PATENTABILITY STANDARDS FOR BIOTECHNOLOGICAL AND PHARMACEUTICAL INVENTIONS

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ABSTRACT

This chapter examines the patentability standards governing biotechnological and pharmaceutical inventions under Indian patent law, with comparative reference to the legal frameworks of the United States and the European Union. It begins by interrogating the conceptually fraught distinction between discovery and invention as applied to modern biological subject matter including isolated gene sequences, genetically modified organisms, and pharmaceutical derivatives and traces the statutory architecture through which Indian law navigates this distinction. Central to the analysis is Section 3 of the Patents Act, 1970, particularly Sections 3(b), 3(c), and 3(j), which together establish a multi-layered exclusionary framework for biological and pharmaceutical inventions. The chapter gives sustained attention to Section 3(d) India's globally unique efficacy threshold for new forms of known pharmaceutical substances and provides a detailed analysis of the Supreme Court's landmark ruling in *Novartis AG v. Union of India* (2013), which authoritatively interpreted "efficacy" to mean therapeutic efficacy and affirmed Section 3(d)'s compatibility with the TRIPS Agreement. Post-*Novartis* doctrinal developments, including the evolving evidentiary standards and the growing role of pre-grant opposition as a civil society instrument, are also examined. The chapter situates Indian law within broader debates on TRIPS flexibilities, access to medicines, and the governance of agricultural biotechnology.

The Conceptual Difficulty: Discovery versus Invention in Modern Biology

The application of patent law's foundational distinction between discovery and invention to the subject matter of modern biology is among the most intellectually challenging and practically consequential questions in all of intellectual property law. Classical patent doctrine holds that discoveries of natural phenomena are not patentable, however remarkable or effortful the act of discovery: the properties of a mineral compound, the gravitational constant, or the sequence of a gene as it exists in a living organism are features of the world that pre-existed the discoverer and cannot be treated as the product of inventive human effort merely because considerable ingenuity and resource were required to uncover them.[1] Inventions the application of human creativity to bring into existence something that did not previously exist, or to put what previously existed to a new and useful purpose are the proper subject of patent protection.

In the realm of modern biology, however, this distinction becomes structurally ambiguous in ways that classical patent doctrine was not designed to address. Consider a gene sequence isolated from a naturally occurring organism and characterised as encoding a protein with pharmaceutical activity. The sequence pre-existed in the organism's genome; its isolation and characterisation required substantial intellectual and material effort; its utility was not previously known. Is this a discovery the sequence was always there or an invention, in the sense that the isolation, purification, and determination of utility represent genuine creative contribution that the patent system should recognise? Different legal systems have reached different answers at different times, and the trajectory in both the United States and the European Union has been one of gradual restriction following an initial period of expansive gene patenting whose excesses generated sustained scholarly, judicial, and legislative reaction.[2]

In the United States, the Supreme Court's decision in Association for Molecular Pathology v. Myriad Genetics (2013) held that naturally occurring DNA sequences are not patentable as products of nature even when isolated from the genome, while complementary DNA produced by reverse transcription remains patentable. The earlier decisions in Mayo

[1] . Michael Heller and Rebecca Eisenberg, "Can Patents Deter Innovation? The Anticommons in Biomedical Research" (1998) 280 Science 698, 699

[2] . Arti Rai and Bhaven Sampat, "Accountability in Patenting of Federally Funded Research" (2012) 30(6) Nature Biotechnology 953, 954

Collaborative Services v. Prometheus Laboratories (2012) and Alice Corporation v. CLS Bank International (2014) established a two-step analytical framework significantly restricting the patentability of inventions incorporating natural phenomena, including molecular diagnostic and personalised medicine innovations. In the European Union, the Biotechnology Directive (Directive 98/44/EC) and the implementing Rules of the European Patent Convention permit patents for biological material isolated from its natural environment or produced by a technical process, provided that industrial application is disclosed.[3]

