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PATENTABILITY OF MICROORGANISMS: LAW & POLICY IN INDIA

Victor Vaibhav Tandon*

Abstract

This paper deals with the patentability requirements in respect of microorganisms under the Indian Law. Patents over microorganisms faced a lot of resistance initially and got entangled in debates concerning the morality and desirability of 'patenting life'. However, the judgment in Diamond v. Chakrabarty paved the way for microorganism patents. Thereafter, TRIPS specifically mandated patents over microorganisms (exhibiting human intervention). Not surprisingly, the law relating to patentability of microorganisms in India is shaped by its commitments under the relevant International treaties on the subject matter, especially the TRIPS agreement and the Convention on Biological Diversity. Patents over Microorganisms or for that matter any biological material raise important questions from the perspective of biodiversity law and patentability requirements in India reflect this. Indian law with respect to microorganism patentability is in consonance with India's obligations under various international treaties and makes wise use of the flexibilities granted thereunder.

Introduction

Biotechnology has emerged as one of the most promising as well as controversial technologies since the last few decades. It finds applicability in the agricultural sector, pharmaceutical sector and several other industrial processes. The Organisation for Economic Co-operation and Development (OECD) defines biotechnology as "the application of science and technology to living organisms, as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods and services".\(^1\) As per the Convention on Biological Diversity\(^2\), biotechnology "means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.\(^3\) In other words, biotechnology involves the utilization of living

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organisms for producing useful new products by using methods of science and technology. Interestingly, biotechnology itself is not new and has been there for a long time⁴. It is only since the 1970s that modern biotechnology evolved and got entangled in controversies⁵.

Considering the fact that biotechnology has the potential to revolutionise several fields including food production and healthcare, one may wonder why it is so controversial. Part of the controversy is because of the kind of raw materials used in biotechnological processes and the resultant products. Biotechnological processes, at times, lead to the production of genetically modified organisms which may harm the environment or human health. This makes biotech products controversial. Moreover, the definition of biotechnology makes it obvious that it relies on biological resources or living organisms as its raw materials. This again makes biotechnology controversial for two reasons. First is the problem of regulating access to bioresources⁶. Secondly, various issues arise with regard to patentability of biotech products since they are based on or comprise of living organisms.

This paper focuses on this last aspect, namely, the patentability of living organisms. This will nevertheless involve dealing in part with the Biodiversity law

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⁵ Article 2, Convention on Biological Diversity, 1992; Also, See Article 2(d), The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization, 2010. This is a protocol to the Convention on Biological Diversity, 1992.
⁶ See Id. at 274-276

Accessing bioresources is important for biotech and pharma industries. But accessing bioresources is controversial for certain reasons. The developing world is rich in biodiversity or bioresources but lacks the technological ability to effectively and efficiently utilize it. This technological ability is possessed by industrialized countries but they may not possess the same kind of biological diversity. The industries in these developed countries need bio-resources as raw products. They also seek IP protection for the end products derived from bio-resources. The end products obtained from utilization of bioresources have a high value and a well-established system of protection. However, the raw materials- bioresources and associated traditional knowledge are not, it is argued, adequately protected. Often they are accessed without any kind of prior informed consent from the donor community or country. Developing countries also feel that benefits arising out of the use of their bioresources should be shared with them. It is in this context that allegations of Biopiracy have been made against Biotech and pharma companies. Developing countries demand a system of prior informed consent, sharing of benefits as well as protection of their bioresources and associated traditional knowledge. The primary international treaties dealing with access and benefit sharing are the Convention on Biological Diversity, 1992 and the Nagoya Protocol, 2010. For a detailed account of the problem of Biopiracy and the interface between Biodiversity and IPRs, see M. B. Rao and Manjula Guru, *Biotechnology, IPRs and Biodiversity* (Pearson Longman, New Delhi, 2007).
due to the complex interaction between the patent system and biodiversity law. Amongst living organisms, the paper focuses on microorganisms. The issues concerning patentability of plants, animals, human clones, embryonic stem cells, gene sequences etc. are outside the scope of this article. The issue of patenting of microorganisms had generated much controversy initially, at least in the United States. But once patents were granted over microorganisms, it opened the ‘floodgates’ for patenting of other biotech innovations and higher life forms. This paper looks at a landmark US Supreme Court judgment regarding microorganism patentability. It also looks at the status of microorganism patentability under TRIPS. The focus then moves to a judgment of the Calcutta High Court that opened the door for microorganism patentability in India. The last part of the paper focuses on the various legal requirements that have to be taken care of as regards patenting of microorganisms in India. Before we move on to these aspects, it will be interesting to deal briefly with patent law.

