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Twenty Years of Patenting Activity of Micro-Organism(s) in India: Trends and Patterns

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ABSTRACT

This paper looks at the innovation activity of micro-organisms (novel, isolated or discovered) in India to decipher the trends in the past twenty years (1995–2022) under the Indian Patents Act, 1970 (hereinafter Patents Act). As of today, the Patents Act expressly specifies that a microorganism is patentable, a result of the Patents (Amendment) Act, 2002. Prior to 2002, the Indian Patent Office (IPO) refused the grant of a patent to a method of producing a vaccine containing a live microorganism on the ground that the term 'manufacture' does not include a process with a living substance as its end product. The Calcutta High Court, however, negated the decision of the IPO as the assessment of the method of manufacture does not concern live or dead micro-organism, and directed the grant of patent. Twenty years on, this paper analyses the patterns and trends based on the response of the IPO regarding the grant/refusal of the patents related to micro-organism. Few observations that emerge from this paper include the distribution of novel and not novel micro-organisms that constitute the patenting landscape in India; contributions of foreign and India patent holders; major sectors where novel micro-organisms are used; the involvement of the applicant and the examiner in the grant/rejection of patents before the IPO, major objections that applicants face before the IPO, and the connection between the Indian guidelines on patenting activity of micro-organisms and the patenting activity before the IPO.

Key words: micro-organisms, patents, India, trends, patterns

INTRODUCTION

Micro-organisms, the tiny creatures in the science and biotechnology, have long emerged as the driving force behind revolutionary changes across diverse industries (Minakshi Prasad, Basanti Brar, Kiran Bala and Namitha Singh, 63 (3) Emerging Microbial Technologies, Indian Journal of Microbiology, 2023, pp. 231–234, at 231). Hailed as the unexpected heroes, micro-organisms (in its many forms as bacteria, viruses, fungi and other forms) have found their way as a part of emerging technologies that address the pressing challenges in healthcare, agriculture, environmental concerns, energy production and beyond (Ibid). In a timely manner, micro-organisms have also found their way into our daily life, with many companies based on development of bioengineered products (Stuart J. Smyth, Regulatory barriers to improving global food security, 26 Global Food Security, September 2020, 100440, https://doi.org/10.1016/j.gfs.2020.100440, accessed on 21 May 2024). Some of these are Genetically Modified Micro-organisms (GMOs) that have given rise to constant innovation in order to address concerns of population explosion. On the other hand, they have also come under scrutiny for risk assessment based on environmental concerns (Dhan Prakash, Sonika Verma, Ranjana Bhatia and B.N. Tiwary, "Risks and Precautions of Genetically Modified Microorganisms, 2017 International Scholarly Research Notices, 2017, pp. 1–13. https://doi.org/10.5402/2011/369573, accessed on 21 May 2024). The biotechnology sector, uses genetic engineering techniques to change the DNA of plants, animals and microbes which has also resulted in the grant of patents for micro-organisms that are man-made or isolated or part of the product or process in the form of GMOs. In these circumstances, the novel microorganisms has to pass the test of patentability under national law and needs to be established as a novel product/process, showing an inventive step and with the capability of industrial applicability. In the Indian context, patents are granted for inventions that contain a micro-organism, whether dead or alive.

The Indian patent landscape has seen a steady rise in patent application, with India clinching a top stop as the main driver of patent application, worldwide (WIPO Report, 2024, https://www.wipo.int/edocs/pubdocs/en/wipo-pub-941-2024-en-world-intellectual-property-indicators-2024.pdf, accessed on 21 May 2024). However, in the case of biotechnology patents, the numbers are low (IPO Annual

Report, 2022–2023, p. 39), even though the Indian biotechnology sector holds 3% of the global share, is the third largest in the Asia-Pacific region, and is among the top 12th biotechnology destinations in the world (Indian Brand Equity Foundation, Biotechnology (2023), 5, https://www.ibef.org/download/1700035272_Biotechnology_August_2023.pdf, accessed on 21 May 2024).

The research landscape is inundated with scientific papers on the role of microorganism in the evolution of plants and animals (Rosenburg and Zilher-Rosenburg, 2008) and discourses around cutting-edge technologies related to microorganism (Garg et al., 2024; Shang L., and Zhang, Dando, 2024; Sarkar and Sarkar, 2024). These changes also result in legal ramifications in the world of patenting of microorganism (Islam, et al., 2024), with patentability of live microorganisms, and its benefits to the public. (Guttag, 1979). A host of concerns were brought to the forefront in the initial years of patenting of microorganisms, most notably around the ethical concerns surrounding patenting and its uses (Dresser, 1988), which was revisited recently to conclude that none of the fears surrounding its misuse have seen fruition (Jordan et al., 2021).

In the early years of patenting of micro-organisms, the scholarly works focused on the determination of whether microorganisms have to be conceived as a manufacture or a composition of matter (Jain and Vydyula, 2019). Questions that were asked early on are also about the necessity of the creation of a depository (Schneide, 1984), the risks associated with the unregulated transportation of potentially harmful microorganisms and the impact on international patenting, and the lack of uniformity among the various patent systems (Schroeder, 1984; Meyer, V.H. 1983). The domestic and international patent systems, its origin, patentable subject matter, patentability of living organisms and the necessity of patenting man-made microorganisms were also part of the discourse that continued to be explored (Mishral et al., 2019).

The commercialization aspect of micro-organisms as a result of the advancements in biotechnology has also raised ethical concerns surrounding its use (Michael et al., 2024). The involvement of the many courts has also been active, right from the early cases that looked into the legality of the grant of a patent right for an engineered microorganism (Diamond v. Chakrabarty, 447 U.S. 303 (1980); Funk Brothers Seed Company v. Kalo Inoculant Company, 333, U.S. 127 (1948)). A human rights approach to create a balance between the creator and the interests of the public is listed under the future concerns of the work of Senan, Haridas and Prajapati (2011), Balachandra Nair, R. and Ramachandranna, P. (2010), Ott, R. (2005).

Specific to the biotechnology sector, there were talks about the substantial costs of experimentation, thereby compelling investors to protect their innovation as much as possible (Giugni and Giugni, 2010).

An analysis on patent statistics as an indication of competition with focus on the different domains of biotechnology and different sectors in different countries have also been studied (Banerjee, Gupta and Garg, 2000). An empirical study establishes a collection of metrics that evaluate the competitive standing of nations or organisations by employing patent statistics in patent applications in the biotechnology sectors of France, Germany, and the United Kingdom. There are indicators utilise patent statistics to rank and compare the technological competencies of firms or nations (Ramani et al., 2002).

In the Indian context, early works focuses on many universal questions surrounding the patentability of microorganisms, and how a developing country like India can address these challenges while positioning itself within the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) (Sekar & Kandavel, 2002, Saha, 2008, Chowdhury, 2010, Senan, Haridas and Prajapati, 2011). Chowdhury (2010), also emphasis on how the domestic regulatory mechanism with its direct linkage between the objective of the TRIPS review and its outcome, could possible found to be TRIPS compliant. There are also analyses of the fundamental aspects of patenting of living organisms and its differences between lower microorganisms, and higher complex, multicellular organisms, from the standpoint of patentability (Balganesh, 2000).

Basheer (2005), examines the 2002 and 2005 Amendments to access that there are enough flexibilities within the TRIPs that can enable the protection of micro-organisms with the Indian patent regime. Basheer also discusses the options available to India regarding incorporating TRIPs flexibilities by introducing definitional flexibilities, addressing issues of scope of patent eligibility grounds especially the discovery and morality exception and ensuring that the patentability criteria are evolved based on the examination guidelines that are formulated by India, followed by its strict application in order to restrict the scope of patentability of micro-organisms. Recent works focus prospects to boost IPR framework

and legislation in the global perspective (Jain, Singh and Das, 2019), and address various issues that still remain including definition of micro-organisms, and other critical issues that are related to microbial patents which if addressed can make the patent regime relating to micro-organisms more meaningful (Mishra, Verma & Singh, 2019). In the Indian context, all of the work till now deal with the cautionary approach regarding patenting of micro-organisms, followed by discussions on the need for a definition clause, alignment with international regime, and in later works, clarity about the necessity of human intervention in patenting of microorganism. However in the India context, a dive into the trends and patterns of novel microorganisms and patenting activity surrounding the same has not been captured. This paper aims to address this gap in literature.

