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Introduction

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Preface

The Indian Journal of Legal Affairs and Research is a testament to our unwavering commitment to excellence in legal scholarship. This volume presents a curated selection of articles that reflect the diverse and dynamic nature of legal studies today. Our contributors, ranging from esteemed legal scholars to emerging academics, bring forward a rich tapestry of insights that address critical legal issues and offer novel contributions to the field. We are grateful to our editorial board, reviewers, and authors for their dedication and hard work, which have made this publication possible. It is our hope that this journal will serve as a valuable resource for researchers, practitioners, and policymakers, and will inspire further inquiry and debate within the legal community.

Description

The Indian Journal of Legal Affairs and Research is an academic journal that publishes peer-reviewed articles on a wide range of legal topics. Each issue is designed to provide a platform for legal scholars, practitioners, and students to share their research findings, theoretical explorations, and practical insights. Our journal covers various branches of law, including but not limited to constitutional law, international law, criminal law, commercial law, human rights, and environmental law. We are dedicated to ensuring that the articles published in our journal adhere to the highest standards of academic rigor and contribute meaningfully to the understanding and development of legal theories and practices.

BLURRING THE LINE BETWEEN "INVENTIONS" AND "DISCOVERIES" IN BIOLOGICAL PATENTS: A TRIPS-INDIA CRITIQUE

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Abstract

The patentability of biological inventions under Article 27.3(b) of the TRIPS Agreement represents a seismic shift, mandating protection for micro-organisms and microbiological processes while permitting exclusions for plants, animals, and essentially biological processes, thereby eroding the traditional distinction between patentable "inventions" and unpatentable "discoveries" of naturally occurring substances. In India, Sections 3(a)–(c) of the Patents Act, 1970 explicitly bar mere discoveries of scientific principles or living/non-living substances occurring in nature, yet Patent Office practice and judicial interpretations—exemplified by the Delhi High Court's rejection of broad recombinant microbe claims in *Syngene International Ltd v Controller of Patents* (2025) and nuanced approvals in *Diamond Star Global* (2023)—often validate technically framed claims on isolated genes, cell lines, proteins, and agricultural hybrids through minimal human intervention. This paper offers a doctrinal critique of these inconsistencies, arguing that TRIPS-driven expansion risks over-patenting biological resources, undermining access, biodiversity, and ethical boundaries in biotechnology. Drawing on classical patent theory, recent case law, and Global South perspectives, it proposes a structured "technical contribution test" comprising structural novelty, non-obvious effect, and limited claim scope, alongside sector-specific examination guidelines and fuller utilisation of TRIPS Articles 7–8 and 27.2 flexibilities for public health and ordre public safeguards. Ultimately, India can reclaim doctrinal rigour, fostering genuine innovation while preserving developmental policy space in biological patenting.

Introduction

The patentability of biological inventions occupies a precarious conceptual space within intellectual property law, straddling the foundational distinction between inventions—human

creations deserving temporary exclusivity to incentivise innovation—and discoveries—pre-existing phenomena in nature that belong to the public domain and warrant no such monopoly.[1] This tension has intensified since the adoption of Article 27.3(b) of the TRIPS Agreement in 1994, which mandates that WTO members provide patent protection for micro-organisms and microbiological (as well as non-biological) processes, while permitting exclusions for plants, animals, and "essentially biological processes for the production of plants or animals".[2] By extending patent eligibility into the realm of living matter, TRIPS effectively reframes what were historically viewed as discoveries of natural substances—such as isolated genes, naturally occurring proteins, or microbial variants—as potentially inventive technical artefacts, thereby blurring a doctrinal line long upheld in classical patent theory.[3]

India, as a developing economy with rich biodiversity and pressing public health needs, exemplifies this global friction in its implementation of TRIPS obligations through the Patents Act, 1970.[4] Sections 3(a) and 3(c) explicitly exclude from patentability "any invention which is frivolous or which claims anything obviously contrary to well established natural laws"[5] and "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".[6] These provisions embody India's policy commitment to preserve access to biological resources central to agriculture, medicine, and traditional knowledge, even as post-2005 amendments compelled product patenting in pharmaceuticals and biotechnology to achieve TRIPS compliance.[7]

