PATENTABILITY OF GENETICALLY MODIFIED MICROORGANISMS UNDER INDIAN PATENT LAW: A SEQUENCED READING OF SECTIONS 2(1)(J), 3(C) AND 3(J) IN THE LIGHT OF TRIPS

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ABSTRACT

Genetically modified microorganisms fall within the scope of three provisions of Indian patent law that are generally read in isolation. Section 2(1)(j) requires that an invention be new, involve an inventive step and be capable of industrial application. Section 3(c) excludes from patentable subject matter the discovery of any living thing or non-living substance occurring in nature. Section 3(j) excludes plants and animals and essentially biological processes for their production or propagation, but expressly leaves microorganisms outside the exclusion. Article 27.3(b) of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) supplies the relevant international context; however, its microorganism clause is neither a self-executing grant of patents nor a licence to exclude genetically modified life as such. The present paper argues for a disciplined, sequenced inquiry. A claim should, first, disclose a human-made technical conception and not the discovery or isolation of what occurs in nature. Next, the claim must independently satisfy the requirements of novelty, inventive step and industrial applicability. Only then should the specific exclusions, disclosure rules and claim-scope limits be applied. The Indian decisions from Dimminaco to ImClone and BTS Research support a human-intervention inquiry. However, the recent remands also indicate that a settled test is absent. The proposed framework asks whether intentional human involvement has produced a lasting, reliable and significant technical difference in the claimed microorganism, while ensuring that the breadth of the claim is consistent with the disclosure made and the deposit furnished. This construction, which respects the text of the Patents Act, satisfies the requirements of TRIPS and ensures that India's public-interest safeguards are not diluted by the appropriation of natural resources, speculative claims and environmentally harmful exploitation.

Keywords: Genetically Modified Microorganisms, Biotechnology Patents, Section 3(c), Section 3(j), Inventive Step, TRIPS Article 27.3(b), Biological Deposit, Indian Patent Law.

I. Introduction

Few areas of patent law test the boundary between invention and discovery as sharply as the patenting of living organisms. A bacterium engineered to degrade an industrial pollutant, a yeast strain rewired to secrete a therapeutic protein, or a live attenuated vaccine strain carrying defined mutations is at once a product of the laboratory and a form of life. The first aspect invites the language of invention; the second invites the language of nature, and of the public interest in what nature has provided freely.

The Patents Act, 1970 (the Act) addresses this boundary through provisions that are usually read separately. Section 2(1)(j) defines an invention as a new product or process involving an inventive step and capable of industrial application.[1] Section 3(c) provides that the discovery of any living thing or non-living substance occurring in nature is not an invention.[2] Section 3(j) removes plants and animals, in whole or in part, and essentially biological processes for their production or propagation from the field of patentable inventions, but does so "other than micro-organisms".[3] The three provisions, read together, do not say that a genetically modified microorganism is patentable. They say only that such an organism is not excluded as a class, and that it must still pass the tests of invention and of non-discovery.

At the international level, Article 27.3(b) of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) permits Members to exclude plants and animals, and essentially biological processes for their production, but not microorganisms and non-biological and microbiological processes.[4] India's statutory language tracks this structure. That correspondence has sometimes been read as though it settled the question of patentability. It does not. TRIPS fixes what a Member may not exclude by category; it does not oblige a Member to patent what is merely found, nor to ignore the disclosure and public-interest conditions that every patent system attaches to a monopoly.