INDIA'S TRYST WITH PATENTABILITY OF MICROORGANISMS

Article 27 clause (1) of Agreement of Trade Related Intellectual Property Rights (TRIPS) states that "patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application." TRIPS also provide flexibility to certain subject matter that can be kept outside the purview of patentability, which includes "plants or animals per se or part thereof" and "essentially biological process" (Article 27 (3)(b)). Microorganisms are excluded from the purview of TRIPS and hence the mandate is that microorganism should be protected by the member states.

Under the Indian Patents Act, 1970, Section 3 lists out inventions that are not patentable and their exceptions. Section 3 (j) mentions that plants or animals including its parts like seeds etc. are not patentable subject matter, with the exception of micro-organisms (See, The Patents (Amendment) Act, 2002, No. 38 of 2002, 25 June 2002. Most of the changes in this Amendment Act was based on recommendations made by a Joint Parliamentary Committee constituted for this purpose by the then government. See, Parliament of India Rajya Sabha the Patents (Second Amendment) Bill, 1999 Report of The Joint Committee, December 2001. See also, https://commerce.gov.in/international-trade/india-and-world-trade-organization-wto/indian-submissions-in-wto/trade-related-aspects-of-intellectual-property-rightstrips/review-of-the-provisions-of-article-27-3-b-communication-from-india/, accessed on 4 February 2024. This means that even if an invention is patentable and withstands the test of novelty, inventive step and industrial applicability, it will not be eligible for the grant of a patent if it falls within the exception of Section 3. In the case of patenting of microorganisms that are discovered, a conjoint reading of Section 3 clauses (c) and (j) stipulate that the micro-organism which occur in nature are not patentable subject matter (According to Section 3(c) of Indian Patent Act 1970, "a mere discovery of a scientific principle or the formulation of an abstract theory or discovery of any living or non-living substance occurring in nature and Section 3(j) plants and animals in whole or in any part thereof other than microorganisms, but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals, both categories cannot be granted patent." The African group also stressed on the need to exclude micro-organisms from patent protection under the local law. India's submissions by the Government of India through the Ministry of Trade and Commerce in World Trade Organisation(WTO) related to Review of the provisions of Article 27 under Clause 3(b), Communication from India, File No: IP/C/W/161 3 November 1999. https://commerce.gov.in/international-trade/india-and-world-trade-organization-wto/indian-submissions-in-wto/trade-related-aspects-of-intellectual-property-rightstrips/review-of-the-provisions-of-article-27-3-b-communication-from-india/, accessed on 4 February 2024). Accordingly, only genetically modified micro-organisms qualify for patentability under the Indian patent regime.

In 2001, the Calcutta High Court (hereinafter CHC) had an opportunity to address the issue of patentability of a Bursitis vaccine that contains a live microorganism, in the case of *Dimminicao v. Union of India*, (hereinafter *Dimminicao*) (2002 I.P.L.R 255 (Cal)). Based on the understanding that the 'manner of manufacture' in the Indian Patents Act, 1970 does not prevent the patenting of the vaccine containing a live organism, the CHC reversed the decision of the IPO and directed it to accept the patent application. The CHC concluded that an invention claiming living matter is a patentable subject matter and issued directions for the patent application to be considered for the grant of the patent by the IPO. A commentator observes that the refusal to grant a patent by the IPO in this case was part of the trend that fewer patents are conducive to a more robust indigenous industry, and that this is a 'policy style' approach to the issue of

patentability (Shamnad Basheer, "Policy Style" Reasoning at the Indian Patent Office, Intellectual Property Quarterly, November 2005, 309, Sweet and Maxwell Ltd. and Contributors, 2005, https://www.researchgate.net/publication/228146700_'Policy_Style'_Reasoning_at_the_Indian_Patent_Office, accessed on 6 February 2024).

The next year, the issue of patent eligibility of microorganisms in the Indian Patent Act, 1970 was determined with the Patents (Amendment) Act, 2002. The Patents (Amendment) Act, 2002 incorporated 'micro-organism' as patentable subject matter within the Indian law. This was done to ensure that India accommodated the minimum standards set by TRIPs within the window period granted to developing countries (India's transition period time was for ten years from 1995 to 2005 when it was signed to make the domestic legislations compatible to the TRIPS provisions and its features and to make amendments, if necessary, wherever needed in the current laws). The Patents (Amendment) Act, 2002 also clarified that 'chemical process' in Section 5 would include a 'bio-chemical', 'bio-technological' and 'micro-biological' process. The presence of Section 5 (1) of the Patents Act, 1970, which states that for certain inventions which claim a patent for substances intended for use, or capable of being used as food or as medicine or drug or relating to substances prepared or produced by chemical processes, "no patents shall be granted in respect of claims for the substances themselves, but claims for the methods or processes of manufacture shall be patentable," meant that, patent could be granted only to process and not to products. However, micro-organisms could be used medicine or drug or even food, if it could be produced by a chemical process (Shamnad Basheer, Limiting the Patentability of Pharmaceutical Inventions and Micro-Organisms: A Trips Compatibility Review, 2005, 1–6, http://dx.doi.org/10.2139/ssrn.1391562, accessed on 17 February 2024). This position changed with the deletion of Section 5 as a result of the Patents (Amendment) Act, 2005 wherein patents would now be granted to both products and processes. However the initiation of the Patents Amendment Act, 2005 also brought with it an expert committee constituted by the Government of India to examine "whether it would be TRIPS compatible to exclude micro-organisms from patenting" (Report of the Technical Expert Group on Patent Law Issues, December 2006, p. 2, https://www.ipindia.gov.in/writereaddata/images/pdf/report-of-technical-expert-group.pdf, accessed on 12 February 2024). Even though this issue was decided as a result of the Patents (Amendment) Act, 2002, and with the incorporation of micro-organism as patentable. A reason for this the review by the Indian government might be the TRIPs agreement that required a review. The review based specifically on the scope of whether plants and animal inventions should be covered by patents under Article 27 including an additional focus was made towards protection of new plant varieties (The background of Article 27 Clause (3) of the TRIPS agreement and its reviews and related issues as mentioned in WTO, https://www.wto.org/english/tratop_e/trips_e/art27_3b_background_e.htm, accessed on 5 February 2024). The review began in 1999 as required by the TRIPs Agreement. India's stand in its submission at the WTO in 1999 during the review of Article 27 (3)(b) was dealt in few responses: One of the points under review was to consider the effect of protection granted to microorganism and non-biological and microbiological processes in terms of scope and definition of microorganisms. On this, the first response was based on the necessity to ensure that there has to be a difference between discovery and invention and only the latter should be patented. The second response was based on the patentability criteria that shall be satisfied before the grant of a patent, which has to include novelty, non-obviousness and usefulness. The third response was based on the coverage of micro-organism, and patenting of which should include a micro-organism that is manmade, genetically engineered bacterium, which shall meet the test of patentability. Another point made was that national policy should decide what are patentable micro-organisms (The TRIPS Agreement Communication from Kenya on behalf of the African Group, WT/GC/W/302 6 August 1999, WTO General Council, https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=Q:/WT/GC/W302.pdf&Open=True, accessed on 16 July 2024).

Few years later, in order to address certain concerns regarding the exclusions for patentability of micro-organism, for example, relating to ordre public, morality, human, animal or plant life or health and environment or the the fear of adverse consequences of patenting of micro-organisms (However, recent works show the fears were misplaced and how advantageous the biotech revolution has been: Matthew Jordan, Neil Davey, Maheshkumar P.