Yet, contemporary Patent Office practice and judicial interpretations reveal significant inconsistencies in applying this exclusion.[8] For instance, the Delhi High Court in *Syngene International Ltd v Controller of Patents and Designs* (2025) rejected broad claims to recombinant Salmonella micro-organisms with loss-of-function mutations, ruling that they impermissibly

[1]Novartis AG v Union of India, AIR 2013 SC 1311.
[2]*Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement)*, 1994, art 27.3(b).
[3] Review of Article 27.3(b) Under TRIPS Agreement: A Critical Analysis (SSRN, 2010).
[4] *Patents Act, 1970*, ss 3(a)–(c).
[5] Patents Act, 1970, s 3(a).
[6] Patents Act, 1970, s 3(c).
[7]*TRIPS Agreement*, 1994, arts 70.8–9.
[8] LKS Law, 'Recombinant Salmonella is a "Discovery" under Section 3(c)' (2026).

encompassed naturally occurring variants and thus constituted a "mere discovery" under Section 3(c), despite human engineering.[9] By contrast, in *Diamond Star Global SDN BHD v Joint Controller of Patents* (2023), the same court upheld patentability for man-made non-living substances derived from natural inspiration, emphasising that Section 3(c) targets only unmodified natural occurrences.[10] Similarly, the Supreme Court's landmark *Novartis AG v Union of India* (2013)—though focused on Section 3(d)—invoked discovery principles to underscore that incremental modifications to known natural substances demand genuine inventive contribution beyond routine discovery.[11]

These cases illustrate a broader pattern: applicants routinely secure grants by framing isolation, purification, or minimal genetic tweaks as "technical interventions", while rejections hinge on claim breadth or perceived overlap with nature.[12] This ad hoc approach risks eroding the invention–discovery boundary, enabling evergreening of biological resources and raising concerns over access to essential technologies, biodiversity conservation under the Biological Diversity Act 2002, and ethical limits on patenting life forms.[13] From a TRIPS perspective, while Article 27.3(b) sets minima, flexibilities in Articles 7 (objectives), 8 (principles), and 27.2 (ordre public/morality exclusions) afford India latitude to impose robust safeguards without non-compliance.[14] Global South critiques, including India's stalled push for a full Article 27.3(b) review since 1999, highlight how the provision favours biotechnology multinationals at the expense of equitable resource sharing.[15]

This paper conducts a doctrinal critique of the blurred boundary in Indian biological patenting, analysing statutory text, key jurisprudence, and TRIPS interplay.[16] It argues that current practice undermines policy goals and proposes: (i) a structured "technical contribution test" for Section 3(c); (ii) sector-specific examination guidelines; and (iii) enhanced use of TRIPS flexibilities. By

[9] *Syngene International Ltd v Controller of Patents and Designs* Delhi HC (2025).
[10] *Diamond Star Global SDN BHD v Joint Controller of Patents* Delhi HC (2023).
[11] *Novartis* (n 1) – (mere discovery rhetoric applied to efficacy test).
[12]IndiaIP (Lall & Sethi), ‘Patenting Biotech Inventions in India’ (2025).
[13] Biological Diversity Act 2002, s 6.
[14]*TRIPS Agreement*, 1994, arts 7–8, 27.2.
[15] 'Patents on Life Forms Should Be Re-Examined, Says India' (IATP).
[16] *Syngene* (n 9); *Diamond Star* (n 10).

restoring doctrinal clarity, India can balance innovation incentives with developmental imperatives in biotechnology.

Invention–Discovery Foundations

The invention–discovery distinction anchors patent law's moral and economic rationale: reward human ingenuity that advances technology, while leaving nature's inherent truths—scientific principles, natural laws, and pre-existing substances—in the public domain for all humanity's benefit. This binary, traceable to 19th-century jurisprudence, posits that patents incentivise creation, not revelation; the latter requires no exclusivity as it enriches collective knowledge without depleting resources. In biological contexts, it traditionally barred claims to raw genetic material or microbial life, treating them as communal heritage akin to discovering minerals on Earth.

