

Patenting Microorganisms: Towards Creating a Policy Framework

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India is bound to implement new patent laws as per TRIPS by the end of 2004 along with the provision of patenting microorganisms. In this context, the paper stresses the need of defining microorganisms and listing out various life forms for patenting. The usage of the term 'biological materials' by the European Union and USPTO system of classification of microorganisms can be referred to evolve our own system. The analysis of the Patent Facilitating Cell (DST, Govt of India) on the issue of patenting microorganisms at the global level revealed the trends in various countries which will help us to frame the system of patenting microbes. Paper further highlights the need of creating culture collection IDAs (International Depository Authorities) in our country too and develop codes of operation for effective patenting with the co-ordination of IP offices and for facilitating indigenous promotion of patenting microorganisms. Also, with the provisions of CBT and WIPO, we need to safeguard the interests of our country and protect traditional knowledge on the use of microorganisms. Indian machinery of patenting has to be geared up and also tuned to cope up with the new trend of patenting life. The strategies and policies to be adopted at present are further highlighted.

Intellectual property rights (IPR) and their protection is a major issue heralded nowadays in the scientific arena. The greater attention and importance given to it is due to the projected idea that IPR is a dependable way by which greater skill and knowledge can be harvested to serve as a reliable resource for uplifting economy. IPR is a general term covering

patents, copyright and related rights, protection of undisclosed information, industrial designs, trademarks, geographical indications, layout design (topographics) of integrated circuits, and anti-competitive practices in contractual licences. An inventor or any other person/company assigned by him can obtain an exclusive monopoly over his invention

for a stipulated period (usually 20 years) granted by the government. When the privilege time gets expired, the patented invention is available in public domain for use by general public¹.

On 16 April 1994 India signed the General Agreement on Tariff and Trade (GATT) along with 116 other nations. The Agreement also established a World Trade Organization (WTO) which succeeded GATT and is now policing the implementation of the Uruguay Round Agreement. The WTO has been successful in having 132 members which account for over 90 per cent of world trade. To comply with the TRIPS requirement, India, as a signatory, is yet to amend its Patents Act, 1970 fully; it has done so in bits and parts².

Under the WTO, no country has the option to choose the parts it likes and abstain from others. The TRIPS(Trade-Related Aspects of Intellectual Property Rights) Agreement of WTO imposes a number of rules on member countries. First, TRIPS ensures that patent protection is available for all fields of technology including agriculture, energy and healthcare. Second, members can exclude certain inventions from patentability if the exploitation of the invention would be affecting the morality of general public. The TRIPS Agreement also stipulates further that no member country can exclude an invention from patentability simply because domestic laws prohibit it. The Uruguay Round Agreement on TRIPS further focused on patentable subject matter in relation to biological materials³ and thereby:

1. Plants, animals, essential biological process of production of plants and animals may be excluded from patenting. However, provides protection of plant variety by a *sui generis* system or by patent or by any combination thereof.
2. Microorganism *per se* and non-biological and microbiological processes are patentable.

For implementing these laws, a time period was allowed for developing countries where product patent protection is currently not available. Since India fits into this category, it can avail itself a period of ten years (1994-2004) as a transition period before implementing them (latest by 31.12.2004).

Defining Microorganisms

A new era ushered in intellectual property when in 1980, the US Supreme Court allowed the patenting of a living microorganism intended to degrade the oil spills. This evoked the contentious issue of life patenting. Even though patent laws were originally framed keeping mechanical and chemical inventions in mind, patenting of life forms was included under the same umbrella. From microorganisms, patent offices have marched on to grant exclusive monopolies for plants, animals, entire species, human cell lines, and even fragments of DNA.