Joshi and Raj Davé Forty Years Since Diamond v. Chakrabarty: Legal Underpinnings and its Impact on the Biotechnology Industry and Society, Centre for the Protection of Intellectual Property, 2021, pp. 1–14), the Commerce and Industry Minister constituted an expert committee for detailed examination. Accordingly, the Committee headed by Raghunath Mashelkar, a retired Director General of the Council of Scientific and Industrial Research (CSIR) was formed, which framed two terms of reference (A Technical Expert Group on Patent Law Issues was set up by the Government of India, Ministry of Commerce & Industry, Department of Industrial Policy & Promotion vide O. M. No. 12/14/2005-IPR-III dated 5 April 2005., Report of the Technical Expert Group on Patent Law Issues, December 2006, p. 2, https://www.ipindia.gov.in/writereaddata/images/pdf/report-of-technical-expert-group.pdf, accessed on 12 February 2024). The one that is relevant for this paper is "whether it would be TRIPS compatible to exclude micro-organisms from patenting." On this point, the Report concluded that excluding micro-organisms per se from patent protection would violate of TRIPS Agreement (A Technical Expert Group on Patent Law Issues was set up by the Government of India, Ministry of Commerce & Industry, Department of Industrial Policy & Promotion vide O. M. No. 12/14/2005-IPR-III dated 5 April 2005., Report of the Technical Expert Group on Patent Law Issues, December 2006, p. 3, https://www.ipindia.gov.in/writereaddata/images/pdf/report-of-technical-expert-group.pdf, accessed on 12 February 2024). The Report went on to comment that strict guidelines need to be formulated for examination of the patent applications involving micro-organisms from the point of view of substantial human intervention and utility (A Technical Expert Group on Patent Law Issues was set up by the Government of India, Ministry of Commerce & Industry, Department of Industrial Policy & Promotion vide O. M. No. 12/14/2005-IPR-III dated 5 April 2005., Report of the Technical Expert Group on Patent Law Issues, December 2006, p. 3, In 2019, guidelines were formed. https://www.ipindia.gov.in/writereaddata/images/pdf/report-of-technical-expert-group.pdf, accessed on 21 June 2024. See also, Srividhya Ragavan, The Mashelkar Report: A Tragedy of the Commons, 3(1) Nalsar Law Review, 146, 2006–2007).

In the context of this paper, some of the responses collected from the Stakeholders that find mention in the Annex to the Report are looked at to understand the issues surrounding the patent eligibility for micro-organisms (Shamnad Basheer, Deconstructing the Marshelkar Committee Report Controversy, Part 1, 2007, https://spicyip.com/2007/02/deconstructing-mashelkar-committee.html, accessed on 30 January 2024). Stakeholder responses stress on the fact that with such a clear provision in the TRIPs to include patentability of micro-organisms, "there is no way to interpret that micro-organisms can be excluded from patentability." (A Technical Expert Group on Patent Law Issues was set up by the Government of India, Ministry of Commerce & Industry, Department of Industrial Policy & Promotion vide O. M. No. 12/14/2005-IPR-III dated 5 April 2005., Report of the Technical Expert Group on Patent Law Issues, December 2006, p. 21, https://www.ipindia.gov.in/writereaddata/images/pdf/report-of-technical-expert-group.pdf, accessed on 12 February 2024). The Oxford Intellectual Property Research Centre, University of Oxford, U.K. New Chemical Entity made its comment only related to Micro-organism by stating that "The world has now moved far beyond this debate and we ought, in view of the rapid progress of our biotech industry, to grant protection to those micro- organism that are new and non-obvious. The above suggestions are confined to addressing the TRIPS compliant legal options." (A Technical Expert Group on Patent Law Issues was set up by the Government of India, Ministry of Commerce & Industry, Department of Industrial Policy & Promotion vide O. M. No. 12/14/2005-IPR-III dated 5 April 2005., Report of the Technical Expert Group on Patent Law Issues, December 2006, p. 27, https://www.ipindia.gov.in/writereaddata/images/pdf/report-of-technical-expert-group.pdf, accessed on 12 February 2024). Others like the Indian Drug Manufacturers' Association, suggested changes in the wording of Section 3 (1) (j) and to replace the word "micro-organism" with "'manmade or biotechnologically altered micro-organisms." (A Technical Expert Group on Patent Law Issues was set up by the Government of India, Ministry of Commerce & Industry, Department of Industrial Policy & Promotion vide O. M. No. 12/14/2005-IPR-III dated 5 April 2005., Report of the Technical Expert Group on Patent Law Issues, December 2006, p. 26, https://www.ipindia.gov.in/writereaddata/images/pdf/report-of-technical-expert-group.pdf, accessed on 12 February 2024). Another stakeholder, Gene Campaign, concur stating that "mere discovery and isolation will not be considered sufficient

human intervention" (A Technical Expert Group on Patent Law Issues was set up by the Government of India, Ministry of Commerce & Industry, Department of Industrial Policy & Promotion vide O. M. No. 12/14/2005-IPR-III dated 5 April 2005., Report of the Technical Expert Group on Patent Law Issues, December 2006, p. 2, https://www.ipindia.gov.in/writereaddata/images/pdf/report-of-technical-expert-group.pdf., accessed on 12 February 2024). However, Shamnad says that TRIPs does not mention this-and that determination of novel and discovery is not suggested by TRIPs and hence that distinction should not be made- the earlier version of this paper has this point. Shamnad Basheer, "Policy Style" Reasoning at the Indian Patent Office, November 2005, Sweet and Maxwell Ltd. and Contributors, 2005, I.P.Q.: No3, https://www.researchgate.net/publication/228146700_'Policy_Style'_Reasoning_at_the_Indian_Patent_Office, accessed on 6 February 2024).

In the same year, Council for TRIPs, WTO, issued a note regarding the review of the provisions of Article 27(3)(b). In the review note, the mandated review of Article 27(3)(b) was considered, in order to access the need for a definition of micro-organism; whether to prohibit or allow the patenting of all life forms specifically plants, animals, micro-organisms and all other living organisms and their parts; clarify the differences between plants, animals and micro-organisms (India, IP/C/M/29, para. 163, IP/C/W/161; Kenya, IP/C/M/28, para. 146, IP/C/M/40, para. 109; Kenya on behalf of the African Group, IP/C/W/163; Zimbabwe, IP/C/M/39, para. 111, IP/C/M/40, para. 75; Bangladesh, IP/C/M/42, para. 103, as cited in https://www.wto.org/english/tratop_e/trips_e/ipcw369r1.pdf, accessed on 5 February 2024); and that there are still areas where a common understanding does not exist and further work is needed in the TRIPs Council. This included "(a) the proposal to eliminate patent availability for all life forms, including elimination of the current TRIPS obligation to patent micro-organisms and microbiological and nonbiological processes for the production of plants and animals." (Summary of the Issues raised and Points made relating to Review of the Provisions of Article 27 clause (3) which was prepared by the Secretariat of WTO without prejudice to the rights and obligations of its members, IPC/W/369/Rev.1, https://www.wto.org/english/tratop_e/trips_e/ipcw369r1.pdf, accessed on 5 February 2024). India responded by stating that there are many grey areas in defining the scope of patentable microorganisms, the need for the scope of patentability of micro-organisms to be best left to national policy, but concluded by submitting that developing countries like India cannot accept any further strengthening of the protection provided to lifeforms at present. This comment was based on the need for balances and exceptions, both necessary for ethical, social and economic needs to the people (Review of the Provisions of Article 27.3.(b)–Communication from India, IP/C/W/161, 3 November, 2020, https://www.commerce.gov.in/international-trade/india-and-world-trade-organization-wto/indian-submissions-in-wto/trade-related-aspects-of-intellectual-property-rightstrips/review-of-the-provisions-of-article-27-3-b-communication-from-india/, accessed on 4 February 2024).

Other than TRIPs, India is si–gnatory to various international agreements which are linked to micro-organisms, like the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (since 2001) and the Convention on Biological Diversity (since 1992). Amendments to the Patents Act 1970 and the introduction of the Biological Diversity Act, 2002 were also calibrated to recognize India's accession to these treaties.