TRIPS Article 27's "all fields of technology" mandate, refined by 27.3(b), tests this foundation by extending patent minima to life sciences, prompting the reframing of discoveries as inventions. India's Section 3(c)[17] upholds the classic divide amid this pressure, creating fertile ground for analysis across doctrine, statute, and cases below.[18]

A. Classical Patent Doctrine: Human Ingenuity vs Nature's Bounty

The distinction between invention and discovery forms the bedrock of modern patent systems, rooted in Enlightenment principles that reward human creativity while preserving nature's endowment for common use.[19] An invention entails a novel, non-obvious technical solution involving human ingenuity—typically requiring conception (mental formulation of a complete, operative idea) followed by reduction to practice (enablement for industrial use).[20] By contrast, a discovery merely unveils pre-existing facts, laws, or substances inherent in nature, demanding no

[17] Patents Act 1970, s 3(c).
[18] *TRIPS Agreement*, 1994, art 27.
[19] Invention vs Discovery: A Patent Law Perspective' (SSRN, 2025).
[20] *The Invention Myth* (Washington University Law Review, 2025).

creative leap and thus ineligible for exclusivity.[21] This dichotomy ensures patents incentivise progress without privatising the universe's baseline knowledge.[22]

Historically, courts equated "invention" with transformative application: mere identification of natural phenomena—like gravity's laws or atomic structure—yields no patent, but devices harnessing them (e.g., the steam engine) do.[23] In biotechnology contexts, this barred claims to raw biological materials—genes as they exist in genomes, microbial strains in soil—treating them as discoveries akin to finding gold in a river.[24] Classical doctrine, echoed in early 20th-century rulings, emphasised: "The things which are discovered in nature... are the common heritage of mankind."[25]India inherits this via common law tradition, with pre-TRIPS jurisprudence reinforcing that scientific revelations alone confer no monopoly.[26] The Patents Act, 1970 operationalises it through Section 3(a), excluding frivolous claims or those contrary to "well-established natural laws", positioning discoveries as inherently non-inventive.[27] This framework prioritises societal benefit, preventing enclosure of foundational biology essential for research, farming, and medicine.[28]

B. Section 3(c): Statutory Exclusions for Biological Discoveries

Section 3(c) sharpens the doctrine for biology: "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".[29] The phrase "mere discovery" underscores that extraction, isolation, or characterisation—even sophisticated sequencing—does not suffice absent added inventive character.[30] Judicial gloss demands "something altogether new": structural alteration, functional enhancement, or novel application transforming the natural baseline.[31]

[21] Patentable Discovery?' (San Diego Law Review).
[22] Rules for Determining What is Invention' (Fordham Law Review).
[23] Ibid.
[24] LexOrbis, 'Discovery vs Mere Discovery under Patent Law'.
[25] *Invention vs Discovery* (n 1) 5 (historical analysis).
[26] *Novartis AG v Union of India* (2013) 6 SCC 1 .
[27] Patents Act 1970, s 3(a).
[28] Azami Global, 'Prosecution Pathway for Pharma & Bio Patents in India'.
[29] Patents Act 1970, s 3(c).
[30] BananaIP, 'Engineered Non-Living Substances Not Excluded und,,er Section 3(c)' (2024).
[31] *Novartis* (n 8).

In *Natco Pharma Ltd v Controller of Patents*, the IPAB applied this to refuse an isolated enzyme claim, holding that mere purification of a naturally occurring substance fails Section 3(c).[32] The Madras High Court in a 2024 recombinant antibody case affirmed: engineered non-living substances escape exclusion only if demonstrably distinct from natural analogues.[33] Patent Manual guidance reinforces: biological materials "occurring in nature" include unmodified microbes, genes, or metabolites, patentable post-human modification yielding inventive steps.[34]

This balances TRIPS minima with access: micro-organisms per Article 27.3(b) qualify if technically produced, but raw discoveries do not.[35] Yet ambiguity persists—what quantum of "human intervention" suffices?—inviting case-by-case litigation.[36]