Biotechnology Innovation & the Relevance of Patents

Biotech companies and researchers strive to protect new developments by utilizing the patent system. Patents and other forms of Intellectual Property Rights are recognized as ‘cornerstone’ of the bio-industry especially for the small and medium sized enterprises (SMEs) which invest substantially in innovation7. Patents are considered important for different industries and for protecting innovation because of the manner in which patent law operates. Patent Law grants exclusive economic rights to inventors(s)/ patent owner(s) to exploit the patented invention(s). A patent, therefore, is a monopolistic right. Other than the inventor/ owner, no one can commercially exploit a patented product or process. Others can only do so if they have the consent of the inventor/ patent owner. Interestingly, monopolies are not considered healthy for competition in the market. The negative impact of creating a monopoly is set off by providing certain safeguards within the patent system and by providing temporal limit for a patent. After the protection period is over, the invention falls in the public domain. Intellectual Property Jurisprudence offers several justifications for granting Patent rights.

Firstly, it is argued that patents allow inventors to recover the costs of their skill, time and labour that go into making anything new and useful. Secondly, it promotes research and innovation by allowing investments in crucial sectors since the investors can recover costs and make profits due to the monopoly protection granted to them8. Thirdly, it prevents copying and misappropriation of labour of

7 Paul Haycock, “Patents in Life Sciences” 6 JIPR 479-486 (November 2001) at 480
8 However, it does not mean that merely having a patent system will increase innovation nor does it imply that a stronger patent system will lead to more innovation. N. S.
innovators by others. Fourthly, patents enable disclosure of inventions. In the absence of patent system, inventors may very well keep their inventions as trade secrets for an infinite amount of time. Patent system awards monopolistic protection and exploitation rights in return of disclosure of invention and the best method of performing the same. Once the invention is in the public domain, others can simply replicate the process or product\(^9\). Therefore, complete disclosure of the invention in the patent application is an important aspect for grant of patent.

However, being monopolistic rights to commercially exploit knowledge goods, patents have always remained problematic. They are seen as reducing access to technology and are particularly problematic in the field of agriculture, food sector and pharma industry\(^10\). Often, patent system is blamed for the misappropriation of biological resources of developing countries as well as for the rising costs of pharmaceutical drugs and other essential items. It must be noted that Patent Law strives to strike a balance between public welfare and private interests of the inventors/patent owners. There are elaborate mechanisms to determine whether a product or process is patentable or not. There are also several mechanisms to check the abuse of patents by the inventors/owners. It must also be noted that patent law had evolved primarily to protect mechanical and chemical inventions. Protection of new technologies like biotechnology within the patent system is fraught with several issues and challenges. These issues and challenges first came to the forefront in the US Supreme Court case discussed in the following section. The case dealt with patentability of microorganisms.

**Microorganism Patentability: From Chakrabarty To TRIPS & Dimminaco**

Microorganisms are living organisms which are invisible to the naked eye and reveal themselves only under a microscope. Microorganisms may include “bacteria, viruses, viroids, eukaryotic single cell and multi-cellular microorganisms like yeast, protozoa, fungi, moulds and algae and cultured plant and animal cells”\(^11\). Interestingly

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\(^10\) A detailed discussion of these aspects of patent law is beyond the scope of this article. However, for issues concerning patents and access to pharma drugs, See, Cynthia M. Ho, *Access to Medicine in the Global Economy* (Oxford University Press, New York, 2011)

\(^11\) Sabuj Kumar Chaudhuri, “Microbial Biopiracy in India: How to Fight Back?” 8 *JIPR* 389-399 (September 2003) at 390
the term itself has not been defined in any treaty or law relating to patenting of microorganisms. Microorganisms have been used for quite some time for a number of purposes— in brewing, wine making, baking etc. They have been used in ethanol production via fermentation and in the production of industrial chemicals such as acetic acid\textsuperscript{12}. It has been stated that the antibiotics industry “was based upon isolation of products from selected strains of microorganisms and … many are still made from microorganisms either found in nature or artificially mutated”\textsuperscript{13}.