Generally, microbes or microorganisms are tiny living things which are invisible to the naked eye. For the purposes of patent protection, the term microorganism often applies to other types of biological

material including cell lines of plants or animals, and not excluding human genetic material. There is considerable confusion and uncertainty regarding the scope of the term microorganism in many countries. It is high time now for India to decide and define when to consider a microorganism for patenting. The term microorganism is generally understood to include⁴:

- Viruses
- Bacteria, actinomycetes
- Yeasts, filamentous fungi, mushrooms
- Protozoa and unicellular algae
- Undeveloped animal or plant cells (cell lines and tissue cultures)
- Fused cells, transformants and vectors utilized in genetic engineering (such as plasmids, phages)
- Variants
- Plant cells
- DNA (of eukaryotic and prokaryotic origin)

In fact, the European Union has decided to do away with the use of the term microorganism. Instead, it has decided to use the term “biological material” which means any material containing genetic information and capable of replicating itself or being reproduced in a biological system⁴.

Conveniently biological material means any material containing genetic information that is capable of reproducing itself or can be reproduced in a biological system. This is also the case for

biological material like gene sequences⁴. We have to decide whether to allow DNA sequences without any functional indication to be patented. This is especially important for expressed sequence tags (ESTs) which were accepted *per se* by the US Patent and Trademark Office (USPTO) if an industrial application is shown.

Status of Microbial Patenting

There is a widespread controversy regarding the consideration of microorganism as an “invention” or “discovery”⁵. After the National Institutes of Health (US) was refused to have patent rights over segments of DNA isolated from the human genome, the European Patent Office highlighted the difference between discovery (not patentable) and invention for a microbiological substance. Accordingly, “.....to find a substance freely occurring in nature has first to be isolated from its surroundings and a process for obtaining it is developed, later that process is patentable. Moreover, if the substance can be properly characterised, either by its chemical structure or by the process by which it is obtained or by other parameters and if it is ‘new’ in the absolute sense of having no previous recognized existence, then the substance *per se* may be patentable.....”⁶. In the United Kingdom and the European Patent Office, only previously undiscovered microorganisms can be patented. In Germany, isolating a strain of a microorganism allows for patentability, since these organisms are no longer “in nature”. In the United States, a “biologically pure culture” may

be patentable (assuming it meets the standard criteria for patentability).

The Ministry of Environment and Forests, Government of India, had entrusted the Patent Facilitating Cell (PFC), Technology Information, Forecasting and Assessment Council (TIFAC), Department of Science and Technology, Govt of India, with the task of generating a position paper on patenting of microorganisms, in order to understand the practices followed in other countries and evolve policy alternatives⁴. An important aspect of the study was to get feedback from different countries for the following questions :

1. Can microorganisms be patented *per se*?
2. Can new uses of an existing microorganism be patented?
3. Can microorganisms, found in nature but discovered or isolated for the first time, be patented?
4. Can a culture of microorganism, which is purer than that found in nature be patented?
5. Can products (new or old) made for the first time by using microorganism be patentable?

Feedback from 16 countries, namely, Austria, Brazil, Bulgaria, Canada, Denmark, Finland, Germany, Hungary, Israel, Netherlands, Philippines, Spain, Sweden, Switzerland, Thailand and UK revealed that microorganisms *per se* are patentable, provided they have novelty, inventiveness and industrial application. All the countries allow patent protection

to new uses of an existing microorganism. There is a divide among developed countries and developing countries regarding the other questions. Developed countries in the sample allow patent protection for microorganisms, found in nature, but discovered or isolated for the first time provided they have an industrial application. Most of the countries in the list allow patenting of genetically modified organisms(GMO's). Patenting of GMOs *per se* will also entail some additional questions. Would the gene responsible for designing the GMO be patentable? If an already known and isolated gene is used, who then will be the owner of the GMO? Should a GMO satisfy biosafety conditions before it is granted a patent. Even if a GMO is allowed to be patented, there will be a tendency to establish biosafety with short term trials which may not be really adequate. In Hungary, microorganisms or any other life form except humans are patentable provided there is technical intervention by man. Except some countries like Brazil, majority allow patenting of microorganism purer than that found in nature. Out of the 16 countries, five countries, viz. Denmark, Brazil, Hungary, Bulgaria and Philippines allow patent protection for products (new or old) made for the first time using a novel microorganism while six others, viz. Canada, Israel, Netherlands, UK, Austria and Germany provide product patent to products that are new and only process patents in respect of old products. Finland, Spain and Sweden provide patents only for the new products and not for the old products⁴.