The Indian case law has moved from the Calcutta High Court's decision in Dimminaco AG v Controller of Patents and Designs, which accepted that a process yielding a live vaccine could be an invention, to the recent decisions of the Madras and Calcutta High Courts in ImClone

[1] The Patents Act, 1970, s 2(1)(j), as amended by the Patents (Amendment) Act, 2002 and the Patents (Amendment) Act, 2005.
[2] The Patents Act, 1970, s 3(c). The words "or discovery of any living thing or non-living substance occurring in nature" were introduced by the Patents (Amendment) Act, 2002.
[3] The Patents Act, 1970, s 3(j).
[4] Agreement on Trade-Related Aspects of Intellectual Property Rights (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 299, art 27.3(b).

and BTS Research, which place human intervention at the centre of the inquiry.[5] Yet remands by the Delhi High Court in 2026 and the publication of a draft set of biotechnology examination guidelines in September 2026 show that the test is still unsettled. Against this backdrop, the present paper seeks to provide a critical overview of the statutory scheme and the case law, and to propose a sequenced inquiry that the Controller and the courts can apply consistently. The paper emphasises the pressing need for a coherent method which gives effect to the Act without diluting the public-interest safeguards that the Act and India's wider regulatory framework contain.

II. The Statutory and Treaty Framework

A. Section 2(1)(j): The Threshold Definition of Invention

Section 2(1)(j) is the gateway through which every claim must pass. An invention must be a new product or process, must involve an inventive step and must be capable of industrial application. Each of these expressions is separately defined. A new invention is one that has not been anticipated by prior publication or prior use in India or elsewhere before the date of filing; an inventive step is a feature involving a technical advance over existing knowledge, or economic significance, or both, that makes the invention not obvious to a person skilled in the art; and capable of industrial application means capable of being made or used in an industry.[6]

For a genetically modified microorganism, each limb has its own content. Novelty requires that the particular modified strain, and not merely its genus or species, was not previously disclosed. Inventive step requires a technical advance, such as improved yield, stability, substrate range or safety, over what a skilled microbiologist would have arrived at from the prior art. Industrial applicability requires a credible use in manufacture, agriculture, environmental treatment or medicine. The important point is that these requirements are independent of Section 3. A claim that clears the exclusions can still fail for want of novelty or inventive step, and a useful and novel organism can still fail if it is only a discovery.

B. Section 3(c): Discovery of Living Things Occurring in Nature

Section 3(c) excludes the mere discovery of a scientific principle, the formulation of an abstract theory, and the discovery of any living thing or non-living substance occurring in

[5] Dimminaco AG v Controller of Patents and Designs (2002) IPLR 255 (Cal).
[6] The Patents Act, 1970, s 2(1)(l) (new invention), s 2(1)(ja) (inventive step) and s 2(1)(ac) (capable of industrial application).

nature. The 2002 amendment that added the third limb accompanied the opening of Indian law to microorganisms: once the Act ceased to treat living subject matter as outside patents altogether, it was necessary to state that finding a living thing was not inventing it.[7]

The provision draws on the old and familiar distinction between invention and discovery. A discovery reveals what already exists; an invention contributes something that did not exist, or that could not be had without the inventor's intervention. A microorganism isolated from soil, characterised and cultured, but otherwise unchanged, is the standard example of a discovery. An organism into which a defined gene construct has been introduced, so that it now possesses a property that no natural strain is shown to possess, is a different thing. Section 3(c) is thus best understood as a filter on the origin of the claimed subject matter and not as a rule against living claims.

C. Section 3(j): Plants, Animals and the Microorganism Carve-Out

Section 3(j) is often cited as the provision that "allows" microorganism patents. The text does less. It excludes plants and animals in whole or in part, including seeds, varieties and species, and essentially biological processes for their production or propagation, other than micro-organisms. The words "other than micro-organisms" remove microorganisms from this particular exclusion. They do not displace Section 3(c), Section 2(1)(j), or any other provision.

A conjoined reading of Sections 3(c) and 3(j) has been adopted by commentators and, as reported, in the Patent Office's draft guidelines of 2026: microorganisms are not excluded under Section 3(j), but a microorganism isolated from nature is a discovery under Section 3(c), so that only modified microorganisms qualify as patentable subject matter.[8] A further difficulty is definitional. The Act does not define "micro-organism", and the Manual of Patent Office Practice and Procedure has not filled the gap, whereas the European practice treats the term as covering bacteria, yeasts, algae, protozoa, plasmids, viruses and, in some formulations, cells of higher organisms.[9] Where the boundary between a microorganism and a cell of a plant or an animal lies is therefore a question that Indian law has not yet answered, and the answer matters for the reach of the Section 3(j) exclusion.

