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'PATENT ASPECTS FOR BIOTECHNOLOGY INVENTIONS – TRADITIONAL BIOTECHNOLOGY AND MODERN BIOTECHNOLOGY'.

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ABSTRACT

Development of science and technology is a boon for the human race as it improves the standard of living and thus enhances the human rights enjoyed by humanity. New technologies pose huge challenges for the application and protection under the legal framework. Biotechnology and its advancement is one such technology which draws the attention of the world community. Be it the Right to life including Right to food or the Right to health and access to medicine, biotechnology plays a major role.

This article attempts to give a bird eye view of one aspect of Biotech inventions being protected under IPR specially patents law. The article concentrates on the Indian legal framework and also draws from some international experience.

All novel technologies require the law to adjust and develop, yet beyond the normal challenges, biotechnology poses fundamental ethical problems also which call for reflection as it touches upon the very foundation of life.

Many a times Law does not keep pace with the development of Science and Technology. Though Science and Law necessarily have a quest for Truth, there is a difference. In regard to the

different goals of Science and the Law in the ascertainment of Truth, the US Supreme Court observed as follows:

> … [T]here are important differences between the quest for truth in the Court room and the quest for truth in the laboratory. Scientific conclusions are subject to perpetual revision. Law, on the other hand, must resolve disputes finally and quickly.[1]

Essentially then, there is a lack of proper legal mechanism to regulate and protect the novel innovations of Science and Technology. Patent is a method of protecting inventions. On the satisfaction of certain essential conditions, inventions can be patented under Patent Law. The traditional patent law does not recognize living beings as inventions, thus living organisms were not considered patentable. Since biotechnology gives rise to living inventions, the traditional patent law cannot provide protection to biotechnological inventions. The need then is, to recognize biotechnological inventions by modifying the existing patent law to offer patent protection.

In the absence of proper legal mechanism, the Courts of law have come up with innovative and liberal interpretation of the existing patent laws to recognize and protect biotechnological inventions; e.g. in Diamond vs. Chakrabarty[2] where the U.S, Court awarded patent protection by stating that "anything under the sun that is made by man" is eligible for patenting. It is also said that;

> …[T]he invention, wherein the patentee had produced a new bacterium with markedly different characteristics from the one found in nature and having the potential for significant utility; i.e.agenetically engineered bacterium capable of breaking down crude oil, is a patentable subject matter.

Also the discovery was not nature's handiwork, but counted as a patentable subject matter under sec 101.[3]

[1] *Daubert v MerrelDov Pharmaceuticals Inc.* [1993] US Supreme Court, 113.
[2] 447U.S. 303 (1980).
[3] 35 U.S. Code S. 101-Inventions Patentable.

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Evolution of Biotechnology Law in present world was much influenced by the liberal approach of the US judiciary. The legal environment in the US is such that anything under the sun can be patentable provided that there is some human intervention.[4] The U.S. Constitution states:

> The Congress shall have the power to promote the progress of Science and useful arts, by securing for limited times, to authors and inventors the exclusive right to their respective writings and discoveries.[5]

The Promotion of science is the threshold of Patent Law.[6]On this for the first time United States Patent Office granted a Patent to Louis Pasteur on 'yeast that is free from organic germs of disease'.[7]

> …Louis Pasteur, the famous French scientist, received US Pat No 141,072 on 22 July 1873, claiming 'yeast, free from organic germs of disease, as an article of manufacture'. With the phenomenal growth of genetic engineering in the late 1970s, the patentability of living microorganisms came into the scene, which involved AnandaChakrabarty's invention of a new Pseudomonas bacterium genetically engineered to degrade crude oil. USPTO rejected the claim on Pseudomonas bacterium, but the Supreme Court decision went in favour of Chakrabarty in a landmark case[8], Chakrabarty's Pseudomonas bacterium manipulated to contain four plasmids controlling the breakdown of hydrocarbons was 'a new bacterium with markedly different characteristics from any found in nature'. Therefore the Supreme Court stated that new microorganisms not found in nature were either 'manufactured' or 'composition of matter' within the meaning

[4]*Supra* note 2 at 1.
[5]Article 1 Section 8 0f U.S. Constitution.
[6]S W E, 'New PTO Guidelines To Affect Biotech Inventions' [2001] NAT'L L.J.
[7] U.S. Patent No.141, 072 granted in1873.
[8]*Diamond v. Chakaraborty,*447 [1979] U.S. 303.