Further, PFC has also indicated the following major aspects and raised certain questions towards evolving a system of patenting for microorganisms⁷.

1. It is opined to use the period up to 31.12.2004 to understand, evolve and stabilize the system of patenting microorganisms.
2. It is cautioned that patenting microorganisms is a complex issue and changes with time and developments in biotechnology.
3. Whether the term 'microorganism' should be defined in a generic manner or not?
4. What is our policy towards patenting of microorganisms already existing in nature and those that are genetically modified?
5. How to develop an IDA depositary in India with the requirement of biosafety and frame rules to access those strains?
6. The need to evolve a system of accessing cultures deposited in foreign IDAs.

Based on the above studies, India can now decide on which aspect, a microbial patent can be allowed. India will have to take firm decision now to reduce the gap between the industrialized and developing countries. We should start negotiations on the ethical and legal issues covering microbial patenting to frame suitable laws that safeguard our interests and form a stronger IPR comparable with those of developed countries.

USPTO Classification System on Microbes

The following subject matter were considered under class 435 of the US Patent and Trademark Office's (USPTO) classification system on microbes⁸:

- a process using a microorganism or enzyme to synthesize a chemical product.
- a process of treating a material with a microorganism or enzyme to separate, liberate or purify a pre-existing substance.
- an *in vitro* process of measuring and testing in which:
 - i) a microorganism or enzyme is used to determine the presence of identity of a compound or composition in a sample.
 - ii) a microorganism is identified by propagation.
 - iii) an enzyme is identified by its catalytic activity.
 - iv) the presence of microorganism is detected.
 - v) a live microorganism is used in an antigen-antibody test as an antigen.
 - vi) fixed or stabilized non-living microorganisms, cells or tissues are involved.
- a process of propagating a microorganism
- a process in which the genetic structure of a microorganism or extrachromosomal genetic structure is altered.
- a process of mashing or malting

- apparatus claimed or solely disclosed for the above six categories.
- microorganism, *per se*, or the sub-cellular parts thereof.
- enzymes, immobilized or containing compositions not otherwise provided for and the processes for purifying enzymes or forming immobilized enzymes.
- compositions claimed or solely disclosed as for the propagation of microorganisms.
- using microorganisms to destroy hazardous or toxic wastes.

Budapest Treaty and Microbial Type Culture Collections (MTCCs)

The Treaty came into effect on 28 April 1977 and was further amended on 26 September 1980. Currently there are fifty-four states and three intergovernmental industrial property organizations party to the Budapest Treaty (Table 1)⁹. Disclosure of information is a basic requirement-cum-problem in patenting. If

the invention involves the use of a new microorganism (i.e., not available to public) the disclosure (written description) cannot be used for repeating the invention dot to the original. For example, if a microorganism is isolated from a sample, "improved" by mutation and selected further, it would be virtually impossible to describe the strain and its selection so that another person can obtain the same strain from the same sample using the disclosure. So, to overcome this problem in obtaining a patent over a new microorganism, the disclosure should be supplemented by the deposit of the microorganism in a recognized culture collection. The culture collection would then make the microorganism available to the public at the appropriate point in the patenting procedure.

In early 1970s when depositions of microorganisms were made in culture collections for patent purpose there was no uniform system of deposit or, perhaps more importantly, recognition of the

Table 1—List of industrial property offices of states and intergovernmental industrial property organizations party to the Budapest Treaty

Patent offices of States

Austria, Australia, Belarus, Belgium, Bulgaria, Switzerland, China, Canada, Cuba, Czech Republic, Germany, Democratic People's Republic of Korea, Denmark, Estonia, Spain, Finland, France, United Kingdom, Greece, Croatia, Hungary, Ireland, Israel, Iceland, India, Italy, Japan, Kazakhstan, Republic of Korea, Liechtenstein, Lithuania, Latvia, Mexico, Monaco, Republic of Moldova, Netherlands, Norway, Philippines, Poland, Portugal, Romania, Russian Federation, Sweden, Singapore, Slovenia, Slovakia, Tajikistan, Turkey, Trinidad and Tobago, Ukraine, United States of America, Uzbekistan, Yugoslavia, South Africa. Intergovernmental industrial property organizations

African Regional Industrial Property Organization (ARIPO), Eurasian Patent Organization (EAPO), European Patent Organization (EPO)

deposit. Lack of firm guidelines combined with the variety of national patent laws led the culture collections into greater confusions.