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[7] The Patents (Amendment) Act, 2002 came into force on 20 May 2003; see S.S. Rana & Co., 'The Patenting of Microorganisms in India' (Mondaq, 3 September 2025).

[8] See Krishna & Saurastri, 'Analysis of Section 3(J) of the Patents Act, 1970' (Asia IP Law, 14 November 2012); 'Biotech Patents And s.3(j) After Harvard V Controller' (iPleaders) <https://blog.ipleaders.in/biotech-patents-section-3j-man-made-construct/> accessed 29 October 2026, reporting the 2026 draft guidelines.

[9] Krishna & Saurastri (n 8).

D. Disclosure, Deposit and Claim Scope: Sections 10(4) and 10(5)

A patent is a bargain: exclusivity in return for enabling disclosure. For living subject matter, a written description is often not enough, because a skilled person cannot reconstruct a strain from words alone. Section 10(4) therefore provides that, where a biological material is mentioned in the specification that cannot be described so as to satisfy the requirements of full description and best method, and the material is not available to the public, the application must be completed by deposit of the material with an international depositary authority under the Budapest Treaty, not later than the date of filing in India, with the available characteristics and the depositary details included in the specification and with access to the deposit available only after the date of the application. The specification must also disclose the source and geographical origin of any biological material used in the invention.[10]

Section 10(5) adds that the claims must be clear and succinct and fairly based on the matter disclosed in the specification.[11] This requirement does much of the practical work in biotechnology. It is the means by which an applicant who has made, and deposited, one engineered strain is prevented from claiming every organism that shares a function. Non-disclosure or wrong mention of the source or geographical origin of biological material is also a ground of pre-grant and post-grant opposition and of revocation, and an applicant relying on biological resources obtained from India must, under the Biological Diversity Act, 2002, obtain the approval of the National Biodiversity Authority before the patent is sealed.[12]

E. Article 27.3(b) of TRIPS and Its Limits

TRIPS Article 27.1 requires patents to be available for inventions in all fields of technology, without discrimination as to the field, provided that they are new, involve an inventive step and are capable of industrial application. Article 27.2 allows Members to exclude inventions whose commercial exploitation must be prevented to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment. Article 27.3(b) permits the exclusion of plants and animals other than micro-organisms, and of essentially biological processes for their production other than non-biological and microbiological processes, and requires Members to protect plant varieties by

[10] The Patents Act, 1970, s 10(4)(ii)(A)–(D); Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (adopted 28 April 1977, entered into force 19 August 1980) 1861 UNTS 361.
[11] The Patents Act, 1970, s 10(5).
[12] The Patents Act, 1970, ss 25(1)(j), 25(2)(j) and 64(1)(p); the Biological Diversity Act, 2002, s 6.

patents, an effective sui generis system, or a combination.[13]

Three consequences follow. First, a Member may not exclude microorganisms as a category from patentability. Second, Article 27.3(b) is a permission to exclude, not a command to grant; the criteria in Article 27.1 apply to microorganisms as to any other subject matter, and nothing in TRIPS requires a Member to treat a discovery as an invention. Third, TRIPS leaves Members free to determine the appropriate method of implementing its provisions within their own legal system and practice, and recognises that Members may adopt measures necessary to protect public health and nutrition and to promote the public interest in sectors of vital importance, provided they are consistent with the Agreement.[14] The Indian scheme of Sections 2(1)(j), 3(c), 3(j) and 10 is, in this light, a permissible and coherent implementation, and not a restriction of what TRIPS requires.