As of today, the Patent Manual on Practice and Procedure, 2019 clarifies that microorganisms, other than those that are naturally occurring, may be patentable (Microorganisms which are discovered from nature cannot be patented but the one with human intervention can be patented subjected to other requirements which satisfy patentability. Eg. Genetically modified microorganism. (Manual of patent office practice and procedure, Version 3.0, 26th November 2019. https://ipindia.gov.in/writereaddata/Portal/Images/pdf/Manual_for_Patent_Office_Practice_and_Procedure_.pdf, accessed on 5 February 2024). The Manual mentions that the finding of a new substance or micro-organism occurring freely in nature is a discovery and not an invention (Manual of patent office practice and procedure, Version 3.0, 26th November 2019, p. 40). Other relevant legal documents include the Guidelines For Examination Of Biotechnology Applications For Patent, 2013, which also discusses Section 3(j) of the Patents Act, 1970 and illustrates the section with two specific examples (Guidelines for Examination of Patent Applications in the Field of Pharmaceuticals, (Oct 2014). "Illustrative Example for Section 3(j): p. 37, Claim 1: A pharmaceutical composition comprising an antigen-presenting cell that expresses a polypeptide comprising at least an immunogenic portion of a breast tumour protein, or a variant thereof in combination with a pharmaceutically

acceptable carrier or excipient, wherein the antigen presenting cell is a dendritic cell or a macrophage. Analysis: Although claim 1 is directed to a pharmaceutical composition, it should be objected under Section 3 (j) of the Act, since the composition essentially contain an antigen-presenting cell as an active ingredient and carriers or excipients are obvious features with the cell while in the composition." https://www.ipindia.gov.in/writereaddata/Portal/IPOGuidelinesManuals/1_37_1_3-guidelines-for-examination-of-patent-applications-pharmaceutical.pdf, accessed on 5 February 2024). There are other guidelines that come into play, including The Manufacture, Use, Import, Export & Storage of hazardous micro-organisms genetically engineered organisms or cell Rules, 1989 and the Recombinant DNA Safety Guidelines, 1990, and the Biotech Pride Guidelines, 2021. There is also the DBT Intellectual Property Guidelines 2023 (Department of Biotech, Ministry of Science and Technology) (hereinafter Guidelines, 2023) which stresses on dissemination of information based on an appropriate approach especially by academic institutes funded through public support. The focus is on commercialization of the research outcome too technologies/products for larger societal impact in an effort to ensure transfer of IP at academic institutes/research laboratories, and to engage in licensing activities. The Guidelines, 2023 refers to IP arising out of public-funded research as a huge asset that must be appropriately harnessed for maximizing socio-economic impact and achieving public good, which can be achieved through a suitable committee comprising of external experts, including from the scientific, legal, finance and other relevant fields may advise the Director/Head of institute.

Judicial efforts have been few in regard to exploring the challenges that patenting of microorganisms brings about. Other than the, *Dimminicao* case (India's transition period time was for ten years from 1995 to 2005 when it was signed to make the domestic legislations compatible to the TRIPS provisions and its features and to make amendments, if necessary, wherever needed in the current laws), another case is that of Monsanto Technology LLC v. Nuziveedu Seeds Ltd., (AIR 2019 SC 559) that came up before the Supreme Court of India in 2019. The case addressed the issue of patent validity in relation to the process and product claims with regard to three different components of the seed in questions, of which one was a man-made gene. The patent that Monsanto Technology LLC (hereinafter Monsanto) held was for Nucleotide Acid Sequence (NAS) containing the gene *Bacillus thuringiensis* (Bt gene), the insertion of which into the DNA of cotton seeds results in the bollworms being killed from inside the seed. This in turn results in reduction of the dependence of farmers on insecticides and pesticides. The dispute began with Monsanto's patent infringement claim against Nuziveedu Seeds Ltd. (hereinafter (Nuziveedu). Nuziveedu in turn challenged the validity of the patent stating that the NAS was not capable of industrial application, and that once the NAS was introduced into the seed, it could not be isolated from the seed as it becomes an integral part of the seed. The argument was also that this process was an essential biological process as it is transmitted in the progeny of the plant. Another point that was raised was that since NAS could not reproduce on its own, it was merely a chemical composition and not a micro-organism, which was outside the purview of patent protection.

At the trial court, it was held that the patent is prima facie valid. On appeal, the Delhi High Court Division Bench (hereinafter DHC DB) revoked the patent stating the ground of the invention of not being patentable subject matter under Section 3(j), while also opining that the product was more suitable under the PPV, resulting in an appeal by both parties to the SC. Before the SC, a myriad number of issues were brought before the court in the form of the patentability under Patents Act 1970, the Protection of Plant Varieties and Farmer's Rights Act 2001(PPVFR), obligations under the World Trade Organisation (WTO), General Agreement on Tariffs and Trade(GATT), TRIPS leading to the Patents Amendment Acts of 2002 and 2005. However, the court did not examine any of these issues, and remanded the matter to the DHC DB holding that deciding the validity of the patent merely on the basis of prima facie examination was incorrect (For a correct reading of the case, see, Kavitha Kuruganti, Was there a victory for Monsanto in India's Supreme Court on a patent matter, DownToEarth, 13 February, 2019, https://www.downtoearth.org.in/agriculture/was-there-a-victory-for-monsanto-in-india-s-supreme-court-on-a-patent-matter--62800, accessed on 5 February 2024).

In a judgment pronounced by the Delhi High Court early this year, the court once again hearing a matter about a genetically modified salmonella bacteria left a lot to be desired in the context of the patentability questions, and the deposit of materials (The Regents of the University of California v. Controller of Patents, High Court of Delhi, 21 February, 2025,

https://indiankanoon.org/doc/116699207/, accessed on 5 May 2024). Another case decided by the Madras High Court late last year in 2024, rejected the IPO's reversal for the patent eligibility for biological process involving human intervention resulting in significant results (Sakata Seed Corporation vs The Controller Of Patents And Design, Madras High Court, CMA (PT) No. 30 of 2023, decided on 19 July 2024).

Considering the legislative and judicial activity in the legal arena of micro-organisms, this paper aims to look at the activity before the IPO to provide a complete picture of the presence of innovation before the IPO.

DATA COLLECTION

Methodology

The data for the study is collected from the official website of the Indian Patent Office (IPO), Office of the Controller General of Patents, Designs & Trademarks. The IPO falls under the Department for Promotion of Industry and Internal Trade, Ministry of Commerce and Industry, Government of India (Information available at: https://www. ipindia.gov.in/, accessed on 5 February 2024). The IPO is the only authority in India that grants a patent, and mentions an application procedure for the grant of a patent which begins with the applicant moving an application (either online or offline, along with the requisite forms). Once an application is filed for the grant of a patent, it is referred to an examiner by the Office of the Controller for conducting the formal as well as substantive examination as per the subject matter of the invention vis-à-vis the area of specialization of the examiner (Organisational structure of Office of Controller General of Patents, Designs and Trademarks, (CGPDTM), Pg 8, Norms of reference for examination as per chronological order, https://www.ipindia.gov.in/writereaddata/Portal/Images/pdf/4__1___b___i__ii__iii__iv__Organizational_Structure_of_office_of_CGPDTM.pdf, accessed on 5 February 2024). At present, the IPO has four examination groups based on the broad area of specialization which are Chemistry and allied subjects; Biotechnology, Microbiology and allied subjects; Electrical, Electronics & related subject; Mechanical and other subjects (Manual of Patent Office Practice and Procedure, Version 3.0, 26 November 2019). The IPO categorizes patents into twenty four different fields (These include: "Agrochemicals, Biotechnology, chemical, civil, communication, electrical, electronics, food, general engineering, mechanical engineering, pharmaceuticals, textiles, computer science, physics, bio chemistry, polymer technology, microbiology, metallurgy, biomedical engineering, drug, agricultural engineering, traditional knowledge biotechnology, traditional knowledge chemical and traditional knowledge mechanical" (as mentioned in the IPO website)). Micro-organisms typically come within the field of biotechnology, a separate field of invention that was added from 2004. Further classification under microbiology, biochemical, biomedical, biochemistry, agrochemicals was done in 2011 (Annual Reports of the Indian Patent Office, from 2002 to 2023).