of US Patent Act S.101 and thus patentable. The 'product of nature' objection therefore failed and the modified organisms were held patentable.[9]

Patentable subject matter

In India, living things like plants, animals, micro-organisms and other living organisms are treated as'Common Heritage of Mankind'[10],and hence not patented, as patent gives rise to private property rights, no one can obtain patent and privatize Common Heritage. Monopolizing and privatizing living beings through patents is considered as immoral and unethical in India.Patenting of life or living beings produced through biotechnology commands special attention due to the complexities of the nature of biotechnology inventions. Three reasons as to why difficulty is felt in patenting a living being:[11]

(i) It is doubtful whether patent protection will be granted to living matter.

(ii) Biotechnology inventions are difficult to describe – Description in specifications to be submitted

(iii) How to consider biotechnology inventions either as inventions or discovery.

Under the Patent Act 1970, every invention must pass a two-step test in order to be patentable – namely, it must:

(i) not fall in any of the categories specifically excluded under Section 3 of the Patent Act; and;

(ii) pass the well-known three-pronged test of novelty, inventive step and industrial applicability.

The essential requirements that a biotechnological invention or an invention including living beings must fulfill the following criteria to be patented:

(a) Patentable Subject Matter

(b) Novelty;

(c) Non- Obviousness (Inventive Step);

(d) Industrial application (Utility);

[9]Chawala, H.S. (2005). Patenting of Biological Material and Biotechnology. *Journal of Intellectual Property Rights*, 10, pp.44-51.
[10]*See:*Deegan, C. (1990). Human Genome Mapping: Policymaking aspects , in Genetics, Ethics and Human Values: Human Genome Mapping, Genetic Screening and Therapy. In: *24th CIOMS Round Table Conference*. Tokyo.
[11]Swaminathan, D. (2000). *An introduction to Guiding Principles in the Decisions on Patent Law*. 1st ed. Delhi: Bahri Brothers, p.331.

(e) Written description or disclosure of the invention and the deposit of the invention.

(A) Patentable Subject Matter Under TRIPs Agreement:

The first and foremost requirement is that the invention should fall within the parameter of the patentable subject matter. Before the TRIPS Agreement there was lack of uniformity with respect to patentable subject matter. Post TRIPS, there is uniformity and internationally biotechnological inventions involving living beings form part of the patentable subject matter. Article 27 of the TRIPs Agreement broadly talks about the patentability of the subject matter. A product, a process, in all fields of technology is patentable if there is novelty, involves inventive steps and is capable of industrial application. Patent shall be available without discrimination as to place of invention, field of technology and whether imported or locally produced.

> …[P]atents 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.[12]

Simultaneously member states could exclude from patentability inventions of life forms of biotechnology on grounds of public order or morality protection to human, animal or plant life, or health or to avoid serious prejudice to the environment.[13] Member states could also exclude from patentability diagnostic, therapeutic and surgical methods for the treatment of humans or animals; plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes.[14]

[12]*Trade Related Aspect of Intellectual Property Rights*. 1995, Art 27.1(herein after 'TRIPS').
[13]*TRIPS*, Art 27(2): Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre publicor 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.
[14]*TRIPS*, Art 27(3): Members may also exclude from patentability:
(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;
(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generissystem or by any combination thereof.

I. Patentable Subject matter in India:

In India only invention and not discoveries are patentable. There is a clear distinction between inventions and discoveries. Indian patent law defines invention under section 2(j) to mean: 'a new product or process involving an inventive step and capable of industrial application[15]. Here inventive step means a feature that makes the invention not obvious to a person skilled in the art'[16]. India patent law does not provide for subjects that are patentable, instead it does provide for an illustrative list where it has mentioned the subjects that are not patentable.[17]Hence any subject matter, which does not fall within the purview of the illustrated list, does constitute a patentable subject matter. The list has been updated and modified to comply with the provisions of the TRIPS agreement.[18] The Indian Patent Act states that the following are not inventions and do not constitute patentable subject matter:[19]The following are the excluded biotechnology-related inventions:

(i) Inventions contrary to public morality are not patentable. Examples include genetic modification of animals which results in suffering of the modified animal without any substantial medical or other benefit, and inventions causing adverse environmental impact.