III. The Judicial and Administrative Response

A. Dimminaco: Live Organisms and the Concept of Manufacture

In Dimminaco, the Calcutta High Court considered a process for preparing a live vaccine for protecting poultry against bursitis infection. The Patent Office had refused the application on the ground that the process involved a living virus and that a product containing a live organism was not a substance produced by manufacture. The High Court held that the word manufacture was not defined in the statute and that it should be given its ordinary commercial meaning; that the vendibility of the product was an accepted test; and that a vaccine, being a vendible product capable of industrial application, was a substance obtained by a process of manufacture notwithstanding that it contained a live organism.[15]

Two features of Dimminaco should be kept in view. It decided that the presence of life in the product did not by itself remove an invention from the Act; it did not decide that every living product is an invention. And it was decided under the pre-2002 text of Section 2(1)(j), which spoke of manufacture and had no Section 3(c) in its present form. The decision therefore

[13] TRIPS, arts 27.1, 27.2 and 27.3(b). On the negotiating history, see Daniel Gervais, The TRIPS Agreement: Drafting History and Analysis (4th edn, Sweet & Maxwell 2012); Carlos M. Correa, Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement (OUP 2007).

[14] TRIPS, art 1.1 and art 8.1. The Convention on Biological Diversity (1992) 1760 UNTS 79, arts 15 and 16, supplies the complementary framework on access to genetic resources and benefit sharing, which India implements through the Biological Diversity Act, 2002.

[15] Dimminaco (n 5). The decision is discussed in Office of the Controller General of Patents, Designs & Trade Marks, Guidelines for Examination of Biotechnology Applications for Patent (2013), which records that the case "opened the doors" to patents where the final product of the claimed process contained living microorganisms.

answers the first of the questions that this paper raises, namely whether life is a bar, but is silent on the second, namely what separates an invention from a discovery within the living world. It is the Patents (Amendment) Act, 2002, with its inclusion of biochemical, biotechnological and microbiological processes within the scope of chemical processes and the new Section 3(c), that raised that second question.

B. The American Reference Points: Chakrabarty and Myriad

Indian decisions and commentary routinely refer to Diamond v Chakrabarty, in which the United States Supreme Court held that a human-made bacterium containing plasmids that enabled it to degrade components of crude oil was a manufacture or composition of matter, and thus patentable subject matter, because it was a product of human ingenuity with a distinctive character and use, and not a product of nature.[16] Thirty-three years later, in Association for Molecular Pathology v Myriad Genetics, the same Court drew the other line: isolated naturally occurring DNA is not patent-eligible merely because it has been isolated, while complementary DNA, which is not naturally occurring, is.[17]

The two decisions are useful as an illustration of the same distinction that Section 3(c) expresses, but they are no substitute for the Indian text. The American exclusion for products of nature is a judge-made exception to a broad statutory definition. The Indian exclusion is a statutory provision with its own words and its own context, and must be construed as such. The comparative material shows that the inquiry in both systems is one of the difference between the claimed subject matter and nature; it does not supply the Indian test.

C. ImClone and BTS Research: Human Intervention as the Organising Idea

In ImClone LLC v Assistant Controller of Patents and Designs, the Madras High Court (Senthilkumar Ramamoorthy J) examined a claim to antibodies generated through a hybridoma process in which murine genetic material had been replaced with human material. The Controller had refused the claim as the discovery of a naturally existing molecule. Setting aside that finding, the High Court read Section 3(c) as one in which the word "mere" qualifies only the first limb, concerning scientific principles; in which "occurring in nature" qualifies only the non-living substance; and in which discovery connotes the finding of something that

[16] Diamond v Chakrabarty 447 US 303 (1980), affirming In re Chakrabarty 571 F 2d 40 (CCPA 1978).
[17] Association for Molecular Pathology v Myriad Genetics Inc 569 US 576 (2013).

already exists, as distinct from the production or engineering of something that did not.[18] ImClone concerned a non-living substance and not a microorganism, but its reasoning on the meaning of discovery applies with equal force to an engineered organism: what has been made through intervention has not merely been found.