1. The Chakrabarty Case

Considering that microorganisms are so valuable in different sectors, it is not surprising that the issue of their patentability was raised in the US in 1972 when Ananda Chakrabarty applied for a patent in respect of “microorganisms having multiple compatible degradative energy-generating plasmids and preparation thereof”\textsuperscript{14}. Basically, Chakrabarty claimed patent over a genetically modified live organism (a bacteria) that could break down components of crude oil and thereby help in the treatment of oil spills. This ability was lacking in naturally occurring bacteria. Interestingly, it has been reported that, during that period, it was the practice of the United States Patent and Trademark Office (USPTO) to refuse patents over living systems or living organisms\textsuperscript{15}. These were not regarded as patentable subject matter regardless of whether there was any human intervention or not\textsuperscript{16}.

In keeping with its practice, the patent was refused by the USPTO. The applicant lost the appeal in the Board of Appeals but succeeded in the United States Court of Customs and Patent Appeals. Thereupon, Sidney Diamond, Commissioner, USPTO approached the United States Supreme Court. The matter generated considerable debate at the time. Ethical, ecological, moral and other questions were raised. There was fear regarding the impact of the case on future research and investments in the then nascent biotech industry.\textsuperscript{17} Those in favour of granting patents over the microorganism (and therefore, generally over biotech innovations) argued that it would foster investments in the sector and provide an incentive for innovation.

\textsuperscript{12} Supra 4 at 274-275
\textsuperscript{13} Ibid.
\textsuperscript{15} Matthew Rimmer, Intellectual Property and Biotechnology: Biological Inventions 24-25 (Edward Elgar, Cheltenham, Glos, UK, 2008)
\textsuperscript{16} See, Ibid.
\textsuperscript{17} An illuminating history and analysis of the debates surrounding the case is presented by Matthew Rimmer, See, Id. p-24-49
Those against the grant of patent argued that it would lead to patenting of higher life forms and reduce nature to a commodity that can be modified and made subject matter of private property. It was also felt that the legislature and not the judiciary should be the one to decide whether microorganisms (and by extension biotechnology inventions) are patent worthy or not\textsuperscript{18}.

The US Supreme Court, by a majority of five to four, held that the microorganism as claimed in the application was patentable\textsuperscript{19}. The Court noted that “anything under the Sun that is made by man” is patentable, thus paving the way for USPTO to take the lead and grant patents in respect of applications concerning genetically modified microorganisms and other biotech innovations. The decision had wider ramifications. It promoted biotechnology innovation and subsequent breakthroughs in the US. Investors knew that backing innovation in the biotech sector was going to yield substantial returns since inventions could be protected by patents. Rimmer has noted that post this judgment, USPTO “granted backlog of patent applications in respect of genes and gene sequences”\textsuperscript{20}. From thereon the boundaries of patentable subject matter have been expanded so much that it is stated that in the US atleast “it is not clear whether the patent system has any subject matter boundaries at all”\textsuperscript{21}.

In other countries such as UK, Australia, Germany and Canada, microorganisms came to be considered as patent eligible provided the criteria of patentability (novelty, usefulness, non-obviousness) were met\textsuperscript{22}. Genetically engineered animals have also been considered eligible for patents\textsuperscript{23}. In fact, isolated or purified form of natural products were also gradually considered eligible for grant of patent in various jurisdictions\textsuperscript{24}. The patenting of higher forms does remain controversial even though microorganism patents have become the norm especially after the TRIPS agreement. The agreement specifically mandates that once the other conditions are satisfied, microorganisms should be considered patent eligible.