> …[A]n invention the primary or intended use or commercial exploitation of which could be contrary public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment.[20]

In order to remove any ambiguity, the act was amended in 2002 to include potentially patentable chemical processes. In Dimminaco, the court clarified that if the end product is a commercial and vendible entity, the presence of the living organism in the end product cannot be a bar to the patentability of the process.

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[15]*The Patent 2nd Amendment Act, 2002*. S.2(1)(j)"Invention" means a new product or process involving an inventive step and capable of industrial application.
[16]*The Patent 3rd Amendment Act, 2005*. S.2(1)(j)(a) "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.
[17]*The Patent 2nd Amendment Act, 2002*. S. 3.
[18]The India Patents Act, as amended in 2002. India having signed the TRIPS agreement has made necessary amendments to its obligations under the agreement. The coming into being of the TRIPS agreement has made biotechnological inventions universally patentable.
[19]For illustrative list of subject matters not patentable under the Act see, Section 3 of the Indians Patents Act as amended in 2002.
[20]*The Patent 2nd Amendment Act, 2002*. S. 3(b).

> ...The judgment opens up new opportunities for obtaining patents in India on microorganism related inventions which were hitherto not granted. Further, the importance of definitions in the Act has been clearly brought out. The law cannot be left to the interpretation of individuals. There has to be a consistent interpretation which should follow some logic.[21]

Although the act does not define an 'essentially biological process', in Monsanto(2013)[22] the Intellectual Property Appellate Board (IPAB) provided some guidelines on what constitutes one. The patent application under consideration claimed a method of producing a transgenic plant. Although the patent application was rejected on other grounds, the IPAB overturned the IPO's objection that it was an essentially biological process. The IPAB agreed with Monsanto's submission that the plant cell in the claimed process was transformed as a result of human intervention in the manner claimed in the application, and was therefore patentable. Thus, although genetically modified plants or seeds are not patentable in India, processes for the genetic modification of plants are patentable. Further, a sui generissystem for protection for plant varieties is available under the Protection of Plant Varieties and Farmers' Rights Act 2001.

(ii) New forms or uses of known substance:[23]A new form of a known substance is unpatentable unless it differs significantly in properties with regard to the known efficacy. This provision essentially prevents the evergreening of patents through trivial modifications or incremental innovations. However, its interpretation has been the source of polarizing debate among legal professionals, academics, non-governmental organizations and pharmaceutical companies.

The Supreme Court provided some guidelines for the interpretation of the scope of this section in its well-known Glivecjudgment.[24] The court observed that the provision sets a higher invention threshold for medicines and drugs and other chemical substances. The term 'efficacy' is not defined in the act. The court held 'efficacy' to mean "the ability to produce a desired or intended result". The efficacy test depends on the function, utility or purpose of the product under consideration. Thus, a medicine will undergo a test for therapeutic efficacy. A

[21]*See:Dimminaco A.G. v. Controller of Patents Designs & Others* [2002] (Cal. H.C.).
[22]*See: Monsanto Technology LLC. v. The Controller of Patents and Designs and the Deputy Controller of Patents and Designs* [2013] Order No. 146 (IPAB).
[23]*The Patent 3rd Amendment Act, 2005*. S. 3(d).
[24]*Novartis AG v. Union of India and Ors.* [2013] Civil Appeal Nos. 2706-2716 (SC).

mere change of form of a chemical substance with properties inherent to that form would not qualify as enhancement of efficacy of a known substance. However, beneficial physico-chemical properties such as better flow ability, process ability, thermodynamic stability and lower hygroscopicity have nothing to do with therapeutic efficacy. Even increased bioavailability might not pass the test laid down by Section 3(d), since it does not necessarily lead to an enhancement of therapeutic efficacy; whether it does so in any given case must be specifically claimed and established by research data. Under Section 3(d), the mere discovery of any new property or new use of a known substance is also unpatentable. Therefore, a second therapeutic effect of a known drug is unpatentable. In Monsanto case,[25] a claim for a method of producing heat, salt and drought-tolerant transgenic plants using cold shock protein was rejected under Section 3(d), since the cold-tolerant property of cold shock protein was already known in the art.

(iii) A mere Mixture:[26]The mere admixture of two or more previously known substances is unpatentable, unless it is shown that the combinative effect of such substances is more than the sum of their individual effects. In other words, such a combination should result in a synergistic effect.[27] The synergism[28] must be properly demonstrated in the complete specification by providing appropriate experimental data.