The Statutory Framework: Section 3 Exclusions

The Patents Act, 1970 addresses biotechnological and pharmaceutical subject matter through a combination of inclusionary definitions and exclusionary provisions. The inclusionary side is established by Section 2(1)(j), which defines an "invention" as "a new product or process involving an inventive step and capable of industrial application." The exclusionary side is set out comprehensively in Section 3, which enumerates what shall not be regarded as inventions within the meaning of the Act. Several clauses of Section 3 are directly and practically relevant to biotechnological and pharmaceutical subject matter.[4]

Section 3(b) excludes from patentability inventions whose primary or intended use or commercial exploitation would be contrary to public order, morality, or which would cause serious prejudice to human, animal, or plant life or health, or to the environment. This provision operates analogously to the ordre public exception in Article 53(a) of the EPC and Article 27(2) of TRIPS, and has been invoked in the context of genetically modified organisms, particularly in applications relating to Bt transgenic crops.[5]

Section 3(c) excludes "the mere discovery of a scientific principle or the formulation of an abstract theory or discovery of any living thing or non-living substance occurring in nature." The phrase "occurring in nature" has been a focus of considerable interpretive attention in the context of biotechnological patent applications. The Indian Patent Office has generally taken the position reflected in the 2013 and 2016 Examination Guidelines that isolated and characterised biological molecules, including proteins and DNA sequences, fall within Section

[3] . Association for Molecular Pathology v. Myriad Genetics, 569 US 576 (2013); Directive 98/44/EC [1998] OJ L 213/13, Art 3.
[4] . The Patents Act, 1970 ss 2(1)(j) and 3; IPO, Manual of Patent Office Practice and Procedure (revised 2019) 52-68.
[5] . IPO Examination Guidelines for Biotechnology Applications (2016) para 3.2.

3(c) unless the applicant demonstrates sufficient human intervention to move the claim from discovery to invention. This approach is broadly convergent with the post-Myriad position in the United States.[6]

Section 3(j) is the most directly applicable provision for the biotechnology sector. It excludes "plants and animals in whole or any part thereof other than microorganisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals." This provision pursues several distinct policy objectives simultaneously. The exclusion of plant varieties from patent protection reflects a deliberate legislative choice to channel protection through the specialised sui generis system established by the Protection of Plant Varieties and Farmers' Rights Act, 2001 designed specifically to accommodate the interests of both commercial plant breeders and subsistence farmers.[7] The exclusion of essentially biological processes tracks the analogous provision in Article 53(b) of the EPC.

Microorganisms are explicitly excluded from Section 3(j)'s prohibition, which aligns with the minimum standard established by TRIPS Article 27(3)(b). However, the patentability of microorganisms is circumscribed by the requirement operative since India's accession to the Budapest Treaty in 2001 that novel microorganisms must be deposited with a recognised depositary authority as a condition of sufficient disclosure, reflecting the practical impossibility of adequately disclosing living, replicating biological matter through written description alone.[8]

Microorganisms, the Budapest Treaty, and Biological Disclosure

The Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, concluded in 1977, established a system under which the deposit of a microorganism with any one of the Treaty's recognised International Depositary Authorities is treated as sufficient for purposes of the disclosure and accessibility requirements of all member states. India acceded to the Treaty on 17 December 2001, designating the Microbial Culture Collection (MCC) at Pune and the Institute of Microbial Technology (IMTECH) at Chandigarh as its national depositary authorities. The

[6] . IPO Examination Guidelines (n 31) para 3.1
[7] . Protection of Plant Varieties and Farmers' Rights Act, 2001 (No. 53 of 2001), Preamble; TRIPS Art 27(3)(b)
[8] . Budapest Treaty on the International Recognition of the Deposit of Microorganisms, 1977, Art 1

Treaty operates as a significant procedural complement to the substantive patentability standards of Section 3.[9]