As the IPO does not maintain a separate list of micro-organisms that are filed, the database used for this study was created by using the patent search option in the 'title' field of the IPO website . Many variations of the keyword 'micro-organsim' were used, specifically: 'micro-organisms,' 'microorganism,' 'micro-organism,' 'micro-organisms' 'micro organism' and 'micro organisms.' We base this on the example of the first patent granted to a microorganism by the United States Patent and Trademark Office to Anand Chakrabarty. His patent application is titled as "Microorganisms having Multiple Compatible Degradative Energy-Generating Plasmids and Preparation Thereof" (Application number: US3813316A). There is also the use of the term micro-organisms in Article 27 (3) of TRIPs, and Section 3 (j) of the Indian Patents Act, 1970. This study looks at patent applications filed before the IPO from 1-1-1995 to 31-12-2022. The year 1995 signifies the year the TRIPs agreement came into force, the first multilateral agreement related to intellectual property rights was introduced, stating minimum standards. This is used as the first year of the search for this study too. The data was extracted for this study from the IPO website by the authors in the first half of 2023 (specifically from 01-04-2023 to 31-06-2023). Additional information regarding the First Information Report (FER) and prior art mentions by the examiner was also collected. The data also captures whether oppositions were filed and responded to by the applicants. Specifically, for rejected patents, the study captured the grounds for refusal after FER, and for granted patents, if the depository requirements were met or not.

Micro-Organism(s) Patents Granted by the Indian Patent Office

The total number of patents based on the use of the keywords is 951. The breakup of the data is

as follows: Patents with a title containing the word 'microorganisms' is 141 patents, 'microorganism' is 93 patents, 'micro-organism' is 348 patents, 'micro-organisms' is 350 patents, 'micro organism' is 8 and 'micro organisms' is 11. In other words, Figure 1 contains numerous iterations of the word micro-organism, for example, singular and plural forms (microorganism and microorganisms), split forms also including singular and plural connotations (mirco-organism and micro-organisms), and lastly, with a space between the word 'micro' and 'organism' in both singular and plural form (micro organism and micro organisms). This provides a comprehensive analysis of microorganism(s) patents filed before the IPO despite the terminological variations used by applicants in their application.

From this, patents that are not linked to micro-organisms and contain the word 'micro' like micro-electrical, micro-structural and micro-deep are filtered out manually. Repetitions when using the word 'micro' and 'micro-' is also filtered out. This brings down the total number of patents granted for micro-organism(s) to 252. From this, five patents have no information available regarding applicant application route, working details etc, thereby bringing the final total number to 247 (Figure 1). Among the granted patents with any variation of the word micro-organism(s), the title and the claims of each patent is scrutinized manually in order to comprehend whether the patent is granted for a novel micro-organism. From the total number of 247 entries, it is found that 39% are patents granted for novel microorganism. Among the novel microorganism, the top three spots are secured in the field of biotechnology (44%), microbiology (25%) and biochemistry (14%). The remaining 61% of patents comprise of products/process including devices that contain a microorganism, either living or dead, or for culturing/identifying a microorganism (Figure 2). Within this, the leading field of invention is microbiology (35%), followed by biotechnology is (15%) and chemical (12%).

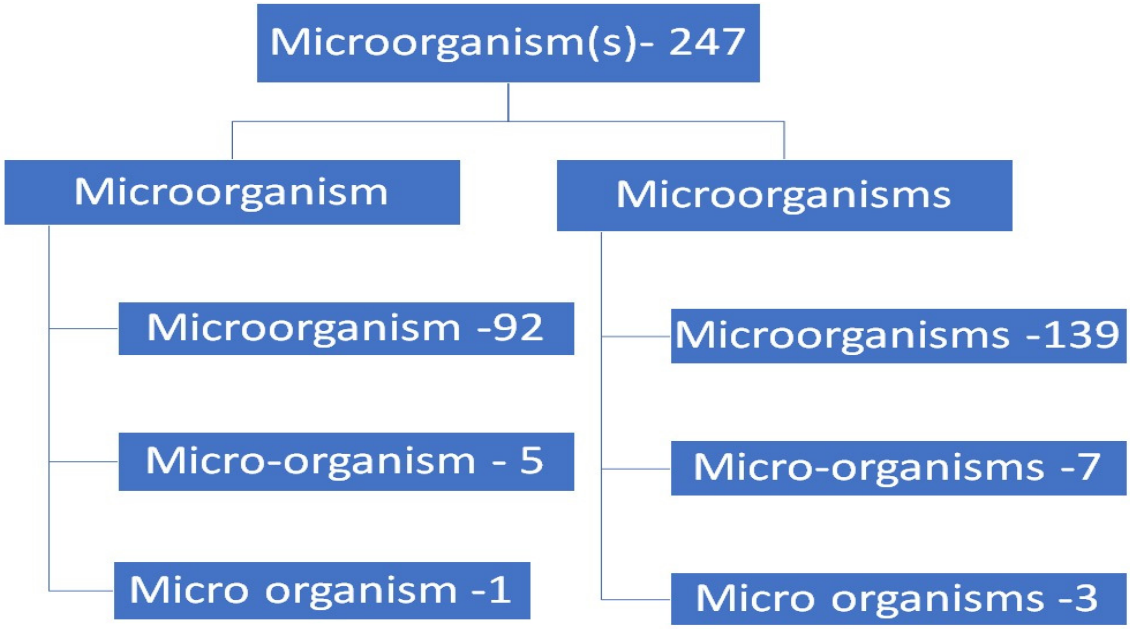

Fig. 1. Various iterations of the word Microorganism(s) in its many forms, including singular and plural.

From 1995 to 2005, the number of patents granted for microorganisms (whether novel or not) is in single digits. A growth is seen from 2006 onwards, peaking at 2011, with a slump the next year before rising again from 2013 onwards (Figure 3).

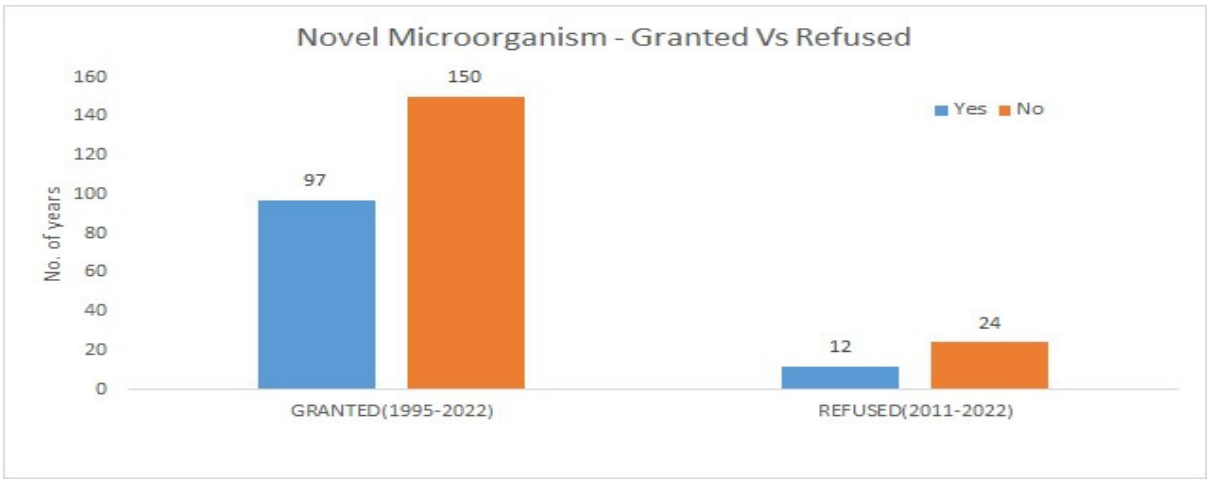

Fig. 2. Novel Microorganism (s)-Granted and Refused.