\textsuperscript{18} See, Id. at 31
\textsuperscript{19} Diamond v. Chakrabarty 447 US 303 (1980)
\textsuperscript{20} Supra 15 at 43
\textsuperscript{22} See, Supra 15 at 45
\textsuperscript{23} For example, The Harvard Oncomouse
\textsuperscript{24} It must be noted that patents are generally available only for inventions and not for mere discoveries. It has been argued that even under the TRIPS agreement there is no obligation to consider as patentable those substances which are found in nature irrespective of the fact that they may be isolated or claimed in a purified form. See, Carlos M Correa, “Intellectual Property Rights under WTO and Animal Genetic Resources” 7 JIPR 7-23 (January 2002)
2. Microorganism patentability under TRIPS

The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS)\textsuperscript{25} lays down minimum common standards for Intellectual Property protection and enforcement. All the member states of the World Trade Organisation have to comply with the provisions of TRIPS. The aim of TRIPS is to achieve uniformity in the protection and enforcement of Intellectual Property. This was done by requiring that the IP laws of member states are at the very least TRIPS compliant. A member state can opt for norms stronger than those mandated under TRIPS but weaker IP laws are not permitted.

TRIPS requires all member states to provide product as well as process patents for inventions “in all fields of technology, provided they are new, involve an inventive step and are capable of industrial application”\textsuperscript{26}. This necessarily implies that member states have to provide for patent protection in fields, such as, inter-alia, pharmaceuticals and biotechnology. It is also clear that mere discoveries are excluded. Patents are to be granted only over inventions provided that the invention satisfies other criteria such as that of novelty (new), inventive step (non-obviousness) and industrial application (usefulness). TRIPS also provides that,

“Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect \textit{ordre public} or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law”\textsuperscript{27}.

The exclusions on the aforementioned grounds have important implications for biotech patents including patents over microorganisms. Any genetically modified organism should be precluded from patent protection if the same can be injurious to the environment or to the health of other living species. Likewise, inventions can be denied patent protection if the same are against \textit{ordre public} or morality. These two terms have variable content. ‘\textit{Ordre public}’ does not have a generally accepted meaning. Likewise, ascertainment of ‘morality’ is dependent on social values that change from place to place and time to time. There can not be a fixed concept of


\textsuperscript{26} Article 27.1, TRIPS, 1994

\textsuperscript{27} \textit{Id.} Article 27.2
moral and immoral. This offers considerable dexterity to member states to exclude from patentability certain kind of inventions like human clones and gene sequences.

The most important provision relating to microorganism patentability is Article 27.3(b) which specifically mandates that patents should be granted over microorganisms (this is subject, of course, to the clauses mentioned above). It states, inter alia, that,

"Members may also exclude from patentability ... (b) Plants and animals other than microorganisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes"

In other words, member states are free to exclude plants and animals but not microorganisms. The article further provides that in respect of plant varieties, protection ‘shall’ be provided by way of patents or another sui generis system. India is a member of WTO. Therefore, it had to ensure that its IP laws were TRIPS compliant. As a consequence, it had to respect the mandate of Article 27. The rest of the paper deals with the current state of Indian law and policy regarding microorganism patentability. But before that it will be worthwhile to deal with a landmark Indian judgment that came in 2002 on this issue.

3. The Dimminaco Matter: Showing the Way Forward

Much before the Indian Patent Act, 1970 came into its present form; a landmark judgment in the field of biotech patentability came from the Calcutta High Court in 2002 in Dimminaco A.G v. Controller of Patents and Designs & Others. Dimminaco can possibly be described as the Indian equivalent of the Diamond matter. The judgment came at a time when the Indian Patents Act was still not fully TRIPS compatible. Product patents in the field of, inter alia, pharmaceuticals were not granted. Only the processes or methods of manufacture of pharma products were patentable and not the product itself. In Dimminaco, the patent application related to a “process for the preparation of infectious Bursitis Vaccine”. The same had been refused by the Patent office merely on the ground that the same did not qualify as an invention since it related to a process whose “end product claimed a living organism”.

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29 Consequently, India enacted The Protection of Plant Varieties and Farmers' Rights Act, 2001
The petitioner contended that there was no bar under the then existing patent law against the grant of patent for a process which led “to an end-product, the manufacture of which involves the live virus”. It was argued that the grant was denied merely on the basis of administrative policies of the Patent office and that the same can not be allowed to prevail over the statutory norms. The court noted that the vaccine as claimed in the application “is useful for protecting poultry against the contagious Bursitis infection”. It was novel as well as useful. The Court was not convinced by the Defendant’s stand that only a non-living, inanimate entity could be classified as a manufactured ‘thing’/‘substance’ and that the “end product must satisfy the meaning of manufacture which rules out any living entity”.