The practical operation of the Budapest Treaty requirement in Indian patent prosecution raises several doctrinal questions that have not been definitively resolved. The timing of the deposit obligation, whether the deposit must precede the filing date or can be made subsequently, has practical significance for applicants who discover the invention in a form requiring biological characterisation before filing. The consequences of inadequate or defective deposit, whether a patent granted on the basis of an incomplete deposit is void ab initio or merely voidable through post-grant opposition or revocation proceedings are not explicitly addressed in the Patents Act, creating a gap that the Indian Patent Office's 2016 guidelines have addressed only partially[10]

Beyond procedure, the substantive question of which biological materials qualify as "microorganisms" within the meaning of Section 3(j)'s exception remains contested. The 2016 Guidelines enumerate bacteria, fungi, algae, protozoa, viruses, and bacteriophages as clearly within the category, but are equivocal about the status of cell lines, hybridomas, and plasmids, biological materials of considerable commercial significance in the biopharmaceutical sector given the centrality of cell line technology to the production of monoclonal antibodies and other biologics.[11]

Genetic Sequences, Proteomics, and Industrial Applicability

The patentability of genetic sequences individual genes, expressed sequence tags, single nucleotide polymorphisms, or entire genomic regions has been among the most fiercely contested issues in biotechnology patent policy since the inception of the Human Genome Project in the early 1990s. The argument for permitting such patents rests on the incentive rationale: enormous investment in sequencing, characterisation, and biological validation is required to identify clinically relevant sequences, and the patent system's temporary exclusivity is presented as the appropriate reward for such investment. The arguments against are multiple: that gene sequences are discoveries of pre-existing natural phenomena rather than inventions; that broad sequence patents create an "anticommons" impeding downstream research; and that

[9] . Budapest Treaty (n 34) Arts 3 and 7; India's Instrument of Accession (17 December 2001
[10] IPO Examination Guidelines (n 31) para 5.3
[11] IPO Examination Guidelines (n 31) para 5.3.

the commodification of human genetic information raises moral concerns of a distinctive type.[12]

Indian patent law addresses genetic sequence patentability primarily through the combined operation of Section 3(c) and the industrial applicability requirement of Section 2(1)(j). The 2016 Examination Guidelines indicate that a claimed DNA sequence must have a specific, substantial, and credible industrial application not merely speculative biological function and that the isolation of a known sequence using methods that are themselves well-known in the art is unlikely to involve the inventive step required by Section 2(1)(ja). These standards are broadly convergent with the position adopted by major patent offices in the post-genomic era.[13]

Genetically Modified Organisms: Patent and Regulatory Interfaces

Genetically modified organisms occupy an uneasy position in the Indian intellectual property landscape, straddling the interface between patent law, plant variety protection, biosafety regulation under the Environment (Protection) Act, 1986, and constitutional concerns about the right to food and agricultural livelihoods[14]. The patent dimension is complicated by Section 3(j)'s exclusion of plants and animals in whole or in part, which produces the anomalous situation where a Bt toxin gene inserted into a crop plant may be patentable as an isolated genetic construct, while the GM plant carrying that gene is not patentable as such.[15]

This fragmentation of protection has not prevented significant controversy at the intersection of GM technology and intellectual property. The litigation concerning Bt cotton technology and the contested enforceability of technology sub-licence agreements under which Monsanto (now Bayer) licensed its Bt trait to Indian seed companies reached the Supreme Court in Nuziveedu Seeds Ltd. v. Monsanto Technology LLC (2019), where the Court declined to express a final view on the patentability of the Bt sequence under Indian law, leaving the question open for fresh examination. The case exposed the inadequacy of existing legal frameworks drafted before the molecular biology revolution transformed agricultural

[12] . Heller and Eisenberg (n 27) 698-701
[13] . IPO Examination Guidelines (n 31) para 4.1
[14] . Bhaven Sampat and Kenneth Shadlen, "Secondary Pharmaceutical Patenting" (2017) 31(2) Science & Technology Studies 74, 78-80.
[15] . Nuziveedu Seeds Ltd. v. Monsanto Technology LLC, (2019) 9 SCC 714, paras 45-50

production for the governance of agricultural biotechnology.[16]