BTS Research International Pty Ltd v Controller General of Patents, Designs and Trade Marks, decided by the Calcutta High Court on 3 April 2025, concerned Section 3(j) and not Section 3(c). The claim was to a method of generating tri-hybrid cells by fusing human and mouse somatic cells. The High Court held that a process is essentially biological only if it consists entirely of natural phenomena, and that the degree of human intervention must be assessed on the essence of the invention, having regard to the totality of human intervention and its impact on the result achieved. The refusal was set aside and the matter remanded for fresh consideration; no grant was directed.[19] BTS Research is not a microorganism case, and it concerns the exclusion of processes. It is nevertheless the clearest Indian statement that the inquiry looks to what human intervention actually produced, and not to the biological character of the materials used.

D. The Regents Case: Natural Variants, Breadth and Deposit

The Delhi High Court's decision of February 2025 in Regents of the University of California v Assistant Controller of Patents and Designs points the other way, or at least adds a caution. The application claimed a recombinant Salmonella carrying a loss-of-function mutation in the dam gene together with a further loss-of-function mutation in one of the genes sifA, spvB or mgtC, for use as a live vaccine. The Controller refused it under Section 3(c) and Sections 10(4) and 10(5). The High Court (Amit Bansal J) upheld the refusal, holding that the claims as drafted were broad, were not fully supported by the disclosure, and could also cover naturally occurring mutants, which are a discovery; and that a recombinant bacterium which is not available to the public had to be deposited under the Budapest Treaty.[20]

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[18] ImClone LLC v Assistant Controller of Patents and Designs, (T) CMA (PT) No 126 of 2023 (Mad HC, 6 March 2024) (Senthilkumar Ramamoorthy J). The reported citations of this decision differ between sources, and the case number and date are therefore used here; see also 'Patentability – High Court Clarifies The Language Of Section 3(c) Of The Patents Act, 1970' (Mondaq).

[19] BTS Research International Pty Ltd v Controller General of Patents, Designs and Trade Marks, IPDPTA 56 of 2023 (Cal HC, 3 April 2025), as reported in 'Biotech Patents And s.3(j) After Harvard V Controller' (iPleaders) (n 8).

[20] Regents of the University of California v Assistant Controller of Patents and Designs, C.A.(COMM.IPD-PAT) 481/2022 (Del HC, February 2025) (Amit Bansal J), concerning Patent Application No 201717005699; see 'S.10(4) Patents Act | Delhi HC Rejects Appeal For Salmonella Microorganism-Based Live Vaccine' (LiveLaw).

The decision has been criticised on two grounds: that microorganisms lie outside Section 3 altogether, so that the Controller should not have applied Section 3(c) to them, and that the finding that the disclosure was inadequate was not supported by an evidentiary basis in the record.[21] The first criticism rests on a reading of Section 3(j) that this paper does not accept, for the reasons given in Part II; the second is a fair point about the reasoning of the order. The enduring value of the decision lies elsewhere. It shows that a claim which names a function or a family of modifications, without tying itself to what the inventor made and disclosed, may extend to what nature already supplies, and that this is a defect in the claim and not in the subject matter.

E. The 2026 Remands and the Draft Guidelines

Decisions of the Delhi High Court in 2026 illustrate the unsettled state of the law. In Harvard (President and Fellows of Harvard College v Controller General of Patents, Designs and Trade Marks), Tejas Karia J on 28 March 2026 set aside a refusal under Sections 3(j), 3(e), 10(4) and 10(5) because the Controller had not considered the amended claims, and directed a fresh decision within six months, expressly without expressing any view on the merits.[22] In Pioneer Hi-Bred International Inc v Controller of Patents, decided on 22 July 2026, the Court remanded because the Controller had refused the whole application on a Section 3(c) objection directed to only two of eight claims, observed that the reasoning of the Madras High Court on the meaning of discovery carried considerable force, and left the Section 3(c) question to be decided afresh.[23]