The Court noted in its judgment that,

“...the controller erred himself in law by holding that merely because the end product contains a live virus, the process involved in bringing out the end product is not an invention. The dictionary meaning of the word manufacture does not exclude the process of preparing a vendible commodity which contains a living substance and in a case like this where there is no statutory meaning of manufacture, the dictionary must be accepted.”

Allowing the appeal, the Court directed the Patent Office to reconsider the petitioner’s application for grant of patent in the light of the observations made in the judgment. This matter became an authority on microorganism patentability in India. In 2005, the Patents Act was suitable amended to meet the ‘TRIPS standard’.

Patentability Of Microorganisms: The Requirements Under The Current Indian Law

1. Requirements under The Patents Act

The Indian Patent law as it stands today is fully TRIPS compliant. In consonance with Article 27.3 (b) of TRIPS, microorganisms are now patentable in India provided that they satisfy the criteria of patentability as set out under the law. Patents are granted for inventions alone. The Indian Patents Act defines an invention as “a new product or process involving an inventive step and capable of industrial application”. This definition gives us the three basic criteria for grant of patent. There should be a product or process which should be, firstly, new. Secondly, the

31 Ibid.
32 Ibid.
33 Ibid.
34 Section 2(1) (j), Patents Act, 1970
35 Id. Section 2(1) (l); It states, “New Invention means any invention or technology which has not been anticipated by publication in any document or used in the country or elsewhere in the world before the date of filing of patent application with complete specification, i.e., the subject matter has not fallen in public domain or that it does not form part of the state of the art.”
product or process should exhibit an inventive step\textsuperscript{36} and thirdly, it should be capable of industrial application\textsuperscript{37}. Each invention has to satisfy these three criteria in order to be patent eligible.

Novelty or ‘newness’ of an invention is determined with respect to the prior art or existing state of knowledge. Anything which is in public domain, is part of the state of art, is published or is used anywhere loses its novelty and ceases to be patent eligible. A non-exhaustive set of circumstances that destroy novelty is provided under the Patents Act\textsuperscript{38}. The second requirement, namely, the presence of an inventive step is considered to be analogous to the non-obviousness requirement. Under Indian law, the invention should exhibit technical advance over existing knowledge or have economic significance and it should also not be obvious to a person skilled in the relevant field. None of these concepts are defined in the Act itself nor are guidelines given. Therefore, the content or guidelines have come from judicial pronouncements\textsuperscript{39}. The third requirement—capable of industrial application can be considered analogous to usefulness\textsuperscript{40}.

This is not all. A further bar is provided by section 3 and section 4 of the Patents Act. Section 4 makes inventions relating to atomic energy non-patentable. Section 3 provides a list of what does not qualify as an invention under the Indian Patent Law. As a matter of fact, if the patent application claims anything that falls under any one or more of the clauses 3(a) to 3(p) or section 4, grant of patent is immediately ruled out even if the other criteria are some how satisfied. Therefore, Section 3 and Section 4 basically limit the boundaries of patentable subject matter under Indian Patent Law.

The most relevant clauses of Section 3 with regard to microorganism patentability are discussed here. It must be noted that other clauses of section 3 must also be taken into consideration to the extent they may be applicable. In consonance with TRIPS, section 3 (j) excludes “plant and animals in whole or any part thereof other than micro-organisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and

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\textsuperscript{36} Id. Section 2(1)(ja); It states, “Inventive step means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art”.

\textsuperscript{37} Id. Section 2(1) (ac); It states, “Capable of industrial application, in relation to an invention, means that the invention is capable of being made or used in an industry”.

\textsuperscript{38} For a detailed discussion, See, Kalyan C. Kankanala, Arun K. Narasani et. al., Indian Patent Law and Practice 25-32 (Oxford University Press, New Delhi, 2010)

\textsuperscript{39} For details, See, Id. 32-42

\textsuperscript{40} However, Carlos Correa has argued that ‘useful’ is a broader concept than industrial applicability. Under the former, research tools and business methods might also be covered but these will not come under the concept of ‘industrial application’. See, Supra 28 at 278
animals”. This clause reinforces the view taken in Dimminaco and makes microorganisms patentable in India.