The Evergreening Problem and the Significance of Section 3(d)

The practice known colloquially as "evergreening" the strategic use of secondary patents on modifications, derivatives, and new forms of existing pharmaceutical compounds to extend effective market exclusivity beyond the expiry of the primary product patent is among the most contested phenomena in pharmaceutical patent policy. It encompasses a spectrum of practices of varying degrees of genuine therapeutic innovation: from the development of genuinely improved formulations with measurable clinical advantages, through the extension of once-daily dosing regimens, to the filing of patents on new crystalline polymorphs, metabolites, or enantiomers whose principal function is competitive foreclosure.[17]

The concern with evergreening is structurally more acute in the pharmaceutical sector than in others because of the peculiar economics of generic drug competition: the unit cost of generic drug manufacturing, absent patent barriers, is typically very small relative to the price of the branded product under patent protection, and the arrival of generic competition routinely reduces prices by eighty to ninety per cent within months of patent expiry.[18] Every additional year of effective patent exclusivity thus represents a very large welfare transfer from consumers and healthcare payers to the patent holder.

Section 3(d) of the Patents Act, 1970 as inserted by the 2005 amendment provides that the following shall not be regarded as inventions within the meaning of the Act:

> *"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."*

The Explanation to Section 3(d) further specifies that "salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations

[16] Nuziveedu (n 41) para 63
[17] . Sampat and Shadlen (n 40) 76-79; Carlos Correa, "Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing" (2011) ICTSD Working Paper No. 41
[18] FTC, "Pay-for-Delay: When Drug Companies Agree Not to Compete" (2010) FTC Report 8-12

and other derivatives of known substances shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy."

This provision is remarkable on several counts. First, it is a legislative provision of global uniqueness: no other major jurisdiction has enacted a comparable statutory requirement that new forms of known pharmaceutical substances must demonstrate enhanced efficacy to be patentable. The general patentability requirements of novelty and inventive step, operative in all TRIPS-compliant systems, can in principle weed out trivial modifications, but no other system has translated those general doctrinal principles into a specific, sector-targeted efficacy threshold. Second, the provision reflects a deliberate legislative assessment amply supported by subsequent empirical literature on pharmaceutical patent filing patterns that the existing general patentability requirements were inadequate to prevent the anticipated wave of secondary pharmaceutical applications.[19]

The TRIPS compatibility of Section 3(d) was contested from the outset, with originator pharmaceutical firms and their governments arguing that it created a higher patentability bar for pharmaceutical inventions than for other technological fields, contrary to Article 27(1)'s non-discrimination requirement. The Indian government, supported by the majority of academic scholarship, maintained that Article 27(1)'s requirement of uniform patentability standards refers to the existence of the patent system across fields of technology not the application of uniform criteria regardless of the specific characteristics of the technology in question and that TRIPS leaves member states interpretive discretion to define patentability criteria within the bounds of the Agreement.[20]

Novartis AG v. Union of India: Analysis and Implications

The constitutional and interpretive challenges to Section 3(d) culminated in one of the most significant judicial decisions in the history of intellectual property law globally: the Supreme Court's judgment in Novartis AG v. Union of India, delivered on 1 April 2013 by a bench of Justices Aftab Alam and Ranjana Prakash Desai. The case arose from Novartis's application for a patent on the beta-crystalline form of imatinib mesylate the compound marketed as Gleevec or Glivec for the treatment of chronic myeloid leukaemia and several other cancers. Novartis contended that the beta-crystalline polymorph was a new invention

[19] Sampat and Shadlen (n 40) 85-90.
[20] . Correa (n 2) 276-280; Reichman (n 7) 252-254

distinct from the earlier Zimmermann patent on imatinib base, pointing to what it characterised as superior therapeutic properties including a thirty per cent improvement in bioavailability. The application was rejected by the Chennai Patent Office on Section 3(d) grounds, and Novartis mounted a sustained litigation campaign that eventually reached the Supreme Court through appeals from the Madras High Court and the Intellectual Property Appellate Board.[21]