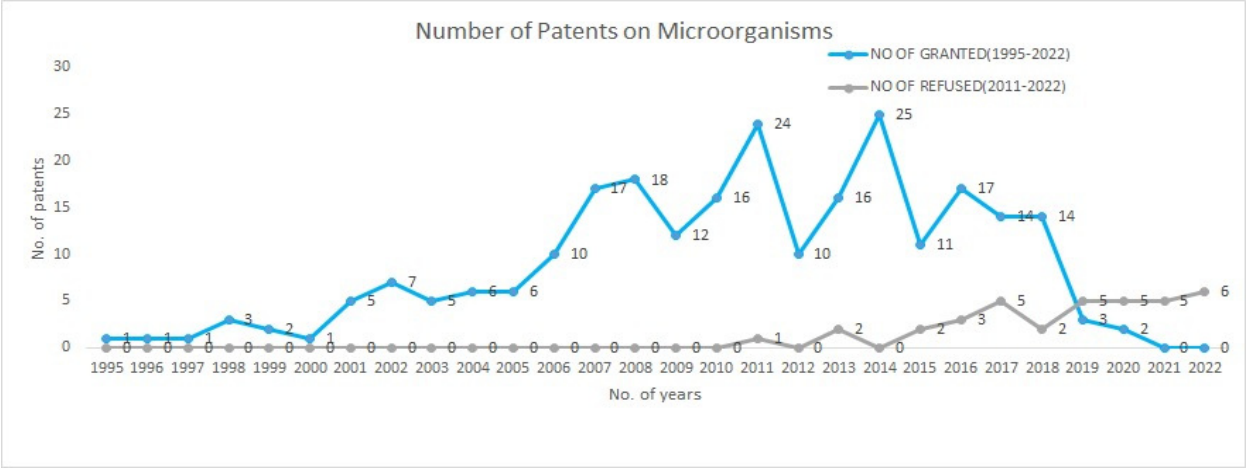

Fig. 3. Number of Patents on Microorganism(s).

The top three applicants in the granted novel micro-organism category is CJ Cheiljedang Corporation, South Korean food and biotechnology company (11%), followed by Lanzatech New Zealand Limited that has offices in USA, China and India and is a fuel production and produces sustainable ethanol based products from industrial waste and biomass syngas (4.4%). In third place is Biomerieux Inc. which is based in France and invests in vaccinology and other infectious diseases (3.6%) (Table 1). Contribution by Indian entities are predominately through the government, by the Council of Scientific & Industrial Research (CSIR), Defence Research and Development Organization (DRDO), Indian Council of Medical Research (ICMR), followed by Reliance Industries Limited (Mumbai), and Nalco Company (Faraday Ozone Products Private Limited, Module Innovations Private Limited, Serum Institute of India Limited, Agricultural Research Council and Institute for Animal Science & Health Research, Indian Council for Agricultural Research, Batech Bioanalytical Technology Limited, Indian Institute of Science, String Bioprivate Limited, National Institute of Plant Genome Research, Department of Biotechnology, Ministry of Science and Technology, Kontest Chemicals Limited, Central Institute on Research for Cotton Technology, USV Limited, Conzumex Industries Private Limited, BMS College of Engineering, Guru Angad Dev Veterinary and Animal Sciences University, and two individuals-P M Gopinath, and Dhanasekaran are placed last (10th rank).

Table 1. Applicant Detail. (PCT: "Patent Cooperative Treaty" Applicants).

Rank	Applicant name	Location	No. of patents	Type of application	IP classification	Years applied	Years granted	Patents detail	Patents inforce/ceased
1	CJ CHEILJEDANG	SOUTH KOREA	27	CONVENTIONAL APPLICATION-2, PCT	BIOCHEMISTRY-4, BIOTECHNOLOGY-18, CHEMICAL-1,	2010–2019	2015–2023	METHOD-13, PROCESS-1, PRODUCT-2, PRODUCT AND	INFORCE-27

	CORPORATION			NATIONAL PHASE APPLICATION -25	MICROBIOLOGY-4			PROCESS-1, PRODUCT AND METHOD-10	
2	LANZATECH NEW ZEALAND LIMITED	USA	10	PCT NATIONAL PHASE APPLICATION -10	BIOTECHNOLOGY -8 BIOCHEMISTRY-2	2013–2017	2019–2023	PRODUCT-7, PRODUCT/METHOD-3	INFORCE - 10
3	BIOMÉRIEUX INC.	FRANCE	9	PCT NATIONAL PHASE APPLICATION -9	PHARMACEUTICALS -1, BIOMEDICAL ENGG-1, MICROBIOLOGY-2, PHYSICS -2 BIOTECHNOLOGY -1, CHEMICAL -2	2007–2014	2015–2023	PROCESS-1, DEVICE-1, METHOD-7,	INFORCE-5, CEASED -4
4	DSM IP ASSETS B.V.	NETHERLANDS	7	PCT NATIONAL PHASE APPLICATION -6, DIVISIONAL PCT NATIONAL PHASE APPLICATION -1	BIOCHEMISTRY -1, BIOTECHNOLOGY -1, CHEMICAL-1, FOOD-1, MICROBIOLOGY-3	2006–2012	2010–2020	PRODUCT/PROCESS-1, PRODUCT/METHOD-1METHOD-1, PROCESS-3, PROCESS/COMPOSITION-1,	CEASED-4, TERM EXPIRED-1, INFORCE-2
5	GENOMATICA, INC.	CALIFORNIA	6	PCT NATIONAL PHASE APPLICATION -5 DIVISIONAL PCT NATIONAL PHASE APPLICATION -1	BIOCHEMISTRY-2, BIOTECHNOLOGY -1, MICROBIOLOGY-3	2011–2018	2019–2022	METHOD -1, PROCESS -1, PRODUCT- 1, PRODUCT/METHOD-3	CEASED-1, INFORCE-4, UNDER EXTENSION-1
6	BASF CORPORATION	GERMANY	5	PCT NATIONAL PHASE APPLICATION -5	MICROBIOLOGY-5	2002–2012	2008–2019	METHOD-2, PRODUCT/PROCESS-1, METHOD/PRODUCT-1,METHOD/DEVICE-1	INFORCE-1, CEASED-4
7	EMD MILLAPORE CORPORATION	USA	5	PCT NATIONAL PHJASE APPLICATION -3, CONVENTIONAL APPLICATION -2	PHARMACEUTICALS-1, MICROBIOLOGY-2, BIOTECHNOLOGY -2	2005–2015	2012–2020	PROCESS-3, COMPOSITION-1, METHOD-1	INFORCE-5
8	3M INNOVATIVE PROPERTIES COMPANY	USA	5	PCT NATIONAL PHASE APPLICATION -5	BIOMEDICAL ENGG-2, BIOTECHNOLOGY -1, MICROBIOLOGY - 2	2010–2018	2017–2022	PROCESS-2, DEVICE-2, PROCESS/DEVICE -1	CEASED-4, INFORCE-1
9	EVONIK DEGUSSA GMBH	GERMANY	4	PCT NATIONAL PHASE APPLICATION -4	BIOTECHNOLOGY -1 BIOCHEMISTRY-2, MICROBIOLOGY - 1	2008–2016	2016–2021	PRODUCT-3, METHOD-1	CEASED 1, INFORCE-3

10	METABOLIC EXPLORER	FRANCE	4	PCT NATIONAL PHASE APPLICATION-4	MICROBIOLOGY-1, BIOCHEMISTRY-2, BIOTECHNOLOGY-1	2006–2019	2010–2023	PROCESS-1, METHOD-1, PRODUCT/METHOD-1, PRODUCT-1,	CEASED-1, INFORCE-1, UNDER EXTENSION-2

Among the granted microorganism patents, irrespective of whether it is a novel microorganism or not, only half of the patents are retained (54.2%). The remaining are either ceased (34%), term is expired (6.8%) or is under the extension period (4.8%). Among novel micro-organism(s), 73% are kept in force, while the remaining are ceased (18%), under extension (5%), with a negligible amount categorized as term expired and abandoned (1% each). From the non-novel microorganism dataset, less than half are ceased (44%) while the remaining is split between inforce (40.6%) term expired (10.6%) and under-extension (4.6%).