(iv)Discoveries, things isolated from nature, plants and animals:[29]Discoveries of living things or non-living substances occurring in nature are not patentable subject matter. Thus, micro-organisms isolated from nature and DNA, RNA or proteins isolated from living organisms are unpatentable. Although naturally occurring micro-organisms are unpatentable, genetically modified micro-organisms and vaccines are patentable, subject to other requirements. Synergistic compositions of new or known micro-organisms can also be patentable, as can processes for isolating such substances.

[25]*See: Monsanto Technology LLC. v. The Controller of Patents and Designs and the Deputy Controller of Patents and Designs* [2013] Order No. 146 (IPAB).

[26]*The Patents Act, 1970*.S. 3(e)

[27]'Synergistic effect': An effect arising between two or more agents, entities, factors, or substances that produces an effect greater than the sum of their individual effects. (1831). In: *Merriam-Webster*. [online] Springfield, Massachusetts, *available at:*http://www.biology-online.org/dictionary/Synergistic_effect (Last accessed on 11November, 2017)

[28]'Synergism': Interaction of discrete agencies (such as industrial firms), agents (such as drugs), or conditions such that the total effect is greater than the sum of the individual effects. (1831). In: *Merriam-Webster*. [online] Springfield, Massachusetts, *available at:* https://www.merriam-webster.com/ (Last accessed on 16 November, 2017).

[29]*The Patents Act, 1970*.S. 3(c).

However, micro-organisms and such other inventions of bio-technology, both products as well as processes, do not constitute patentable subject-matter.[30] India has amended its patent law in 2002 to bring life and living beings created through biotechnology within the purview of patentable subject matter.[31] The term chemical process is redefined through amendments to include bio- chemical, biotechnological and microbiological processes.[32] As per the modified definition of the chemical process it is implied that biotechnological processes and products of such processes are unambiguously patentable. However, there are no decided case laws in India on the patentability of biotechnological inventions. Meanwhile, patent laws universally exclude certain inventions from the purview of patentable subject-matter. The following inventions including certain biotechnological inventions do not constitute patentable subject matter:[33]Discoveries & inventions against public order and morality, such as:

(a) Human body, discovery of its elements and genes in natural form (isolation of human genes and gene sequences are patentable if isolated by technical means,) processes for cloning human beings;

(b) Processes for modifying the germ line genetic identity of human beings;Plants, animals, and essentially biological processes. (Microbiological and non-biological processes and products resulting from such processes seem to be patentable.)

II. Novelty of Biotechnology inventions in India

Novelty is not defined in the patent law of India. But invention is defined to mean a new product or process involving an inventive step and capable of industrial application.[34] The Indian Patents Act defines inventive step and industrial application but it does not define the term novelty. Hence it is left to the patent office and the courts to define and mean the term novelty. The Patents Act specifically states that a few subject maters are not inventions. In doing so, it indirectly states that such subject matters are not novel or new. In particular, the subject matters such as discoveries and finding of a living thing or substances occurring in nature are considered

[30]*The Patent 2nd Amendment Act, 2002.* S. 3(j).
[31]*The Patents Act,1970*.S. 5 was deleted, thereby paving the way for product patents in the area of pharmaceutical and other chemical inventions.
[32]*The Patents Act,1970.* S. 5 (as it stood after the 2002 amendments) had provided that, in the case of inventions being claimed relating to food, medicine, drugs or chemical substances, only patents relating to the *methods or processes of manufacture* of such substances could be obtained.
[33]*The Patent3rdAmendment Act, 2005.* S.3(a), S.3(b), and S. 3(c).
[34]*Supra* note 16 at 5.

as not new and do not constitute an invention.[35] Further, plants, animals, and essentially biological processes are not considered new and do not constitute an invention. [36]

However, micro-organisms are considered new and can be patented.[37] Further, human genetic material in isolated and purified form is also considered new invention. For the first time in the history of Indian patent law a living process was claimed for patent. On 15th January 2002, the Calcutta High Court delivered a land mark judgment in Dimminaco A.G. v. Controller of Patents Designs & Others[38]which is set to change the landscape of patenting of life form in India. Dimminaco A.G had filed a patent application for the process for preparation of infectious bursitis vaccine. The end product contained a living organism in the form of virus. Under the Patent Act 1970, it cannot be patented. The High Court held that the process was patentable and merely because the end product contained a live virus did not inhibit the process of manufacture from being patented. The Court held there is no statutory bar to accept a manner of manufacture as patentable even if the end product contains a living organism. This case has paved a way for the further research and development in life forms and essentially biological process.