Neither remand decides whether an engineered organism or molecule is patentable. Each insists on a complete and reasoned examination of every claim actually pressed. In September 2026, the Patent Office published for comment draft Guidelines for Examination of Patent Applications in the Field of Biotechnology, which, as reported, adopt the totality-of-intervention approach of BTS Research for Section 3(j) and read the microorganism carve-out together with Section 3(c), so that only modified microorganisms are patentable.[24] A draft of

[21] See 'Delhi High Court Stirs the Pot for Biotech Patent Applicants in India' (SpicyIP, 26 February 2025) <https://spicyip.com/2025/02/delhi-high-court-stirs-the-pot-for-biotech-patent-applicants-in-india.html> accessed 29 October 2026.

[22] President and Fellows of Harvard College v Controller General of Patents, Designs and Trade Marks, C.A.(COMM.IPD-PAT) 493/2022 (Del HC, 28 March 2026) (Tejas Karia J), 2026:DHC:2597, as reported in 'Biotech Patents And s.3(j) After Harvard V Controller' (iPleaders) (n 8).

[23] Pioneer Hi-Bred International Inc v Controller of Patents, C.A.(COMM.IPD-PAT) 35/2024 (Del HC, 22 July 2026), as reported in 'Not a Mere Discovery: Delhi High Court Revisits Section 3(c) Patentability for Recombinant Proteins' (BananaIP Intellepedia, 26 August 2026).

[24] See 'Draft Biotechnology Patent Examination Guidelines 2026: What the Indian Patent Office Has Proposed'

this kind is not law, and it cannot enlarge or reduce the Act, but it signals where examination practice is likely to go.

IV. Critical Analysis and Need for Reformation

The material surveyed above shows a gradual convergence on human intervention as the organising idea, but it also shows that the convergence is incomplete. Four difficulties stand out.

The first is that the three provisions are applied together without a stated order. In practice, an examiner confronted with a recombinant bacterium may raise Section 3(c), Section 3(j), lack of inventive step and insufficiency in a single objection, and a tribunal reviewing the order must unpick which finding supports which ground. The remands in Harvard and Pioneer are examples of what follows: orders which do not deal with every claim, and decisions on exclusions that were never properly put to the applicant. A fixed sequence would assign each provision a distinct function and make each finding reviewable.

The second is that human intervention, standing alone, is necessary but not sufficient. If any act of laboratory manipulation sufficed, the patent system would reward trivial modifications, such as the selection of a spontaneous mutant or the insertion of a marker gene with no effect on function, and would blur the line that Section 3(c) draws. Conversely, if intervention were irrelevant, all engineered organisms would be treated as natural. What the cases point toward, and what the statute requires, is a technical difference between the claimed organism and what is found in nature that is the product of intention, that is stable, that can be reproduced reliably, and that is significant enough to confer the technical advance on which inventive step depends.

The third is the problem of claim breadth. The Regents case exposes a recurrent pattern in biotechnology drafting: claims framed by function or by a broad set of permitted modifications, which read onto naturally occurring variants. Where a claim covers what nature supplies, the objection is properly one under Section 3(c) for the overlapping part and under Section 10(5) for want of fair basis, and the remedy is amendment and not outright refusal of the whole. A related difficulty is that the Controller has argued that the Act contains no power to sever valid

(Intepat) <https://www.intepat.com/blog/draft-biotechnology-patent-examination-guidelines-2026-india> accessed 29 October 2026. The draft is a consultation document and, as reported, does not state that it supersedes the 2013 Guidelines.

from invalid claims, which has led to refusals of whole applications on the strength of objections to some claims; Pioneer shows the need for claim-by-claim examination.