Biological inventions which tend to raise morality and public order concerns are excluded by virtue of section 3(b)41. A genetically modified microorganism that may harm the environment or cause serious prejudice to human, animal or plant life or health shall be liable to be excluded from patentable subject matter by virtue of this section. It must be noted that considerations with regard to morality and public order are subjective and no fixed criteria can be laid down with regard to the same. The Indian Patent Office offers the following examples of inventions which are barred by this clause—“process for cloning of human beings or animals, use of human embryos for commercial purposes etc.”42.

It must also be noted that some kind of human intervention must be there in the microorganism for which patent protection is claimed. Merely discovering the microorganism will not entitle any one to a patent under Indian patent system. This is for the simple reason that patent law rewards ingenuity and protects inventions. It is not applicable to discoveries. This is reflected in section 3 (c) which excludes “the mere discovery of a scientific principle or the formulation of an abstract theory or the discovery of any living thing or non-living substances occurring in nature”. It must be noted that mere isolation of microorganisms from its natural surrounding will also not entitle anyone to a patent in India43. This appears to be contrary to the practice in most developed countries but is nevertheless absolutely in conformity with TRIPS. Therefore, with respect to Indian law, patents over microorganisms should necessarily be understood as patents over microorganisms that involve some kind of human intervention (or genetically modified microorganisms).

In addition to these requirements, the procedural requirements with regard to specification/disclosure of the invention should also be satisfied. This is because the purpose of patent law is to ensure disclosure of the invention as a price for protection on a quid pro quo basis. Under the Indian Patent Law, specifications are of two kinds—provisional and complete. A provisional specification should necessarily be followed by a complete specification within a period of twelve months else the application for patent is deemed to have been abandoned44. Provisional and Complete

41 Section 3 (b), Patents Act, 1970 excludes “an invention the primary or intended use or commercial exploitation of which could be contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment”.
43 Ibid.
44 Section 9 (1), Patents Act, 1970
Specifications should contain title of the invention, its subject matter and should describe the invention\textsuperscript{45}. Also, drawings and/or models of the invention may be supplied to the Patent Office for the purpose of imparting clarity\textsuperscript{46}.

A complete specification should fully describe the invention\textsuperscript{47}, its operation or use\textsuperscript{48}, the method of performing the invention\textsuperscript{49} as well as the best method for performing the invention that is known to the inventor\textsuperscript{50}. It should also comprise of claims which basically define the scope of the invention\textsuperscript{51}. It should provide technical information about the invention in the abstract\textsuperscript{52}. The basic purpose of the specification is that the invention should be completely described so that once it falls into the public domain it can be easily replicated by others. It also ensures that others know what the patent covers so that they can avoid violating the same during the term of patent. The specification is filed as part of an elaborate procedure of filing the patent application. The norms regarding the filing process are covered under the relevant provisions of The Patents Act, 1970 as well as the Patents Rules, 2003 (as amended till 2014).

As regards inventions related to microorganisms, apart from the general requirements discussed above, two special requirements also exist. These requirements should be met while filing the patent application. These requirements relate to all biological or biotechnology inventions. The first of these is due to The Biodiversity Act and the second is due to the Budapest Treaty.

\textbf{2. The Biological Diversity Act & additional requirements for microorganism patentability}

India is a party to the Convention on Biological Diversity, 1992. It is also incredibly rich in biodiversity and has had the bitter experience of being at the receiving end of Biopiracy of its biological resources and valuable traditional knowledge\textsuperscript{53}. As a consequence, it is not surprising that the Biological Diversity Act, 2002 was enacted for the following purposes—firstly, “the conservation of biological diversity”; secondly, “sustainable use of its components” and lastly, “fair

\textsuperscript{45} Id. Section 10 (1)
\textsuperscript{46} Id. Section 10 (2) and Section 10 (3)
\textsuperscript{47} Id. Section 10 (4) (a)
\textsuperscript{48} Ibid.
\textsuperscript{49} Ibid.
\textsuperscript{50} Id. Section 10 (4) (b)
\textsuperscript{51} Id. Section 10 (4) (c)
\textsuperscript{52} Id. Section 10 (4) (d)
\textsuperscript{53} For details regarding instances of Biopiracy from India, See, Srividhya Ragavan, “Protection of Traditional Knowledge”, 2(2) Minn. IP Law Rev. 1 (2001). See also, the segment on Biopiracy at the TKDL website available at http://www.tkd1.res.in/tkd1/langdefault/common/Biopiracy.asp?GL=Eng (visited on February 8, 2015)
and equitable sharing of the benefits arising out of the use of biological resources” and for connected matters.$^{54}$