Among the granted patents, majority of the patents are not worked (63%), and only (10%) is worked. Information regarding the status of working is not available for the remaining patents (27%). A percentage of this is the result of patents being a fresh grant of below 3 years, which does not require the patent to be worked (13% of the "not available" data) (Section 84, Patents Act, 1970). Among the granted patents, a little more than half of the patents are in force (54%), while other have ceased due to non-payment of the renewal fee (34%) or as a result of the term being expired (7%) or being under the extension period (5%). Patentees provide a host of reasons for not working the patents, the top three include: efforts are being made (this include funding, negotiations and looking for opportunities, 37%), 14% is R&D, market research (12%) and for 11%, no information is provided. When it comes to worked patents, these include licenced patents too (Under the category of granted patents, for assuring the working of patents Form 27 has to be submitted with reference to the Controller of Patents, whether license has been granted and the present status of the invention should be updated every year). In revenue disclosure, most of the patentees have mentioned the amount, however some have stated that the revenue is confidential. This claim is made in spite of the evidentiary value of the disclosure as mandated by law under Section 146 of the Patents Act, 1970. There is also mention of transfer of know how. This also relevant in the context of the DBT Intellectual Property Guidelines 2023 (Department of Biotech, Ministry of Science and Technology) which mentions the need for commercialization and licensing of the IP product.

In terms of delays regarding the grant of a patent, only 12% of the applications are granted within the 3 years of the date of filing. Majority of the applications are decided between the 4th and 9th year (85%), with the maximum number of applications granted a patent being in the 7th year (18%). In the patent application phases, the PCT National Phase is the most used route (80%), followed by a distant second for ordinary applications (12%). Indians use ordinary application route, and foreign based companies use the PCT National Phase. A small percentage (5.6%) also used convention application.

Among the granted patents, the grounds of objections listed in the First Information Report (FER) by the examiner are under Sections 10 (4) and (5), along with Sections 2 (1) j Section 3 (d) (Figure 4). Prior art citations show many patents relating to WO and USA, and in the non-patent category relating to relevant literature. Once the process of the FER is over, the applicants have made the necessary amendments leading to the grant of the patent. However, in about 32 % of the granted patents, the IPO has asked for the depository information to be provided (Figure 5).

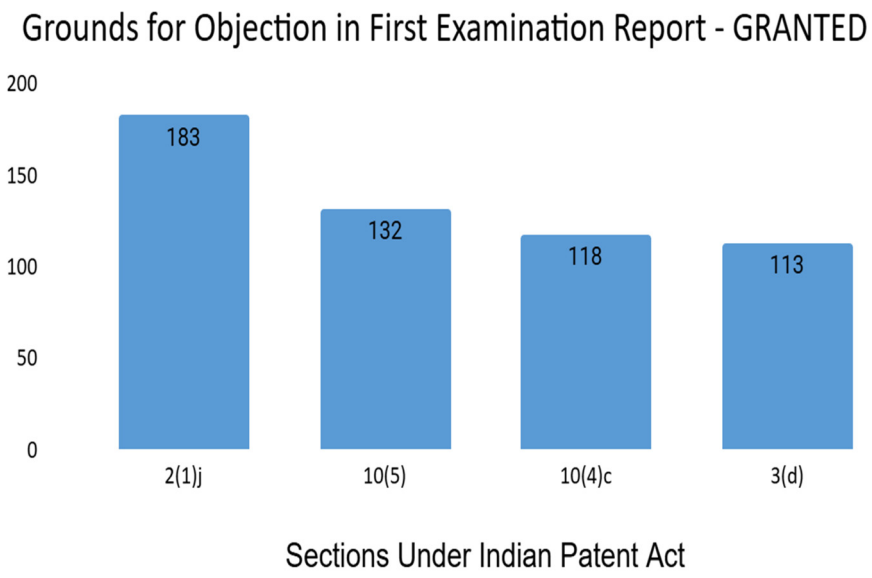

Fig. 4. Grounds for Objections in First Examination Report when patent is granted.

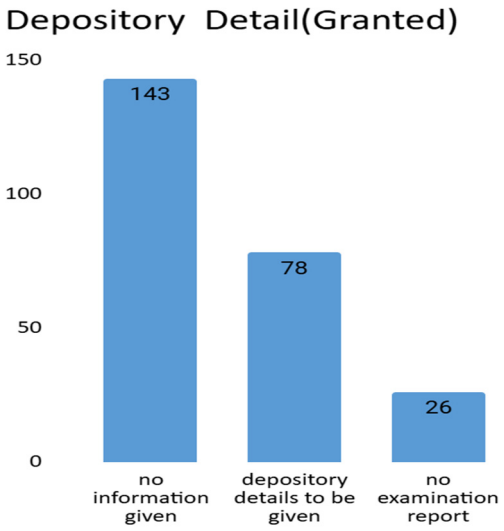

Fig. 5. Depository details for granted patents.

Innovations Refused by the IPO Related to Micro-Organism(s) Related Inventions

The same method of determination of refused patent applications with micro-organism(s) is identified from the IPO. However, information about refused patent applications is available only from 2011 onwards, limiting the data of this paper to the refused innovations for the years 2011–2022 (Before 2010 the results yield the message: data not available). The search yields a total of 3297 entries. From this, applications were manually filtered based on the same keywords used for granted patent data collection relating to micro-organism(s). This yields a total of 36 entries. From this, novel microorganism form 33% of all refused entries and the remaining are not novel (67%). Refusals are very less in the beginning years but have risen up and remain constant from 2019. Categorization into the field of invention, irrespective of the patent being novel or not, micro-biology (52.8%), biotechnology (25%), bio-chemistry (17%) emerge at the top three. The top three applicants are Genomatica Inc., a San Diego, California based biotechnology and chemical manufacturing processes company (14%), Biomerieux Inc. (11%) and 3M Innovative Properties Company, a US based patent and innovation company (8%). Premier Evolvics Private Limited and an individual, Walmik Subhash Patil also are listed in the refused list.

Among rejected patents, there are multiple grounds of objection that are listed under the FER. Section 10, which deals with the contents of the patent specification, emerges as most cited section for objection through the FER (collective percentage is 110). Specifically, Sections 10 (4) and (5) show the most objections garnered via the Office of the Controller. Sections 2 (1) j and 3 (d) are also mentioned in most of the objections.

Prior art is mentioned in the FER, with most references falling under the patents filed through PCT and US patents. When prior is cited, examiners use both patent and non-patent resources as prior art. However, there are instances when examiner do not cite prior art in (13%) (Figure 6). (Not citing prior art-see lit review.-can be mentioned in conclusion too). Based on the FER objections, applicants have amended their claims in majority of the patent specifications (89%), however it still led to the rejection of the application as a result of objections being outstanding (69% of the total applications), followed by the reasons that applicants who did not want to proceed with the application (5%), as mentioned in the order of the Controller (Figure 7).

Among the rejected and granted patents, there were no oppositions were filed.

