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Microorganisms Patent Law Puzzlement: To the Point Tactics

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Abstract

Microorganisms and its associated patent laws are discussed at global level and interpretations of various international gatherings mainly TRIPS, Budapest, Paris Convention are discussed. Innovative patent laws formulated after TRIPS agreement provide patenting of microorganisms for first time in various developing countries. Key provisions related to microorganism patenting of (Indian) Patent Act 1970, EPC and USPTO are also discussed. In this framework, the paper emphasizes the need of defining microorganisms at international level in reference to intellectual rights and coding unit form procedure for microorganism related certifications globally. Moreover, the paper features the deposition of culture in IDAs (International Depository Authorities) in various countries and general criteria of patentability. In an attempt to reach threshold between science and law possible pre and post objections with infringement issues are highlighted which will further help in creating awareness in scientific and legal community.

keywords: Microorganisms; Patent; Biotechnology; International depository authorities;, TRIPS; Infringement; Patent opposition, PCT, IPR

Introduction

Concept of Intellectual Property Rights (IPR) is not new to the world; the origin of IPR can be traced to the idea of trade secrets, privilege rights or monopoly in ancient time, which was followed by various civilizations to promote science and arts. This concept of privilege monopoly over certain skills gave birth to social system in various cultures.

Patent is the most prized possession of an inventor, "If Intellectual Property Rights vanish what will remain with the intellectual?" Patent rights invoke feeling of pride and consequently promote invention and investment. Otherwise money invested in R&D activities will go contrary from investor view point as others will take credit by standing on his efforts without any investment in R&D resulting in unfair competition. Nowadays IP Rights have escalated from solely prestige issue to revenue generating rights resulting in legal battle between industries.

A creator or an inventor or any other individual/firm designated by him as an assignee (owner of rights) can acquire a privileged monopoly over his creation for a contracted span which is generally 20 years, inside a particular territory bestowed by the respective government [1]. The patented claims are open for use by general public when the benefit time gets terminated. Patent is a way by which immense knowledge and skill can be gathered to deliver as a dependable resource for raising nation's economy.

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The promotion of protection of intellectual property throughout the world is controlled by World Intellectual Property Organization (WIPO) which is an agency of United Nation [2-4].

According to estimation there are more than 1,000,000 species of bacteria (Archaebacteria and Eubacteria) there are also approximately 600,000 species of Protoctists (algae, protozoa, etc.) [5,6]. It can be said that 'Microorganisms' represent a significant proportion of the world's biodiversity and are likely to create competition between nations in biodiversity claims. Every sovereign nation has right to control the genetic resources. But confinements of the usage of biological heterogeneity are not in human profit.

Range of international level gatherings like General Agreement on Tariff and Trade (GATT), PCT, Budapest and Trade Related Aspects of Intellectual Property Rights (TRIPS) have been organized in order to resolve disputes. In which TRIPS agreements are important form biotechnology point of view which introduces patenting of microbes *per se* and microbiological operations in fellow countries [7]. The TRIPS agreement of WTO assigns a number of guidelines on fellow constituent countries in order to bring uniformity in international law related to IPR. To abide with the TRIPS prerequisite, India had revised its Patents Acts, 1970 thrice. It is also additionally specified by the TRIPS Agreement that no member nation can reject an invention from patentability merely by giving excuse that native laws do not permit or sanction it. No republic has the liberty to select the segments it prefers and refrain from others. At that time various developing nations which include India also, where patent provisions is not at par, a time period was allotted for implementing uniform laws [8].

Microorganism associated patents and their safeguarding is a critical subject heralded these days in the biotechnology realm. The extensive recognition and significance given to it is because of the predicted fact that besides research activities microorganism is used as a most important tool in bioprocess industries which include food, beverages, pharmacy [9].

Growth in patenting related to microorganism reflects the importance of microorganisms as a rich and largely untapped source of DNA, amino acids, and proteins such as enzymes for the pharmaceutical, food, agricultural and chemical industries**.** IPR literacy especially in developing countries is in such a pitiable situation that even highly qualified microbiologists are not aware of basic criteria of microorganism patenting which is matter of concern. Moreover patenting of microorganism has been fraught with uncertainty and ambiguity because of the nature of the field.

Microorganisms linked patentability criteria

The following are the general steps (this concept is almost similarly enforceable in every country) in potential array of significance which needs to be satisfied for microorganisms associated patents.

Subject matter

Interoperating EPC Art.-52(fifty two), USC Art.-101(one hundred one) and famous *Diamond v. Chakrabarty* **[11].**case we can say that Basic principle is that invention should not be frivolous or against morality. A good deal of misunderstanding with regard to ambit and scope of microbe patent per se have been avoided in TRIPS agreement which allows microorganism patenting [10].