In the light of the TRIPS agreement considering biotechnological inventions as new, India being a signatory to the agreement, amended its patent law to implement the agreement. Now with the amendments to the patent law biotechnological inventions, both products and processes are considered new. There was no strong debate in India unlike in the US on the novelty of biotechnological inventions. As the matter is settled in developed countries like US and in the European Union that biotechnological inventions are novel over and above the pre-existing biological products there was no difficulty for India to follow suit.

III. Inventive step of Biotechnology inventions in India:

In India patents are granted for inventions involving an inventive step.[39] Inventive step is defined to mean a feature that makes the invention not obvious to a person skilled in the art.[40] Any new

[35]*The Patents Act, 1970*.S. 3(c)…[T]he mere discovery of a scientific principle or the formulation of an abstract theory or discovery of any living thing or non-living substance occurring in nature.
[36]*The Patents Act, 1970*.S. 3(j)…[P]lants 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 animals.
[37]*Supra* note 31at 8.
[38]*See:Dimminaco A.G. v. Controller of Patents Designs & Others* [2002] (Cal. H.C.).
[39]*Supra* note 17 at 5.
[40]*ibid*

product or process that involves an inventive step is patentable in India. In India the patent law [41] provides that when an application for patent is made, the patent examiner[42] will have to conduct an investigation to find the relevant prior art. If in the investigation it is found that the invention has been anticipated by publication in India or elsewhere before the date of the applicant's filing of the complete specification, the patent shall not be granted. In such circumstances the invention falls within the realm of prior art, the knowledge in the public domain involving no inventive step. Such knowledge in the public domain being obvious to a person skilled in the relevant art shall not be given patent.[43] The requirement is no different with reference to biotechnology inventions.

In Dimminaco A.G. v. Controller of Patents Designs & Others[44]a vaccine invented, which was useful for protecting poultry against contagious bursitis infection. The inventors contended that the process claimed involved certain chemical steps under specific scientific conditions. The patent office initially rejected the application by stating that living virus or living process did not constitute invention under the Indian Patents Act. However, the Calcutta High Court held that there was no statutory bar to patent living processes or product that involved inventive step. In the present case the process claimed did involve certain inventive step, as it required certain chemical steps to be taken in the production of the vaccine. The High Court directed the patent office to grant patent on the claimed process. TheCalcutta High Court held that a patent on a micro-organism is valid.

Therefore, as per the decision of the Calcutta High Court a biotechnology invention involving a new process or product could be patented if it involved an inventive step. Further, as per the patent law if the invention was anticipated in the prior art or is published, used, or patented, it did not involve an inventive step. In case of biotechnology inventions also the claimed inventions did not constitute an inventive step if it was anticipated or published or used or patented earlier or in any way formed part of the prior art.

However, nowhere in the United States patent law or in the Indian patent law the term prior art is used or denied. The European Patent Convention uses the term 'state of the art' which is

[41]*The Patent3rd Amendment Act, 2005.*
[42]*See:The Patents Act, 1970*…[T]he examiner is a person who will scrutinize the patent application and conduct a patent search to find relevant prior art.
[43]See: *The Patents Act, 1970.*S.13.
[44]*See:Dimminaco A.G. v. Controller of Patents Designs & Others* [2002] (Cal. H.C.).

equivalent to prior art and states that state of the art comprises everything that is made available to the public by means of a written or oral description or by use in any other way before the date of filling of the European Patent application. The United Sates Patent law, the European Patent Law and the patent law in India state that any invention which is known or published or patented, being part of the prior art, is obvious and does not involve inventive step. Therefore, an invention, which is a part of the prior art, does not involve inventive step and is not patentable. The invention shall be a leap forward from the state of art or it shall be a step forward from the already existing knowledge that is prior art. It shall be an advancement of existing knowledge in the public domain. It implies that courts while determining the obviousness of any invention shall have to consider the scope of the prior art. In fact, law courts have taken into consideration the knowledge in the public domain or in the state of the art in deciding obviousness of an invention. The presumption is that on the basis of prior art, if an invention becomes obvious to the person having skill in the relevant art, such invention does not constitute an inventive step and must not be patented.

