pharmaceutical patent cases by heightened judicial caution where public health considerations, such as the availability of a life-saving drug, are implicated.

VII. Recent Developments

The Patents (Amendment) Rules, 2024, notified on 15 March 2024, mark the most significant procedural overhaul of the patent regime since 2016. In addition to shortening the timeline for requesting examination, the Rules introduced a certificate of inventorship, permitted 'divisionals of divisionals' applications, relaxed the requirement of filing details of corresponding foreign applications by allowing periodic updated statements instead of continuous disclosure, introduced a grace period mechanism under Rule 29A read with Section 31 for inventions previously disclosed at recognised learned societies or exhibitions, and offered a ten per cent fee discount for renewal fees paid in advance for at least four years through electronic mode[13]. A further Patents (Second Amendment) Rules, 2024 recalibrated the periodicity of the Form 27 working statement from an annual to a triennial requirement. Collectively, these reforms are aimed at reducing the pendency of applications, easing compliance costs, and improving India's standing on international indices of patent-filing efficiency, while leaving the substantive patentability standards under Sections 3 and 84 untouched.

VIII. Challenges and Concluding Observations

Despite these reforms, several structural challenges persist. The pendency of patent applications and disputed matters, though reduced, remains higher than in comparable jurisdictions; the transfer of appellate patent jurisdiction from the Intellectual Property Appellate Board to the High Courts has produced inconsistent practice across benches pending the development of settled procedure; the scope of patentability of computer-related and artificial-intelligence inventions under Section 3(k) continues to generate divergent outcomes at the examination stage; and the tension between

[12] See Raj Prakash v. Mangat Ram Chowdhry, AIR 1978 Del 1; Bishwanath Prasad Radhey Shyam v. Hindustan Metal Industries, (1979) 2 SCC 511.

[13] Patents (Amendment) Rules, 2024, G.S.R. 195(E), notified Mar. 15, 2024, Ministry of Commerce and Industry, Government of India.

robust patent protection, as sought by innovator industries, and affordable access to medicines, as mandated by public health imperatives, remains an enduring feature of Indian patent policy, as the Novartis and Bayer litigation illustrate.

Patent law in India today reflects a deliberate and, on the whole, judicially endorsed attempt to reconcile India's TRIPS obligations with its constitutional commitments to public health and technological self-reliance. The jurisprudence developed in Novartis and Bayer v. Natco, together with the procedural streamlining introduced through the 2024 Rules, suggests a regime that is maturing rather than static — one that continues to draw upon both domestic constitutional values and international best practice as it evolves to meet the demands of a rapidly changing innovation landscape.