The fourth is the neglect of the public-interest safeguards that the Act already contains. Section 3(b) excludes inventions whose primary or intended use or commercial exploitation would be contrary to public order or morality or would cause serious prejudice to human, animal or plant life or health or to the environment; Section 3(p) excludes inventions which in effect are traditional knowledge; and Section 10(4), Sections 25 and 64 and the Biological Diversity Act, 2002 together address access to, and disclosure of, biological resources.[25] It is also important to distinguish a patent from a regulatory approval. A patent confers a right to exclude; it does not authorise the release of an engineered organism into the environment, which is regulated separately under the Environment (Protection) Act, 1986 and the 1989 Rules for hazardous microorganisms and genetically engineered organisms or cells.[26] A coherent approach to patentability should not collapse the two, and should also not assume that Section 3(b) can be disregarded because the organism is useful.

A fifth, definitional, difficulty has been noted already. The Act does not define "micro-organism", and BTS Research and the 2026 draft show that the dividing line between a microorganism and a cell of a higher organism will be drawn in cases about cells and not about microbes. A statutory definition, or at the least a definition in the examination guidelines, would remove a major source of uncertainty.

It follows that reform need not take the form of amendment of the Act. The better course is for the Patent Office to issue final guidelines, and for courts to adopt in their reasoning, a clear order of inquiry that respects the text. The next Part sets out such an order.

V. A Sequenced Inquiry for Genetically Modified Microorganisms

The inquiry proposed here has three stages. Each stage asks a different question, and a claim must pass each in turn. The order matters: a later stage should not be used to decide a question that belongs to an earlier one, and an earlier finding of invention should not relieve

[25] The Patents Act, 1970, ss 3(b) and 3(p). The Supreme Court has repeatedly emphasised that the patent system serves the public interest and not only the interest of the patentee: see Novartis AG v Union of India (2013) 6 SCC 1. On the limits of summary determinations of Section 3(j) questions, see Monsanto Technology LLC v Nuziveedu Seeds Ltd (2019) 3 SCC 381, in which the Supreme Court left the question of validity under Section 3(j) to be decided at trial.

[26] Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Microorganisms, Genetically Engineered Organisms or Cells, 1989, framed under the Environment (Protection) Act, 1986.

the applicant of the later conditions.

A. Stage One: Is the Claim to a Human-Made Technical Conception?

The first question is whether the claim discloses something made by human intervention, or only something found. This is the Section 3(c) question, and it is addressed before the remaining requirements, because a discovery is not an invention however novel or useful it may be. The claim, read with the specification, must identify the human contribution: the construct introduced, the gene altered or deleted, the pathway assembled, or the process of selection that produced a defined strain. An organism isolated from the environment and purified, a wild-type strain cultured in the laboratory, and a naturally occurring mutant identified by screening, fail this stage.

Intervention alone is not enough. The test proposed is whether intentional human involvement generated a lasting, reliable and significant technical difference in the claimed organism. The difference must be lasting, in that the modification is stably inherited and does not revert; reliable, in that it can be reproduced from the disclosure and the deposit; and significant, in that it produces a functional change that is not trivial or incidental. The three attributes correspond to the concerns that run through the case law: the contribution must be the inventor's and not nature's (ImClone), it must have an actual effect on the result (BTS Research), and it must be capable of being practised by others (Section 10(4)). This stage is concerned with kind and not with degree of merit; the question of advance over the prior art belongs to the second stage.

B. Stage Two: Does the Claim Independently Satisfy Section 2(1)(j)?

Once the claim is found to be to a human-made conception, it must meet novelty, inventive step and industrial application on their own terms. A strain that differs from the closest prior art only by a known and predictable modification does not involve an inventive step merely because it was made by recombinant methods. Conversely, a modification that is human-made but shown to produce an unexpected technical result, such as a vaccine strain with attenuation that is stable and does not revert, will normally satisfy the requirement of technical advance. Industrial application must be credible on the disclosure and not speculative. Keeping this stage separate from Stage One avoids the error of treating a finding of human intervention as a finding of inventiveness, and the opposite error of rejecting an engineered organism for obviousness on the ground that its parent is found in nature.