IV. Requirement of Industrial application of biotechnology invention in India:

The patent law of India states that any new product or process involving inventive step and capable of industrial application does constitute an invention[45] and is patentable. The expression 'capable of industrial application in relation to an invention' means that the invention is capable of being made or used in an industry.[46] The requirement of industrial application of inventions in India is no different from the industrial requirement of Europe or utility requirement of the US. However, there is no substantial case law development with regard to the industrial application of biotechnology inventions in India as the industry is in an infant stage. In Dimminaco A.G. v. Controller of Patents Designs & Others[47]the vaccine was useful for protecting poultry against contagious bursitis infection. Initially the patent office rejected the patent application on the ground that the claim did not constitute an invention. But the utility of the invention was not disputed.

[45]*Supra* note 16 at 5.
[46]*The Patents Act, 1970.*S.2(ac)…"capable of industrial application", in relation to an invention, means that the invention is capable of being made or used in an industry.
[47]*See:Dimminaco A.G. v. Controller of Patents Designs & Others* [2002] (Cal. H.C.).

Likewise, the utility of biotechnology inventions like genetically engineered plants, animal gene, DNA and the like is indisputable. Therefore, the utility or industrial application of bio technology inventions is accepted and assumed in India.

V. Written description or disclosure of the invention and the deposit of the invention:

Article 29 of the TRIPS Agreement[48] states that the patent application should disclose the invention in a sufficiently clear, concise and complete manner so that a person skilled in the art couldcarry out the invention. Also the applicant shall disclose the best mode for carrying out the invention known to the inventor.

The requirement of written description of the invention serves the purpose of evaluating the inventor whether he does possess the invention at the time of filing the patent application. Written description is a public notice that the inventor possesses the invention.

The claimed micro - organism[49] itself or a new product obtained from it, the patent will be valid only if it gives a disclosure of the invention which is sufficient to enable it to be reproduced. It is practically impossible to define a strain of micro-organism unambiguously by a written description and it is not always possible to say whether observed differences between two cultures are such as could be expected within a single strain, or if they are large enough to compel identification as two different strains. Even if a complete description were possible, this would not necessarily put the public in possession of the invention when the patent has expired. One, who wished to carry out the process of the invention, would have to first catch the bacterium, which is a difficult task, as to get it by search in nature or by random mutation might take years or never.

The solution to this problem is that of the deposition of the strain in a recognized culture collection, which will maintain the strain in a viable condition and make it available to the public.

[48]*TRIPS*, Art 29Conditions on Patent Applicants: 1. Members shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application.
2. Members may require an applicant for a patent to provide information concerning the applicant's corresponding foreign applications and grants.

[49]The term micro-organism is interpreted broadly so as to include not only bacteria and fungi, but also viruses, and animal and plant cells.

The Budapest treaty:

The majority of developed countries have now adopted the solution of requiring deposit of a microorganism,[50] and the Budapest treaty of 1977, which came into force in 1980, establishes a list of International Depository Authorities and provides that a single deposit made at any of these will suffice for all signatory states The Regulations under the Treaty lay down in detail the procedures which depositors and IDA[51]s must follow, the duration of storage of deposited microorganisms[52]at least 30 years or five years after the most recent request for a sample, whichever is later. The Treaty and Regulations make various provisions to guard against the loss and consequent non-availability of deposited microorganisms. Thus the IDA must have the expertise and facilities necessary to keep the microorganism viable and uncontaminated throughout the storage period required by the Treaty. If for any reason an IDA is no longer able to furnish samples of a microorganism, a new deposit of the same organism can be made and can benefit from the date of deposit of the original. If for any reason an IDA ceases to function as such, the Treaty provides for the microorganisms deposited with it to be transferred to another IDA.

There is also a provision for the possibility of redeposit if a strain becomes non-viable on storage.[53]Most of the countries now have early publication of patent applications, 18 months from the priority date. As part of the publication, the deposited strain must be made available from this time. A serious problem arises here. In short, the applicant must make the means for carrying out his invention available to the public, including his competitors, before there is any assurance that he will actually obtain any patent protection. The traditional concept of patent protection as quid pro quo for disclosure has thereby been distorted so as to require, before any

[50]*The Budapest Treaty,* Art 2 (ii)… "[D]eposit of a microorganism" means, according to the context in which these words appear, thefollowing acts effected in accordance with this Treaty and the Regulations; the transmittal of a microorganism to an international depositary authority, which receives and accepts it, or the storage of such a microorganism by the international depositary authority, or both the said transmittal and the said storage;

[51]International Depository Authorities.