The Biological Diversity Act has several provisions which are relevant for patentability of biological resources including microorganisms. The Act defines biological resources as “plants, animals and microorganisms or parts thereof, their genetic material and by-products (excluding value added products) with actual or potential use or value”$^{55}$. But human genetic material is specifically excluded$^{56}$. The Act makes a distinction between Indian nationals and entities and non-Indian individuals and entities$^{57}$. The Act also establishes a three tier structure— a National Biodiversity Authority at the Centre$^{58}$, State Biodiversity Boards$^{59}$ and Biodiversity Management Committees at the local level$^{60}$. As regards non-Indian individuals or entities, ‘previous approval’ of the National Biodiversity Authority is required for accessing Indian Biological Resources for the purposes of research, commercial utilization, bio-survey or bio-utilisation$^{61}$. On the other hand, Indian nationals and entities have to merely give prior intimation to the State Boards for accessing Indian biological resources for similar purposes$^{62}$.

This basically implies that any foreign entity has to take relevant permissions for accessing microorganisms found in India. This becomes even more important considering the mandate of section 6 of the Biological Diversity Act which requires everyone to take ‘previous approval’ of the National Biodiversity Authority before applying for IPRs (including patents) on any invention based on Indian Biological Resource$^{63}$. While granting such approval, the National Biodiversity Authority can impose, inter-alia, benefit sharing fee.$^{64}$

This basically imposes two other requirements with regard to patents related to microorganisms. If the microorganisms are obtained from India then the same can be patented only if the requirements of Section 6, Biological Diversity Act are satisfied. Additionally, legitimate access requirements should also be satisfied otherwise the penal provisions of the Act will be activated$^{65}$. These requirements

$^{54}$ Introductory Note, Biological Diversity Act, 2002
$^{55}$ Id. Section 2(c)
$^{56}$ Ibid.
$^{57}$ See, Id. Section 3 (2), for what are not considered to be Indian nationals or Indian entities.
$^{58}$ See, Id. Section 8
$^{59}$ See, Id. Section 22
$^{60}$ See, Id. Section 41
$^{61}$ Id. Section 3(1)
$^{62}$ Id. Section 7
$^{63}$ See, Id. Section 6 (1)
$^{64}$ See, Id. Section 6 (2)
$^{65}$ See, Id. Section 55

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are also reflected in the Indian Patent Law. In filing the application for patent, a
Declaration has to be made regarding use of biological material from India. Also,
"the necessary permission from the competent authority" has to be communicated/
submitted in the Patent Office before the grant of patent. Here the competent
authority refers to the authorities under the Biological Diversity Act, 2002.

A requirement of disclosure of "source and geographical origin of the biological
material in the specification" is also mandated by clause (ii) D of the proviso to
Section 10 (4) of the Patents Act. Infact, considering the importance of biological
resources and the problem of Biopiracy, the National Biodiversity Authority is
given the function of opposing any 'wrong' patent or erroneous grant of other IPRs
outside India if the same is/ are based on Indian biological resources including
microorganisms. These requirements, it is hoped, will help combat the Biopiracy
of Indian biological resources in general and microbial Biopiracy in particular.
Infact, India has been at the receiving end of microbial Biopiracy as well. The
current legal framework is designed to prevent this and ensuring that proper approvals
are sought before utilizing bioresources. It must also be noted that the present
consults with regard to biotech patents relate more to ensuring prior informed
consent for access of biological material and benefit sharing rather than focusing
on ethical or moral aspects.