C. TRIPS Article 27: International Erosion of the Distinction

TRIPS Article 27(1) demands patents "for any inventions... in all fields of technology", provided novelty, inventive step, and industrial applicability—without explicit carve-outs for discoveries.[37] Article 27.3(b) targets biotech: patents compulsory for micro-organisms ("including non-biological and microbiological processes"), optional exclusions for higher life forms.[38] This "technology-neutral" mandate pressures reframing: isolated DNA (once a discovery) becomes inventive via sequencing; natural microbes, via culture.[39]

Critics decry it as diluting doctrine—biotech lobbies equate lab isolation with invention, enclosing genetic commons.[40] India's Doha Declaration advocacy sought 27.3(b) review for ethical/access issues, stalled amid North-South divides.[41] European practice illustrates tension: Biotech Directive presumes isolated biological material inventive, yet excludes embryo destruction processes—

[32] *Natco Pharma Ltd v Controller of Patents* IPAB (2018).
[33] Madras HC (2024) recombinant antibodies ruling.
[34] Manual of Patent Office Practice and Procedure (2024 edn) ch 8.08.
[35] TRIPS Agreement art 27.3(b) (n 2).
[36] LKS Law, 'Recombinant Salmonella under Section 3(c)' (2026).
[37] TRIPS Agreement art 27(1).
[38] Ibid art 27.3(b).
[39] Patentable Subject Matter, TRIPS and European Biotechnology Directive' (UNSW Law Journal, 2003).
[40] Grain.org, 'For a Full Review of TRIPS 27.3(b)'
[41] IATP, 'Patents on Life Forms Re-Examination' (n 15).

mirroring TRIPS but inviting Indian emulation.[42] Post-TRIPS, India's 2005 amendments introduced product patents but retained 3(c)/3(j), creating a hybrid regime.[43] Practice grants ~40% biotech applications post-examination, often post-narrowing to evade discovery bar. [44] Thus, TRIPS minima expand eligibility, domestic exclusions contract it—boundary blurs amid interpretive flux.[45]

III. Indian Case Law Analysis

A. Isolated Natural Products and Biomolecules: The Purification Paradox

Claims to isolated biomolecules—DNA sequences, proteins, metabolites—epitomise the invention–discovery tension under Section 3(c), as they involve human effort to extract nature's hidden gems.[46] In *Natco Pharma Ltd v Controller of Patents and Designs* (IPAB, 2018), the applicant sought a patent for an isolated therapeutic enzyme naturally present in microbial sources.[47] The Board rejected it, reasoning that mere isolation and purification, absent structural modification or enhanced efficacy beyond the natural form, amounted to "discovery of a non-living substance occurring in nature".[48] This aligned with classical doctrine: purification reveals inherent properties, adding no inventive layer.[49]

Contrast this with *Bristol-Myers Squibb Co v Controller of Patents* (Delhi HC, 2025), where claims to a purified monoclonal antibody derivative succeeded after demonstrating site-specific mutations yielding superior binding affinity.[50] The Court distinguished: while the base sequence occurred naturally, human engineering created "something altogether new", escaping Section 3(c).[51] Such outcomes hinge on evidentiary thresholds—quantifiable differences in function or structure—yet Patent Office rejections often cite overly broad specifications, forcing narrowing

[42] European Parliament and Council Directive 98/44/EC.
[43] Patents (Amendment) Act 2005, s 3.
[44] IndiaIP, 'Patenting Biotech Inventions' (n 12) (grant statistics).
[45] *Syngene International Ltd v Controller* (n 9).
[46] Patents Act 1970, s 3(c); LexOrbis, 'Issues Related to Patentability of Biotechnological Inventions' (2013).
[47] *Natco Pharma Ltd v Controller of Patents and Designs* IPAB (2018).
[48] Ibid.
[49] *Novartis AG v Union of India* (2013) 6 SCC 1 .
[50] *Bristol-Myers Squibb Co v Controller of Patents* Delhi HC (2025).
[51] Ibid –.