[52]Meaning of the Term "Microorganism" The term "microorganism" is not defined in the Treaty so that it may be interpreted in a broad sense as to the applicability of the Treaty to microorganisms to be deposited under it. Whether an entity technically is or is not a microorganism matters less in practice than whether deposit of that entity is necessary for the purposes of disclosure and whether an IDA will accept it. Thus, for example, tissue cultures and plasmids can be deposited under the terms of the Treaty, even though they are not microorganisms in the strict sense of the word.

[53]*The Budapest Treaty,* Art 4.New Deposit:(1)(a) (i) where such microorganism is no longer viable.

protection exists, not merely disclosure, but what has aptly been described as making available a 'pocket factory handed over to the imitator on a silver plate.'[54]

Another serious problem relating to deposits of micro-organisms is that most states not only require deposits to be made, but in addition, require a written description. In Germany, it was held[55] that a deposit may be essential to comply with the general rule of sufficiency of the description as a whole, but that a deposit alone is not enough to support a product per se claim to the micro-organism. This can only be based on a reproducible written description, which in most cases of course cannot be provided.

Understandably, industry would like to see a uniform practice applied in all developed countries, ideally one in which a deposited strain would be recognized as a sufficient description, but the strain would not be released until the patentee had enforceable rights. Failing such additional safeguards, a company inventing a process for making a known substance by using a new strain of micro-organism should consider keeping the new process as a trade secret instead of trying to patent it. Patenting will require deposit of the strain, and if anyone obtains this and uses it, it will be practically impossible to prove that the patent is being infringed. The best form of protection in this case is to keep the new strain safely in one's own hands.[56]

Initially it was necessary to deposit vectors containing DNA, or hybridomas producing monoclonal antibodies, because reliable DNA sequence information was not available. Now it is sufficient for this type of invention to file a sequence identifier giving the complete sequence of the DNA or protein in question.

Written description or disclosure of the invention and the deposit of the invention in India.The description of the invention for a patent is termed as specification. It is an essential part of the patent application as patent is a quid pro quo for disclosure. Depending on the sufficiency of the disclosure, there are two types of specifications:

- Provisional Specification: This contains only general description and not claims. It is important for fixing the date of priority.

[54]Grubb, P. (2006). *Patents for Chemicals, Pharmaceuticals and Biotechnology*. Oxford University Press, p.250.
[55]Backerhefe (1975)6 IIC 207(BGH)
[56]Grubb, P. (2006). *Patents for Chemicals, Pharmaceuticals and Biotechnology*. Oxford University Press, p.250.

- Completed Specification: comprises of full description of the invention containing all the claims over which the applicant is claiming monopoly rights.

In case of Biological materials mentioned in the specification may not be properly described and if the material is not available to the public, the application shall be completed by depositing the material to an international depository authority under the Budapest Treaty. The deposit of the material shall be made not later than the date of filing the patent application in India.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.[57]

Conclusion

The inventions of biotechnology, in the present day, are very much useful in different sectors, specifically and substantially. Biotechnology is being used vastly in agriculture, Environment, medical, Pharmaceutical, chemical industry, animal husbandry, and many others. Biotechnology has brought up innovative medical treatments and surgical procedures that are useful for the society. Biotechnology inventions are useful in treating pollution, fisheries, forestry, and others. This technology has got enormous importance in present-day life.The debate on biotechnology has come a long way since it first drew the attention of the patent specialists. They called into question the patentability and unpatentability of living and the natural phenomenon. It now commands the attention of a wide range of legal and non-legal communities embracing a variety of issues some ranging from the past, questions like the nature of the invention, to the present, like the patent jurisprudence and methodology due to the manner in which modern

[57]The Patents Act, 1970, S.10(4)(d)(ii)…[I]f the applicant mentions a biological material in the specification which may not be described in such a way as to satisfy clauses (a) and (b), and if such material is not available to the public, the application shall be completed by depositing the material to an international depository authority under the Budapest Treaty and by fulfilling the following conditions, namely:—
(a)the deposit of the material shall be made not later than the date of filing the patent application in India and a reference thereof shall be made in the specification within the prescribed period;
(b) 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;
(c) access to the material is available in the depository institution only after the date of the application of patent in India or if a priority is claimed after the date of the priority.

biotechnology has been accommodated within the patent system. The path forward has to have the breadth and depth to properly understand and accept in the legal system.