The more authentic decisions regarding the patentability of microorganisms were made by the US Supreme Court in 1980 (Diamond v. Chakrabarty case), when the genetically modified bacterium was granted a patent on the basis that genetically altered microorganisms were indeed patentable as they were man-made and have industrial application

Legal position is absolutely clear that microorganism is patentable if it has industrial application, but silence on the question what is microorganism?? There is great deal of ambiguity in defining subject matter.

Usefulness

From EPC Art-57(fifty seven) and (Indian) The Patents Act, 1970 we can construe a meaning of usefulness. According to TRIPS an invention involving biological material (microorganism) will be regarded as useful if: It is regarded as being capable of industrial application if it can be shown that it is capable of being used in a manner which provides a demonstrable public benefit. Public benefit means that the invention must be capable of being used in a manner conducive to public health and to social, environmental and economic welfare [12].

Some of the patentable uses of Microorganisms are

Fermentation process, Bioprocess involving microorganisms, Bioremediation, Microbial biosensor, Enzyme analysis, Clinical testing, Medical use, Waste treatment, Product formation, reducing toxicity.....

Logic is clear that there can be no patent for useless inventions [13]

Novelty of invention

EPC-Article 54 (fifty four) speaks about the novelty of invention and according to TRIPS an invention [14] involving biological material (microorganism) will not be regarded as novel if:

- the information is already in the public domain; and/or
- The invention merely replicates biological material, or the function of biological material, which already occurs naturally.
- If it lack inventive step i.e. it merely identifies the biological material or its natural function.

Invention *vs.* discovery

- A discovery adds to the amount of human knowledge by disclosing something already existent, which has not been seen before
- An invention adds to the human knowledge by creating a new product or processes involving a technical advance as compared to the existing knowledge.
- If the discovery leads to the conclusion that the material can be used for making a particular article or in a particular process, then the article or process could be patentable

Non obviousness

As per EPC art 56(fifty six), Invention should be new to person skilled in specific Art (i.e. person skilled in microbiology or allied field) and it should have application.

Indian Patent Act (sec 3) provides that, "The mere discovery of a scientific principle or the formulation of an abstract theory or discovery of any living thing or non-living substances occurring in nature".

Specifications

Indian Manual of patent procedure, 2005 provide the purpose of specification and help can be taken from of EPC Art 83(eighty three) for in-depth understanding.

The patent should disclose all the details. Detailed information which can be used by a person skilled in art, to get the results claimed in patent. Purpose is clear that invention should be workable and reproducible.

Specification draws a line between patent and trade secret.

Defining Microorganisms

The Budapest Treaty, TRIPS, PCT, Paris convention etc. does not offer a definition of a micro-organism. The term 'micro-organism' does not appear anywhere within patent legislation at international level. Extensive puzzlement and guesswork taking are prevailing in defining the term microorganism lies in many nations. However according to interpretation of law convention is that if the relevant treaty or Convention fails to provide a definition then the ordinary meaning of that term should be used.

Dictionary definition (The Concise Oxford Dictionary) is "Any of various microscopic organisms, including algae, bacteria, fungi, protozoa and viruses". This definition is not sufficient to describe the term microorganism precise and scientifically for the purposes of providing a clear definition as per the requirement of Article 27.3(b) of TRIPS agreement

Generally the term 'micro-organism' includes; Bacteria and cyanobacteria, Archaeabacteria, Algae, Protozoa, Slime moulds, Bacteriophages, Plasmids, Viruses, actinomycetes, Virus strains, Yeasts, filamentous fungi and mushrooms, cell lines and tissue cultures, Fused cells, vectors, Plant cells [15].

A microorganism or a microbe is generally a small living thing that is visible under microscope. Many macro animals and plants have juvenile stages which are also microorganisms**.**

The European Union has introduced new term "biological material" as substitute for microorganism for patent purposes which symbolizes any substance holding genetic information and capable of replicating itself or being duplicated and multiplied in a biological system. Biological materials like gene sequences also undergo same category [16].

Brazilian legislation defines the term 'transgenic micro-organism' for the purposes of patent Law, transgenic micro-organisms are organisms, except for all or part of plants or animals, that express, by means of direct human intervention in there, genetic composition, a characteristic normally not attainable by the species under natural conditions [17].

EPC 53-2

Still it has to be settled whether to permit sequences of DNA deprived of any operative evidence to be patentable.