C. Stage Three: Specific Exclusions, Disclosure and Scope

Only a claim that has passed the first two stages is tested against the specific exclusions and the conditions of disclosure. Section 3(j) is considered here: the microorganism carve-out is applied by determining whether the claimed organism is a microorganism or a plant or animal part, and, in a process claim, whether the process is essentially biological, applying the totality-of-intervention approach of BTS Research. Section 3(b) is considered where the exploitation of the organism would cause serious prejudice to human, animal or plant life or health or to the environment, and Section 3(p) where the claim is in effect to traditional knowledge. This is also the stage at which the Section 10 conditions are applied: the specification must enable the invention, the biological material must be deposited with an international depositary authority where it is not available to the public, and the source and geographical origin must be disclosed, with the approval of the National Biodiversity Authority where required.

Claim scope is calibrated at this stage as well. The breadth of the claim must be consistent with the disclosure and the deposit. A claim to a deposited strain and to strains carrying the specified modification is supported; a claim to every organism which has a given function, or to every mutation of a gene, is not. Where a claim overreaches by reading onto naturally occurring variants, the proper course is to require amendment to the disclosed modifications, and not to refuse the entire application where claims that are properly limited survive. This is the point at which the Regents decision is best understood: as a decision on breadth and sufficiency, and not as a statement that recombinant organisms are outside patent law.

D. Why the Sequence Is Consistent with the Act and with TRIPS

The sequence is consistent with the Act because it gives each provision the function that its text assigns it. Section 3(c) is a filter on origin; Section 2(1)(j) is a test of merit; Section 3(j) and the other exclusions mark out categories which the legislature has withheld; and Section 10 is the price of the monopoly. It is consistent with TRIPS because microorganisms are not excluded as a class, the Article 27.1 criteria are applied to them, no discovery is treated as an invention, and the disclosure obligations that Article 29 of TRIPS itself contemplates are enforced. And it preserves the public-interest safeguards, because the later stage keeps open Section 3(b), the Biological Diversity Act, 2002, and the separate regulatory control over release, which the first two stages do not touch.[27]

[27] TRIPS, art 29.1, which requires a Member to require an applicant to disclose the invention in a manner

VI. Conclusion

The patentability of genetically modified microorganisms in India is not governed by a single rule, but by the interaction of Sections 2(1)(j), 3(c), 3(j) and 10 of the Patents Act, read against the background of TRIPS. The carve-out for microorganisms in Section 3(j) is a statement of what is not excluded; it is not a grant, and it does not displace the requirement that the claimed subject matter be an invention and not a discovery. Article 27.3(b) of TRIPS, likewise, forbids the exclusion of microorganisms as a class but does not oblige any Member to patent what nature has already supplied.

The Indian decisions from Dimminaco to ImClone and BTS Research support an inquiry directed to the contribution of human intervention. The recent remands, and the draft guidelines of 2026, show that the courts and the Patent Office have not yet settled the test that governs. The sequenced approach proposed in this paper offers a means of settling it: first, whether the claim discloses a human-made technical conception, meaning a lasting, reliable and significant technical difference from what occurs in nature; second, whether it independently satisfies novelty, inventive step and industrial applicability; and third, whether it survives the specific exclusions and meets the requirements of disclosure, deposit and claim scope. Applied in that order, the approach gives effect to the Act, meets the requirements of TRIPS, and ensures that India's public-interest safeguards are not diluted by the appropriation of its natural resources, by speculative claims or by environmentally harmful exploitation.

Its adoption does not call for legislation. It calls for final examination guidelines that state the order of inquiry, a definition of microorganism, examination that deals with each claim separately, and judicial reasoning that identifies which provision a finding rests upon. The effective administration of the law, and not only its text, will decide whether biotechnology innovation in India is rewarded without the public's interest in nature and in the environment being traded away.

sufficiently clear and complete for it to be carried out by a person skilled in the art, and permits a requirement to indicate the best mode.