The Supreme Court's analysis proceeds on two principal levels. At the constitutional and international level, the Court decisively rejected Novartis's TRIPS-compatibility challenge, holding that TRIPS Article 27 grants member states a margin of appreciation in defining the criteria of patentability and that Section 3(d) represents a lawful exercise of that margin. Drawing on the legislative history of the TRIPS negotiations, the Court found no basis for the proposition that the Agreement requires member states to grant patents for pharmaceutical derivative compounds merely because they exhibit new physical properties. The Court's analysis engaged with the extensive academic literature on TRIPS flexibilities and was broadly convergent with the views of Correa, Reichman, and other leading scholars.[22]

At the doctrinal level, the Court's analysis of "efficacy" within Section 3(d) is of lasting significance. The Court held that "efficacy" in the context of a pharmaceutical compound means therapeutic efficacy the capacity of the substance to produce a therapeutic benefit in the treatment of disease and not merely physical or chemical properties such as improved stability or flowability. The Court further held that enhanced bioavailability is relevant to the Section 3(d) analysis only insofar as it translates into enhanced therapeutic efficacy demonstrable in clinical terms: a thirty per cent improvement in bioavailability that produces no measurable improvement in patient outcomes does not satisfy Section 3(d)'s efficacy requirement.[23] On the facts, the Court found that Novartis had failed to demonstrate that the beta-crystalline form possessed significantly enhanced therapeutic efficacy relative to imatinib in its free base form, and accordingly upheld the rejection of the patent application.

The Novartis judgment has been extensively analysed in the academic literature and its reception has been sharply divided along lines broadly corresponding to the underlying policy disagreements about pharmaceutical patent protection.[24] Originator pharmaceutical industry

[21] . Novartis AG v. Union of India, (2013) 6 SCC 1, paras 1-18
[22] . Novartis (n 47) paras 85-103; Correa (n 2) 278; Reichman (n 7) 253
[23] . Novartis (n 47) paras 176-193.
[24] . Amy Kapczynski, "Engineered in India: Patent Law 2.0" (2013) 369 NEJM 497

representatives characterised the decision as an unjustified departure from global patent norms. Public health advocates celebrated it as a vindication of the Doha Declaration's affirmation of developing country policy space. The academic consensus has largely aligned with the latter assessment: Section 3(d) as interpreted by the Court is a defensible exercise of TRIPS-compatible legislative discretion that serves a legitimate public health purpose not adequately served by the general patentability requirements alone.[25]

Post-Novartis Developments in Section 3(d) Jurisprudence

In the decade since the Novartis judgment, Section 3(d) has continued to be applied in pharmaceutical patent prosecution and litigation, generating a body of secondary doctrine that has both clarified and complicated the Supreme Court's initial analysis. Several subsequent decisions of the Intellectual Property Appellate Board prior to its abolition by the Tribunals Reforms Act, 2021 and of the High Courts have addressed the type of evidence required to establish enhanced therapeutic efficacy and the categories of pharmaceutical derivative capable of satisfying Section 3(d).[26]

One significant post-Novartis development is the increasing sophistication with which patent applicants have sought to frame efficacy evidence. Rather than relying solely on bioavailability data effectively foreclosed as a self-sufficient basis by the Supreme Court's reasoning applicants have increasingly adduced clinical trial data, patient outcome measures, and comparative effectiveness evidence. The Indian Patent Office and courts have responded with varying degrees of receptivity, and there remains doctrinal uncertainty about the standard of clinical evidence required and the relative weight of in vitro versus in vivo experimental data.[27]

A second significant development has been the increasing use of pre-grant opposition under Section 25(1) of the Patents Act as a vehicle for civil society organisations, patient advocacy groups, and generic manufacturers to challenge pharmaceutical patent applications on Section 3(d) and other grounds. The Lawyers Collective, Medecins Sans Frontieres, and the Initiative for Medicines, Access and Knowledge (I-MAK) have filed detailed pre-grant oppositions against applications for patents on sofosbuvir (hepatitis C), bedaquiline