So, under the Budapest Treaty, 1980, certain culture collections are recognized

as "International Depository Authorities" (IDAs). From then onwards, it became a prerequisite that for obtaining a patent involving a microorganism, a deposit be made in any one of the IDA (Table 2)¹⁰.

Any culture collection can become an

Table 2—Culture collections currently holding IDA status

S.No.	Country	Depository Institution
1	Australia	Australian Government Analytical Laboratories (AGAL)
2	Belgium	Belgian Coordinated Collections of Microorganisms (BCCM TM)
3	Bulgaria	National Bank for Industrial Microorganisms and Cell Cultures (NBIMCC)
4	Canada	National Microbiology Laboratory, Health Canada (NMLHC)
5	China	China Center for Type Culture Collection (CCTCC) China General Microbiological Culture Collection Centre (CGMCC)
6	Czech Republic	Czech Collection of Microorganisms (CCM)
7	Germany	Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH (DSMZ)
8	Spain	Coleccion Espanola de Cultivos Tipo (CECT)
9	France	Collection nationale de cultures de micro-organismes (CNCM)
10	United Kingdom	Culture Collection of Algae and Protozoa (CCAP) European Collection of Cell Cultures (ECACC) CABI Bioscience, UK Centre (IMI) National Collection of Type Cultures (NCTC) National Collection of Yeast Cultures (NCYC) National Collections of Industrial, Food and Marine Bacteria (NCIMB)
11	Hungary	National Collection of Agricultural and Industrial Microorganisms (NCAIM)
12	Italy	Advanced Biotechnology Centre (ABC) Collection of Industrial Yeasts (DBVPG)
13	Japan	International Patent Organism Depository (IPOD)
14	Republic of Korea	Korean Cell Line Research Foundation (KCLRF) Korean Collection for Type Cultures (KCTC) Korean Culture Center of Microorganisms (KCCM)
15	Latvia	Microbial Strain Collection of Latvia (MSCL)
16	Netherlands	Centraalbureau voor Schimmelcultures (CBS)
17	Russian Federation	National Research Centre of Antibiotics (NRCA) Russian Collection of Microorganisms (VKM) Russian National Collection of Industrial Microorganisms (VKPM), GNII Genetika.
18	Slovakia	Culture Collection of Yeasts (CCY)
19	United States of America	Agricultural Research Service Culture Collection (NRRL) American Type Culture Collection (ATCC)
20	Poland	IAFB Collection of Industrial Microorganisms Polish Collection of Microorganisms (PCM)

IDA provided it has been formally nominated by the contracting state on whose territory it is located and that the contracting state has furnished solemn assurances that the collections complies and will continue to comply with requirements and the regulations of the Treaty. The Budapest treaty deals with the following aspects¹⁰:

- (i) International Depositary Authorities and Recognition of Single Deposit: about recognizing IDAs and the deposits made in any IDAs.
- (ii) Deposit and Furnishing of Samples: on procedures of deposition, storage and furnishing of samples of microorganisms in co-ordination with the industrial property office.
- (iii) Safeguard of Deposits: about the manner of keeping viable, uncontaminated cultures and the needed expertise and facilities.
- (iii) Meaning of the Term "Microorganism": the term "microorganism" is not defined in the Treaty so that it may be interpreted in a broad sense.