The Budapest Treaty & Deposit Requirements for microorganism related patent
applications

Budapest Treaty regulates the deposit of microorganisms as part of the patent
procedure. Under its substantive provisions, it requires contracting states to
necessarily recognize the deposit of microorganisms with any International

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66 See Form 1 as incorporated in The Patents Rules, 2003 (as amended till 2014).
67 See, Section 18 (4), Biological Diversity Act, 2002
68 A list of microbial piracy cases from India before 1992 is provided by Sabuj Kumar
Chaudhuri. See, Supra 11 at 392
69 See, Jonathan Crucci, "The New Challenges to the International Patentability of
Biotechnology: Legal Relations between the WTO Treaty on Trade Related Aspects of
Intellectual Property Rights and the Convention on Biological Diversity" 2 Intl' Law &
Mngmnt. Rev 1-42 (Winter 2005) at 35. Crucci has stated that India and Brazil had
sought the introduction of an additional patentability requirement under TRIPS at the
TRIPS Council. The fourth requirement is providing proof of Prior Informed Consent
for access. This, it is argued, shall ensure benefit sharing and will prevent "erroneous
issuance of patents".
70 The Budapest Treaty on the International Recognition of the Deposit of Microorganisms
also a Regulation accompanying the treaty, available at http://www.wipo.int/edocs/lexdocs/
Depository Authority (hereinafter, IDA) where such deposit is a requirement for patent procedure\(^7\). The contracting state may ask for copy of the receipt of the deposit\(^8\) as part of the patent procedure.

It also prescribes the qualifications required by any depositary institution to qualify as an IDA\(^9\). The requirements are, inter alia, that the institution has to be located on the territory of a Contracting State and that state has to give assurance that the Authority shall comply with all the necessary norms specified in the treaty for being recognized as an IDA. If the requirements are not complied with then the status as an IDA can also be terminated\(^10\). At present there are 79 contracting states and 42 International Depositary Authorities under the Treaty\(^11\). India is a contracting state. There are two International Depositary Authorities in India\(^12\), namely, the Microbial Type Culture Collection and Gene Bank, Chandigarh and the Microbial Culture Collection, Pune.

As a consequence of the Budapest Treaty, an application for patent over a micro-organism will also have to fulfill another requirement under the Indian Patent system. If a biological material is mentioned in the specification but the same can not be sufficiently described and the material is also not available to the public, then the material (for eg: Microorganism) has to be deposited at an IDA under the Budapest treaty\(^13\). Moreover, the deposit has to be made “not later than the date of filing the patent application in India” and a reference of the same has to be made in the specification\(^14\). Also, the applicant has to ensure that “all the available characteristics of the material required for it to be correctly identified or indicated are included in the specification including the name, address of the depository institution and the date and number of the deposit of the material at the institution”\(^15\). This requirement aids sufficiency of disclosure. It has been argued that in respect of biological materials and microorganisms which are subjected to human intervention or are “improved”, it is usually not possible to verbally describe the invention so that others may replicate the same. In such cases, a written disclosure is not enough.

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\(^7\) Article 3(1) (a), Budapest Treaty, 1977
\(^8\) Id. Article 3(1) (b)
\(^9\) Id. Article 6
\(^10\) Id. Article 8
\(^13\) Section 10 (4) proviso (ii), Patents Act, 1970
\(^14\) Id. Section 10 (4) proviso (ii) A
\(^15\) Id. Section 10 (4) proviso (ii) B
and deposit of the microorganism is required as part of patent procedure to sufficiently describe the subject matter of patent/ patent application\textsuperscript{80}.

**Concluding Remarks**

It is clear that the patentability requirements for microorganisms under the current Indian law are quite elaborate and complex. Considering the nature of the subject matter, this is not surprising. The patentability of microorganisms had in the past raised a number of issues. These issues concern the ‘patenting of life’ in general. Today, patents over microorganisms are the norm in the biotech industry. The issues with regard to patents over higher life forms are still quite complex and a bone of contention between different interest groups. However, at least with regard to the patenting of microorganisms, Indian law is at par with the global norms and the requirements are geared to promote as well as protect innovation in the microbial biotech industry. A microorganism is patent eligible in India as long as human intervention is exhibited (other than merely isolating it) and the other criteria are satisfied. However, there is a myth that the Indian Patent law is anti-innovation or that it does not fully protect the interests of the innovators. This is far from the truth. So far our Patent and other IP related laws are in consonance with our international treaty obligations. The law attempts to strike a balance between different competing interests and only makes use of the flexibilities that are granted under the relevant treaties. This is clear from the elaborate microbial patenting requirements discussed above. The need is to create IP awareness so as to dispel myths regarding Indian patent law and patentability requirements.

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\textsuperscript{80} S Sekar and D. Kandavel, “Patenting Microorganisms: Towards Creating a Policy Framework” 7 JIPR 211-221 (May 2002) at 216