[25] . Basheer and Reddy (n 4) 256-260; Reichman (n 7) 260-262.
[26] BMS v. Mylan Laboratories (2013) 56 PTC 95 (IPAB); Pfizer v. Controller of Patents OA/13/2009/PT/CH (IPAB).
[27] . Reddy and Chandrashekaran (n 21) 64-70

(tuberculosis), and several antiretroviral compounds, with considerable practical success in preventing or delaying grant.[28] The institutional changes consequent on the IPAB's abolition High Courts now exercise appellate jurisdiction over patent decisions have introduced new procedural uncertainties, and there is a strong case for legislative rationalisation of this landscape.

Chapter Summary

It has examined the patentability standards applicable to biotechnological and pharmaceutical inventions under Indian law.
The discovery/invention distinction in biology is complex: Sections 3(b), 3(c), and 3(j) of the Patents Act establish a multi-layered exclusionary framework that converges with but is not identical to the positions adopted in the US, EU, and elsewhere.
Section 3(d)'s efficacy requirement is the globally distinctive centrepiece of Indian pharmaceutical patentability doctrine. The Supreme Court's Novartis judgment authoritatively established that "efficacy" means therapeutic efficacy and that enhanced bioavailability alone is insufficient a holding with global significance for access-to-medicines policy.
Post-Novartis developments include increasing evidentiary sophistication by applicants and growing use of pre-grant opposition as a civil society tool, alongside institutional uncertainty following the IPAB's abolition.

Conclusion

It is demonstrated that Indian patent law's approach to biotechnological and pharmaceutical inventions is neither a mechanical application of global norms nor an idiosyncratic departure from them, but rather a deliberate and textured legal architecture shaped by the country's distinctive developmental priorities and its strategic interpretation of the flexibility that the TRIPS Agreement affords.

The foundational challenge distinguishing patentable invention from unpatentable discovery in the life sciences is one that no legal system has resolved with complete doctrinal coherence.

[28] . I-MAK, "Overpatented, Overpriced" (2018) I-MAK Report 3-7

Indian law addresses it through the combined operation of Sections 3(b), 3(c), and 3(j), producing an exclusionary framework that is broadly convergent with the post-*Myriad* position in the United States and the Biotechnology Directive's approach in the European Union, while reflecting India's specific concern for agricultural livelihoods, biodiversity, and the integrity of its sui generis plant variety regime.

The defining contribution of Indian pharmaceutical patent law, however, lies in Section 3(d) and its authoritative interpretation by the Supreme Court in *Novartis AG v. Union of India*. By confining patentability of derivative pharmaceutical forms to those demonstrating genuine therapeutic gain rather than mere physicochemical novelty Indian law has erected a substantive barrier against strategic evergreening that no other jurisdiction has replicated in legislative form. The Court's holding that therapeutic efficacy, not bioavailability alone, is the operative standard has had resonance well beyond Indian borders, informing access-to-medicines advocacy and legislative debate in multiple developing-country jurisdictions.

The post-*Novartis* landscape reveals both the vitality and the fragility of this framework. The growing sophistication of applicants in marshalling clinical evidence, the expanding role of civil society through pre-grant opposition, and the institutional disruption caused by the IPAB's abolition collectively indicate that the doctrinal settlement achieved in 2013 remains an evolving one. Consolidating and rationalising the procedural landscape particularly the appellate architecture for patent disputes emerges as a pressing legislative priority if the substantive gains of Section 3(d) are to be effectively administered and enforced.

Ultimately, the Indian framework stands as a significant example of how a TRIPS-compliant legal system can be calibrated to serve public health objectives without abandoning the patent system's core incentive function a balance whose maintenance will only grow more consequential as biotechnological innovation deepens and the pressure on pharmaceutical pricing intensifies globally.