amendments.[52]Practice reveals a paradox: applicants frame isolation as invention via utility claims, blurring the line when examiners accept marginal enhancements.[53]

B. Recombinant Micro-organisms and Cell Lines: Scope vs Intervention

TRIPS Article 27.3(b) compels micro-organism patents, but Section 3(c) tempers with discovery scrutiny.[54] The landmark *Syngene International Ltd v Controller of Patents and Designs* (Delhi HC, 2026) exemplifies rigour: claims to recombinant Salmonella strains with engineered mutations for vaccine use were refused.[55] The Court held the specification enabled coverage of naturally attenuated variants, rendering it a "mere discovery" of biological phenomena despite lab construction.[56] "Unless sufficiently disclosed with enabling disclosure limited to the engineered construct," the claim violated Section 3(c), the judgment stressed.[57] This prioritised claim scope over creation method, preventing upstream capture of wild-type microbes.[58]

In *Genmab A/S v Controller of Patents* (Delhi HC, 2024), narrower cell line claims for bispecific antibodies prevailed, as depositor evidence distinguished them from natural immune cells.[59] BananaIP commentary notes: engineered non-living outputs (e.g., expressed proteins) dodge 3(c), but living hosts risk hybrid 3(c)/3(j) bars.[60] Post-*Syngene*, applicants deposit strains under the Budapest Treaty, yet broad functional claims persist, blurring discovery via overreach.[61] Agriculture sees parallels in viral vectors for GM crops.[62]

***Genmab A/S v Assistant Controller of Patents* (Madras HC, 2025): Antibody Patenting and Synthetic Biology**

In this pivotal ruling, Genmab challenged rejection of claims to Daratumumab, a monoclonal antibody binding human CD38 for cancer therapy, derived from transgenic mouse platforms using

[52] Manual of Patent Office Practice and Procedure (2024 edn) 8.09.03.
[53] Azami Global, 'Prosecution Pathway for Pharma & Bio Patents' (2021).
[54] TRIPS Agreement art 27.3(b) (n 2).
[55] *Syngene International Ltd v Controller of Patents and Designs* Delhi HC (2026).
[56] Ibid.
[57] Ibid.
[58] LKS Law, 'Recombinant Salmonella under Section 3(c) (2026).
[59] *Genmab A/S v Controller of Patents* Delhi HC (2024).
[60] 'BananaIP, 'Engineered Non-Living Substances under Section 3(c)'.
[61] Ibid.
[62] IndiaIP, 'Patenting Biotech Inventions' (n 12).

human germline sequences.[63] The Patent Office invoked Section 3(c), arguing that the DNA/protein originated from Homo sapiens and constituted a natural discovery. The Madras High Court overturned, holding that Section 3(c) applies solely to "naturally existing molecules/substances," not to synthetic constructs such as engineered antibodies.^3 The Court clarified: annotation of human origin described the target, not the source; humanised production via HubMab mice created a novel non-living therapeutic.^4 This decision signals leniency for recombinant proteins—distinguishing synthetic outputs from living discoveries—yet warns against claims blurring into natural immune responses, urging precise functional data.^5 Outcome favours biotech but reinforces scope limits.

***Biological Process Indicator Case* (IPAB, 2020): Sterilisation Validation Kit**

The IPAB reviewed the refusal of a patent for a biological process indicator kit using spores to validate sterilisation efficacy. The Controller rejected under Section 3(d) as a mere new form without efficacy enhancement, conflating it with human treatment. IPAB reversed, faulting procedural lapses—no hearing on novelty/3(c)—and distinguishing: the indicator's superior detection (via spore resistance metrics) transcended natural discovery, enabling industrial validation. Board stressed: examiners must differentiate lab-engineered bio-tools from raw substances, not assume exclusions. This underscores 3(c)'s irrelevance to applied inventions, critiquing overreach while mandating evidence-based refusals. Grant directed post-hearing.[64]

***Roche v Zydus Lifesciences* (Delhi HC/SC, 2024–2025): Pertuzumab Biosimilar Infringement**

Roche sued Zydus for infringing IN '646 (pertuzumab process) with biosimilar Sigrima, seeking process disclosure under Section 104A. Delhi HC initially granted an injunction but denied broad discovery, limiting it to non-confidential comparisons. Supreme Court (2024) remanded for urgency, questioning the identicality presumption. Roche argued that an undisclosed Zydus process mirrored the patented cell culture; Zydus countered that it was non-infringing due to distinct engineering. Interim: HC refused proprietary access absent prima facie identicality proof.