Microorganism may also be define as biological material that is able to replicate without human interference and contain some genetic element in it

The role of the IPR Professionals in interpretation of microorganism definition in current scenario should not be underestimated. In absence of clear definition ability to define microorganism in such a way as to attain desired objective becomes key.

Procedure for microorganism identification, submission and patenting

One of the major obstacles for the emerging arenas of microorganism patent prior to PCR technology was the time consuming process involved in replicating or amplifying DNA (deoxyribonucleic acid) which had to be performed by hand.

In identification process

First isolation is done from natural environment by suitable technique. Then identification is done by DNA fingerprinting. Differential property of microbe is that their mini and microsatellite varies among species, this property is use to identify microbe and comparing it with pre identified microbe.

In submission process

PCT procedure steps for microbial patent after deposition [18]

- 1st. File patent application in domestic nation e.g. India, UK, Pakistan.
- 2nd. File PCT application (generally after 12(twelve) months of step 1st)
- 3rd. International search and publication (after4-6(four to six)months of filing PCT application)
- 4th. Finally apply for PCT patent in regional offices e.g. countries where you desire to shield your invention.

International Depository Authorities

Patent can only be granted when subject matter is available to the public otherwise anyone can claim patent for name shake. In case of microorganism it is difficult to maintain culture for long time thus creating unique problems associated with microbes. The Budapest pact came into impact to overcome the problem related to deposition of microbial culture and their recognition. Insufficiency of consistent instructions blended with the diversity of national patent laws led the culture collections in bigger chaos. Under this pact certain culture collections are identified as "International Depository Authorities" (IDAs) to avoid any misconceptions. So, it has become mandatory that for getting a patent (in countries party to treaty) comprising a microorganism, a deposit has to be made in any one of the IDA. There are numbers of recognized IDA spread throughout the world.

IDA can also be used as a center for documentation for microorganism related research activities. Therefore, a depository can also be habituated as a conservation center i.e microbial bank.

If the applicant mentions biological material in the invention and he is not able to produce the disclosed sample for specification the disclosure can be proclaimed by depositing such material in an International Depository Authority under the Budapest Treaty. The same shall be deposited not later than the date of filing, however, the reference number to the deposit shall be made in the specification within 3 months from the date of filing the application. The complete specification shall contain the details of such deposition and the source and geographical origin of the biological material [19].

Materials that may be deposited under the Budapest Treaty include:

- cells (bacteria, fungi, cell lines, plant spores)
- seeds that can be dried to a low moisture content and stored at -20C or lower
- genetic vectors such as plasmids or bacteriophage vectors or viruses containing a gene or DNA fragments
- Organisms or systems used to produce a protein from a gene. These include:
    - bacterial, yeast, viral, plant or animal cell cultures
    - yeast, algae, protozoa, eukaryotic cells, cell lines, hybridomas, viruses, plant tissue cells, spores, and hosts containing materials such as vectors, cell organelles, plasmids, DNA, RNA, genes and chromosomes
    - purified nucleic acids
    - deposits of materials not readily classifiable as micro-organisms, such as 'naked' DNA, RNA, or plasmids, subject to the qualification given below.

In India the Patents Act, 1970 was amended in 2005 in order to recognize the International Depository Authorities (IDAs) under the Budapest Treaty. If the Application pertains to a biological material obtained from India, the applicant is required

to submit the permission from the National Biodiversity Authority at any time before the grant of the patent. However, it would be acceptable if the permission from the National Biodiversity authority is submitted before the grant of the patent. [20].

In USA, deposition can be done any time before final grant of patent as compared to EPO where it has to be done before filling application (rule 31-1a)

Important point to note is that deposition should be made by inventor (or his assignee) himself or person having authorization by inventor (or his assignee).

Status of Microbial Patenting

Patent laws were initially framed from chemical, mechanical and electrical invention point of view but later on information technology, electronics, pharmacy and biotech emerged as chief field of IPR resulting in changes in prior laws. Although first patent related to microorganism was granted in 1873(one thousand eight hundred seventy three),but after that no significant development in microorganism patenting has been observed for a long time, but with the advancement of genetic engineering there is an overflow of patent claims associated with microbes.

Major debatable concerns besides the question what is meant by term microorganisms are

- Can a microorganism be patented in itself? If yes should it be in accessible in live form.
- Are new applications of pre-existing microbes patentable?
- Can isolated microorganisms that exist in nature patented?
- Are microorganism products patentable?
- Are processes of producing microorganism patentable? if yes what is process.

Patentability of microorganisms is governed by various international and national legislation and interpretation of case laws. After TRIPS agreement it is well settled that microorganism per se are patentable and member countries are under obligation to provide patent for microorganism *per se* [21].