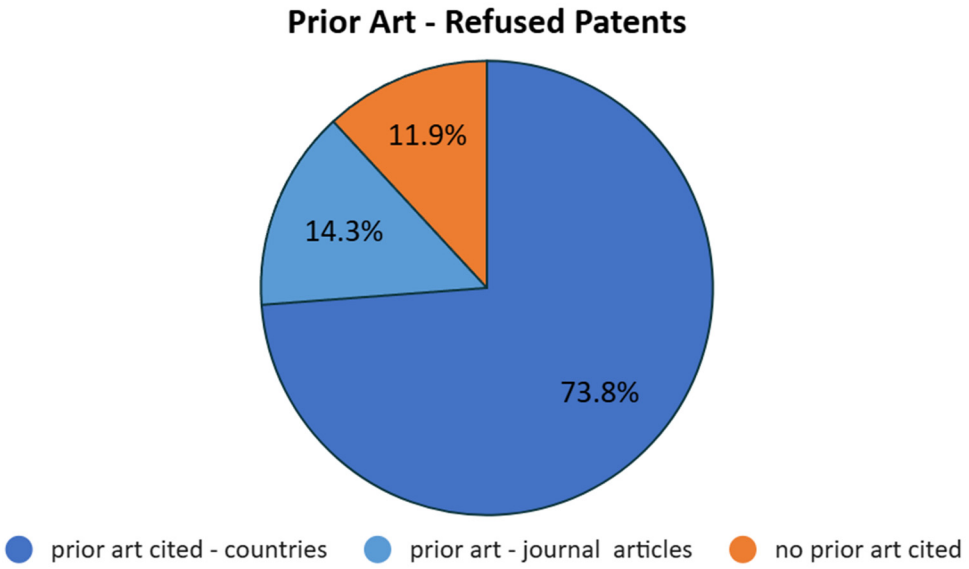

Fig. 6. Prior Art mentions in refused patents.

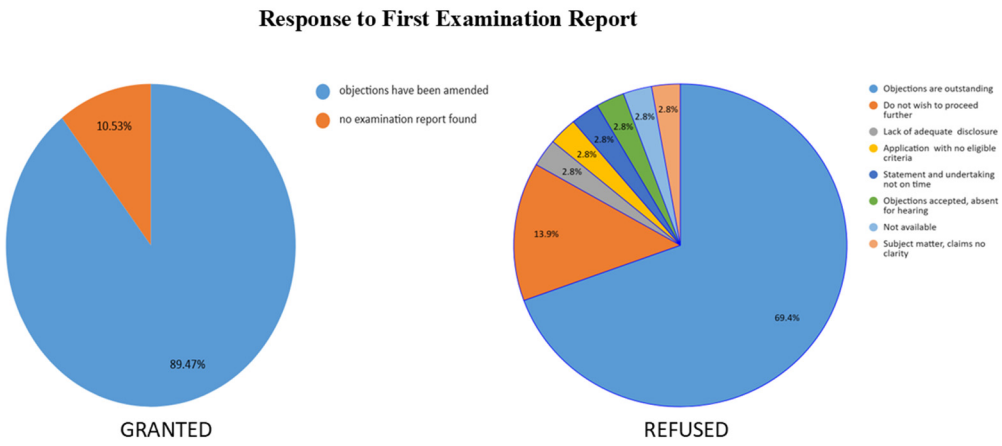

Fig. 7. Response filed to First Examination Report.

OBSERVATIONS IN THE FORM OF TRENDS AND PATTERNS CONCERNING PATENTS AND APPLICATIONS RELATING TO MICRO-ORGANISM(S)

The changes brought about in terms of patentability of microorganisms in terms of the amendments in 2002 and 2005 have brought about a legislative shift. There is also the 2019

Guidelines that have clarified a great deal about the patenting of micro-organisms. Even then, the grants for novel micro-organisms have reached only to single digits (Figure 2). The patenting activity of innovations around novel microorganisms are still at a low number, but it can be seen that there is some contribution by the presence of micro-organisms in devices and products. This in turn should be limited by the boundaries of the claims so that the exclusive rights do not fall entirely into private hands. It is also significant to notice that the activity in terms of patent grants have not increased in tantum with the increase of the importance and relevance of the sector. Specifically, from 1995 to 2005, the number of patents granted for microorganisms (whether novel or not) is in single digits. A growth is seen from 2006 onwards, peaking at 2011, with a slump the next year before rising again from 2013 onwards. This is in sync with the Annual Reports of the IPO from early 2000's, where the growth is seen at a plateau stage rather than peaking, as seen in the general trends of patents in India. There is also a spike in the grant of biotechnology patents related to micro-organisms in our dataset.

It is also interesting to notice that inventors constitute a mix of government bodies, government-aided bodies, private limited companies. Universities, Ayurveda Centre and individuals also find mention among the patent holders. However, it is observed that the working of patents remains low, especially in the context of the (DST) Department of Science and Technology Guidelines, 2023.

When it comes to worked patents, include licenced patents (Under the category of granted patents, for assuring the working of patents Form 27 has to be submitted with reference to the Controller of Patents, whether license has been granted and the present status of the invention should be updated every year), majority of the Indian and foreign patentees are not working their patents. In revenue disclosure, most of the patentees have mentioned the amount, however some have stated that the revenue is confidential. This claim is made in spite of the evidentiary value of the disclosure as mandated by law under Section 146 of the Patents Act, 1970. In one patent at least there is also mention of transfer of knowhow, but no other details are mentioned. This also relevant in the context of the DBT Intellectual Property Guidelines 2023 (Department of Biotech, Ministry of Science and Technology) which mentions the need for commercialization and licensing of the IP product.

Objections filed through the FER for granted and rejected patents show that focus is on Section 2 (1) j, and rightfully so, as the invention is tested for patentability under the Patents Act. Section 2 (1)j encompasses the patentability criteria within the definition clause wrt an invention: novelty, inventive step and industrial application. The focus of the objections is also around the technicalities of the specification and the claims. Section 3 (d) of the Patents Act, 1970 relates to prohibitions to the grant of a patent despite its success under the patentability criteria, and addresses inventions that do not enhance the therapeutic efficacy of the drug, for example (Supreme court case read with Section 3 (d)). Section 3 (d) states that "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." Both sections are of special significance under the patent jurisprudence in Indian law.

Prior art citations also show the same trend as the rejected dataset, with many prior art patents relating to WO (a Patent Co-operative Treaty Application or a PCT application that is published by the World Intellectual Property organisation (WIPO)) and USA, and in the non-patent category relating to relevant literature.

The depository information to be provided is a significant objection and is all the more relevant in today's context, given the 2024 WIPO Treaty on mandatory disclosure of course, and the presence of depository systems in India.

Even though the total number of oppositions filed before the IPO is a small number (0.4% for 2023-2024), (Mentioned from p. 13 of the annual report of the Indian Patent Office–2022–2023), it still holds significance is terms of weeding out bad patents by involving the public, and it is interesting to note that none of the patents among microorganism are opposed (from the data that is collected). This is not the case for pharmaceutical patents, and even for other patents in other categories and shows the attention/importance of patenting in this area (Tania Sebastian, Nancy Sebastian, "Local working of pharmaceutical patents in India: an empirical exploration into its determinants, volume 14, Issue 4, p. 374–404).

CONCLUSIONS

Even though the fears associated with its

patentability has simmered down, especially after more than twenty years after the grant of the world's first patent on microorganism (Diamond v. Chakrabarty), and the conflicts surrounding its discovery and invention debates, much is desirable when it comes to its legal discourse of the patentably aspects.

In order to further encourage the use of the patented microorganism for research through technology transfer and commercialization and licensing, we need to look closely at the DBT guidelines and see its need in the upcoming cohort of patents granted to micro-organisms to get the full benefits of the system and of the patents.

The findings from this study can be a step forward to necessitate more public discussions based on patenting of micro-organisms and bring about more clarity from the courts by ensuring a robust opposition regime, and a close watch on its working status. The disclosure of the invention through its specification, and the working requirement can be used to further innovations in the field of biotechnology, by enabling complete access to existing resources in the hands of those who need it.

The patent regime in the context of a biotechnological invention has to be used as a tool for further research. This is possible only when there is a match between the many aspects of the patentable aspects of micro-organisms, ranging from its grants, to its application in real life.

CONFLICTS OF INTEREST

The authors declare no conflict of interest.

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