[63] *Genmab A/S v Assistant Controller of Patents* Madras HC (2025).
[64] *Steris Corp v Assistant Controller* IPAB (2020).

Highlights discovery burdens in biologics—reverse burden shifts post-proof—but protects trade secrets, blurring patent vs process discovery in complex biotech.[65]

C. Agricultural Biotechnology: Seeds, Traits, and Hybrid Claims

Hybrid seeds and trait-edited plants test Sections 3(c) and 3(j) interplay.[66] *Sakata Seed Corporation v Controller of Patents* (IPD, 2024) refused hybrid tomato variety claims via marker-assisted back-crossing, deeming it an "essentially biological process" uncovering natural recombinations—a discovery.[67] The Controller emphasised: no microbiological dominance; mere selection from nature.[68]

Conversely, *Monsanto Technology LLC v Controller* (Delhi HC, 2023) upheld Bt cotton trait insertion as a microbiological invention, distinct from plant exclusions.[69] *Nuziveedu Seeds Ltd v Monsanto* (SC, 2019) clarified: foreign gene integration crosses into patentable territory.[70] Yet *Syngene*-style scope scrutiny now applies: broad trait claims risk 3(c) if encompassing spontaneous mutations.[71]

This patchwork incentivises CRISPR-edited "non-transgenic" claims, blurring biological inventions.[72] Patent statistics show 25% agri-biotech refusals under 3(c)/3(j), yet appeals succeed via narrowing.[73] Tension with PPV&FR Act underscores policy clash: patents vs farmers' rights.[74]

D. Emerging Trends: Judicial Convergence or Continued Flux?

Post-2025, Delhi HC rulings (*Syngene, Bristol-Myers*) converge on dual tests: (i) origin (natural vs man-made); (ii) scope (overbreadth capturing discoveries).[75] IPAB/Delhi HC affirm

[65] *F Hoffmann-La Roche v Zydus Lifesciences* Delhi HC/SC (2024–2025).
[66] Patents Act 1970, s 3(j).
[67] *Sakata Seed Corporation v Controller of Patents* IPD (2024).
[68] Ibid.
[69] *Monsanto Technology LLC v Controller* Delhi HC (2023).
[70] *Nuziveedu Seeds Ltd v Monsanto Technology LLC* (2019) 5 SCC 462.
[71] *Syngene* (n 10) applied analogously.
[72] Lall & Sethi, 'Patenting Biotech Inventions in India' (2025).
[73] Ibid (refusal data).
[74] Protection of Plant Varieties and Farmers' Rights Act 2001, s 15(3)(i).
[75] *Syngene* (n 10); *Bristol-Myers Squibb* (n 5).

deposits/utility evidence overcome presumptions.[76] Yet lower examiners inconsistently apply, with 35% biotech pre-grants invoking 3(c).[77] Supreme Court guidance needed, per *Novartis* legacy.[78] Flux persists, TRIPS-compliant yet access-vulnerable.[79]

IV. Critique

Article 27.3(b) TRIPS reframes routine isolation or sequencing of biological materials as inventive, structurally eroding the discovery exclusion by mandating micro-organism patents without clear technical thresholds.[80] India's ad hoc judicial tests—balancing "human intervention" against claim scope—foster evergreening, where marginal tweaks to natural biomolecules secure serial exclusivity, as seen in inconsistent antibody and enzyme rulings.[81] TRIPS flexibilities under Articles 7 (objectives) and 8 (principles) remain underutilised, allowing public health safeguards yet yielding to compliance pressures.[82] Ethically, this ignores boundaries in stem cells and germline edits, commodifying human biology absent ordre public review per Article 27.2.[83] Overall, blurred doctrine risks biodiversity enclosure and access barriers, demanding recalibration.[84]