Until 1980(one thousand nine hundred eighty) patents over microorganisms were confined to processes relating to microorganisms rather than the microorganism itself as such. The main legal landmark in the extension of patenting to microorganisms is the well-known and widely cited Supreme Court case *Diamond v. Chakrabarty*[22]*in which genetically modified bacteria gets patent per se.*

Industrial application is one of the necessary criteria to be fulfilled for patenting. Same can be treated as sufficient criteria for patent if no other law is contradicted.

Microorganisms isolated from its environment can be patented if it is not pre known. A “biologically pure culture” i.e. isolating a strain that is now not in its natural environment could be suitable for patenting in the United States ,Germany. EPC (Art 23-c) and (Rule 27) also try to throw light on issue.

Microorganism production process and its product are patentable. In India important case of 2001 *Dimminaco – A.G v. Controller of Patents & Designs and others* can be cited as guiding precedential law, the issue involved was the patenting of the process for preparation of infectious bursitis vaccine, which is invented for protecting poultry against infectious bursitis. The Controller held that the process of separation of the vaccine which has living entity cannot be considered as a manufacture and hence not patentable under section 2(1) (j)(i.e. section Two, sub section 1, clause j)of the Patents Act, 1970. He also held that since the vaccine contains living organism it cannot be patented. The court held that the matter involved is of a new process of preparation of vaccine under specific scientific conditions and the patentee said vaccine is useful for

protecting poultry against contagious bursitis infection and there is no statuary bar to accept a manner of manufacture as a patentable even if the end products contain living organism**.**

Assessment response from most of the developed countries disclosed that microorganisms themselves are patentable, only if they have the provision of innovation, originality, imagination and industrial application. Patent protection to newly developed uses of a pre-existing microorganism and genetically modified microorganisms are provided by all the developed countries.

In India subject is governed by Patents Act 1970 of which section 2(1)i [section Two, sub section, 1 clause i], 2(1)j [section Two, sub section 1, clause j], 3(c, I , j) [three-c,I,j] are most decisive. However, in India, any discovered micro-organism from the nature is not patentable. Indian Patent Act (2002 Amendment) added explanation to chemical process, which states; chemical processes include biochemical, biotechnological and microbiological process. The definition of "invention" was also changed to "any new product or process involving an inventive step and capable of industrial application" thereby deleting the word "manner of manufacture" as mentioned in the earlier Act. There have been also judicial decisions which create confusion and conflicts.

The important distinction between developing and developed countries is that the former, unlike the latter, do not allow patenting of microorganisms already existing in nature; some do not even consider such a `discovery' an invention. However, as WTO members many countries have now allowed patenting of genetically modified organisms.

Critics against microorganism patent

Patenting of microbes potentially raise several ethical and moral issues could patenting development be tantamount to owning living creature

The utility of invention should be for humanity any microbe is a property of nation, is it appropriate to properties a particular microbe, a living creature to particular person and to devoid others from its benefits. Microbes are common heritage and it is not moral perspective to devoid others

Time limit of 20(twenty) years given to patentee is too much. Moreover it is negative rights in logic that it means injunction (stopping other to do certain things).

Moreover Indian culture as per Smriti (ancient Hindu text) states that 'knowledge and its benefits should never be taken into custody '

Strongest argument is that microbes are natural living entity and there isolation is mere discovery and not invention and their products generation processes are natural phenomena.

Product generated by microbes is natural phenomena.

Sec25-2----------

Legal issues of fact and law

It is widespread tendency of human psyche to copy and modify the work of others and represent it as their own and get it patent by claiming improved method or process resulting in malfunction of patent system.

Two key legal concerns related to patent of microorganism is pre/post oppositions (against patentee) and infringement (against trespassers) this concerns are almost similar in nature throughout the world with minor deviation. Major drawback is that remedies are available in territorial region to which patent is granted this problem is somewhat encountered by PCT

system. In light of above fact it is submitted that there should be uniform patent code enforceable at global level and all the countries should come within the umbrella of PCT.

Generally legitimacy of microorganism patent comes into doubt when it is challenges on ground of novelty, application, territorial issues, subject matters etc.

pre and post oppositions to patent are useful in a sense that it provide scrutiny to patent and add as a valuable right to patentee and general public whose right might have reduce or overlapped with already claimed patents in light of such opposition patent may be granted with denial or modification of few claims

Pre and post grant Opposition:

General grounds of Pre and post grant opposition based on Indian law are:

- Prior publication, claiming, known, used.
- Statutory prohibition.
- No disclosure or wrong mention of the source or geographical origin of the biological material used for the invention;
- Convention application not filed within 12(twelve) months of the basic application
- Wrongfully obtained
- Any or all claim is a subject of prior grant.
- Patentee was not eligible as per statutory law.
- Patent was wrongfully obtained by fraud.
- Not an invention.
- Any or all claim invention is not useful.
- Insufficient disclosure.
- That the claims are not clearly defined and not sufficiently based on the disclosure.
- Failure to disclose information regarding foreign application.
- Non-compliance with any secrecy direction issued under any provision of the Act.
- That the specification wrongly mentions or does not disclose the geographical origin of any biological material used for the invention.
- Non deposition of culture to IDA ie. Non availability of culture.

Possible defenses against opposition of patents are;

1. Not each step is disclosed to public (section 29 [twenty nine]),
2. Patent is applied within one year (31 d & a [thirty one a & b])

Infringement issues arise after grant of patent are predominantly concerned with the execution of patent rights. Rights start from publication of patent application. When rights of patentee are implemented by others without authorization Infringement is synonymous to piracy. Major unhelpful aspect is that patentee in most of the cases are unaware of unauthorized use of their patent. If patent application is in process, alternative remedies available are based on unfair competition. In Infringement issues generally the burden of proof is on defense.

Once the patentee comes to know about the infringement of one or more claim patentee can approach the court within time frame limited by law for enforcement of IP Right. Important point is that only claims approved in patent are enforceable, so it is recommend including all probable claims clearly and specifically leaving no scope for trespassers.

Possible defenses against patent infringement in India are;

i. Government use (u/s 47-1(forty seven, one) of The Patents Act, 1970)
ii. Research and education use (u/s 47-3 (forty seven, three) of The Patents Act, 1970)
iii. Patent exhausted
iv. Misuse by patentee

In the lack of case law related to patent issues it is difficult to construe and analyze the patent laws to fullest extent

In microorganism related patent main line of attack from patent aspirant or patentee side may be

- Description of all chemical and physical properties to eliminate further patent claims which can be made under the bearing, development of new application.
- As patent grant rights only to corresponding claims one must describe all probable claims. According to convention "what is not claimed is disclaimed".
- For processes describe each and every step with alternative steps
- Describe all probable uses
- Get it patented under PCT and if possible parallel patents from countries are not covered in PCT
- Use patent or sell it to competent body in order to eliminate claim of compulsory licensing
- Never claim something that appear too important for general public, to avoid government acquisition
- In injunction suit, claim all the damages at the first site, otherwise principle of waiver of rights may evoke.
- Remember the in most of the countries law is "First to file is the first to invent".
- Transfer technology as soon as possible ,help can be taken from professional bodies
- To escape principle of estoppels safest rule is to admit nothing about prior art and say little about prior art and that too in nonspecific manner.
- Opponent has no *locus standi* in case.
- Do not gift sample to any one before grant of patent

Restriction of time

As conventional principles of law there is restriction of time period in which legal action is to be taken otherwise it may be assumed that patentee have give off its rights. This provision is based on the following two principles 1) interest of state requires that there should be an end to litigation.2) law assists the vigilant and not who sleeps over his rights [23].

In India the period of restriction for bringing a suit for infringement of a patent is three years from the date which patentee comes to know about infringement (article88 and section 22 of the Indian Limitations Act) and for post patent opposition within one year from the date of publication of grant of a patent (under section 25(2) of (Indian) patent act).

This restriction of time is not binding on controller of patent in India as these proceedings are not equals to court proceedings**.**

In Europe restriction of time is 9 months from the date of publication [24].

Get patent economically

Various fee to be paid are

1. Transmittal fee,
2. International filing fee,
3. Search fee,
4. Supplement per sheet (in excess of 30 sheet),
5. Fee for priority document,
6. Late payment fee,
7. Late furnishing fee,
8. Fee for requesting restoration of priority,
9. Renewal of patent fee for copy of document,
10. Patent attorney fee,
11. Fee for deposition of microbial culture.

Few suggestions to reduce expenses are

1. Do an extensive prior search,
2. Description including the drawings and abstract should be kept below 30(thirty),
3. Follow the time limits very carefully ,
4. Fix the professional fee at initial phase.

Conclusion

Advancement in technology throws up new unforseen possibilities and offer new challenges to legal system which has to be assure as techno legal field needs frequent updation

There is a need to elaborate microorganism's related patent law at international level with constitution of uniform patent code enforceable at global level.

Author submitted that hyper-technical view should not be adopted by office granting patent in interpretation of patent eligibility an inventor cannot be denied of his right because of ambiguousness of law.

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