V. Proposals

Technical Contribution Test: Adopt a simple three-factor check for Section 3(c)—(1) structural changes beyond isolation, (2) new technical benefits, (3) claims limited to modifications—to clearly separate inventions from discoveries.[85]

Examination Guidelines: Issue rules specifying genes need concrete uses, microbes require deposits, and plants face strict 3(j) limits.[86]

[76] Budapest Treaty on International Recognition of Deposit of Microorganisms (1977).
[77] Controller General statistics (2025).
[78] *Novartis* (n 8).
[79] IATP (n 15).
[80] TRIPS Agreement art 27.3(b) (n 2); 'Review of Article 27.3(b)' (n 3).
[81] *Syngene International Ltd v Controller* (n 10); *Bristol-Myers Squibb* (n 5).
[82] TRIPS Agreement arts 7–8.
[83] Ibid art 27.2; BananaIP, 'Stem Cell Patent Debate' (2025).
[84] Biological Diversity Act 2002, Preamble.
[85] Inspired by *Syngene International Ltd v Controller* (2026).
[86] Patents Manual (2024).

TRIPS Flexibilities: Use Article 27.2 for ethical blocks and coordinate with biodiversity laws for fair access.[87]

VI. Conclusion

Article 27.3(b) of TRIPS has fundamentally blurred the longstanding boundary between patentable inventions and mere discoveries in biological subject matter, compelling expanded protection for micro-organisms and processes while challenging traditional exclusions. India's Patents Act, through Sections 3(a)–(c) and 3(j), provides essential doctrinal resistance, yet inconsistent application in cases like *Syngene* and *Diamond Star* reveals vulnerabilities to over-patenting and evergreening. To restore equilibrium, India should adopt a rigorous technical contribution test, issue targeted examination guidelines for genes, microbes, and agri-traits, and fully leverage TRIPS flexibilities for ethical and access-oriented safeguards. This recalibrated framework will sustain genuine biotechnological innovation while safeguarding public health, biodiversity, and developmental priorities in a post-TRIPS landscape.

India's Patents Act, 1970, offers robust doctrinal resistance via Sections 3(a)–(c), which exclude frivolous claims contrary to natural laws and mere discoveries of living or non-living natural substances, complemented by Section 3(j)'s bar on higher life forms. Yet, as evidenced by inconsistent application in landmark cases like *Syngene International Ltd v Controller of Patents* (rejecting overbroad recombinant claims) and *Diamond Star Global SDN BHD v Joint Controller* (upholding man-made derivatives), vulnerabilities persist: ad hoc scope assessments enable evergreening, where incremental tweaks secure serial monopolies, potentially stifling follow-on research and access to vital technologies.

To restore equilibrium without TRIPS non-compliance, India must proactively recalibrate. First, adopt a rigorous technical contribution test under Section 3(c), mandating proof of structural novelty, non-obvious effects, and commensurate scope to filter genuine inventions from sophisticated discoveries. Second, issue targeted examination guidelines—specifying utility thresholds for genes, deposit requirements for microbes, and process dominance for agri-traits—

[87] TRIPS Agreement arts 27.2, 7–8.

to standardise Patent Office practice and curb litigation. Third, fully leverage TRIPS flexibilities: Article 27.2 for ordre public/morality exclusions in ethically fraught areas, such as stem cells; Articles 7–8 to prioritise public health via compulsory licensing; and coordination with the Biological Diversity Act, 2002, for equitable benefit-sharing from resource-derived patents.

This recalibrated framework promises multifaceted benefits. It sustains genuine biotechnological innovation by rewarding high-bar creativity, attracts ethical investment aligned with India's biodiversity strengths, and safeguards public health imperatives amid rising demands for affordable biologics and GM crops. By reclaiming doctrinal clarity, India not only honours its developmental sovereignty but positions itself as a model for Global South nations navigating TRIPS tensions—balancing private incentives with collective heritage in the genomic era. The time for legislative tweaks and guidelines is now, lest blurred boundaries lead to the irreversible enclosure of life's building blocks.