It is a requirement under the Budapest Treaty to build an internationally recognized depositary of microorganisms strictly following the regulatory frames in the Treaty. India has already joined the Budapest Treaty and sufficient funds have been sanctioned to refurbish a culture collection depositary, it is an expensive process. The Microbial Type Culture Collection & Gene Bank

(MTCC) jointly established by the Department of Biotechnology (DBT), Govt of India, and Council of Scientific and Industrial Research (CSIR), is located in the Institute of Microbial Technology, Chandigarh, for upgradation to India's first IDA. This could be used by Indian scientists and foreign scientists, especially from neighbouring countries to deposit their patentable cultures at less expensive rates. It could also be used as a documentation centre for microbial works carried out. According to the experts' estimations, if species continue to disappear at the current rate, then 50% of species on the earth are expected to disappear over the next hundred years with 20 to 75 biological species disappearing every day by 2040¹¹. So a depositary could also be used as an conservation center¹².

Role of CBD and WIPO

Microbial patent laws have to be framed in accordance with the TRIPS Agreement, Budapest Treaty and the Convention on Biological Diversity (CBD). The CBD was negotiated in 1992 and came into force in December 1993. The main objective of the CBD is the conservation of biological diversity, its enduring use, and fair and equitable sharing of the benefits arising out of the utilization of genetic resources from the country of origin. It gives every nation-state the sovereign right over its own biological resources. This means that each state has the right to control access to genetic resources within its territory and to determine the conditions under which this will be allowed^{3, 13}. However,

it has to be clearly stated that the goal of the convention is not to prevent the use of the biological diversity.

The World Intellectual Property Organization (WIPO), a UN agency based at Switzerland, is responsible for promoting the protection of intellectual property throughout the world. As on 14 March 2001, 177 states including India are members of WIPO. WIPO commissioned a joint study with the United Nations Environment Programme (UNEP) to explore the activities needed on intellectual property and genetic resources.

An Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore was formed by WIPO under direction from the Standing Committee on the Law of Patents (SCP) and declared open to all Member States of WIPO¹⁴. WIPO would facilitate the participation of representatives of developing countries and of certain countries in Europe and Asia. The themes consist of intellectual property issues that arise in the context of: (i) access to genetic resources and benefit sharing (like Material Transfer Agreements (MTAs), etc.) (ii) Protection of traditional knowledge, innovations and creativity, whether or not associated with those resources; and (iii) the protection of expressions of folklore, including handicrafts (like *sui generis* system of legal protection, etc.)¹⁴.

In the context of CBD and WIPO, we should develop means of deriving benefits from patented microorganisms that are isolated from India and being used elsewhere. It is also essential to

check biopiracy of microorganisms either with the provisions of CBD or by other means.

Indian and Third World IP Regime in Relation to Microorganisms

There is definitely a gap between the Third World and other developed nations. Under the current socio-economic, technological and political conditions, it is difficult yet essential to frame our national system of IPR in harmony with those of the developed nations. India still has to develop its skills and competence to manage IPR focusing on biological materials. The difficulty in framing our national system can be attributed to various reasons like government practices, both legal and administrative; skeptical attitude about a stronger IPR regime on biological materials, which influence the implementation of national policies and procedures designed to encourage the flow of technology to, and its acquisition by, developing countries.

Most governments and legislatures in the Third World neither have the expertise and intergovernmental coordination necessary to deal coherently and successfully with complex issues involved in microbial patenting. Nor do they have the political or economic clout to face up to the enormous pressures put on by the transnational corporations, which increasingly control the world's trade. Inadequate preparedness of national IP offices in many developing countries is also a serious concern¹⁵. India is not bound to introduce laws for patenting microorganisms *per se* before 31.12.2004. Before that the complexities

involved in this has to be understood by our professionals and patent examiners keeping in mind our research and corporate base. Patenting of microorganisms and related issues including biosafety has to be discussed radically by a forum comprising scientists, patent attorneys, patent examiners, policy-makers and general public. Our agenda should balance the interests of the inventor and that of the society in an optimum way.

Strategies And Policies

Finally, we propose the following aspects for due consideration for meeting the aim:

1. It is better to use the time available up to the end of the year 2004 and maximally avail another two years from now for framing laws on patenting microorganisms. It is essential to prepare draft proposals and discuss their biological and legal implications and consequences with a forum consisting of expert representatives from all segments.
2. We need to define 'microorganisms'. The broad categorization as 'biological materials' as used in European union is preferable. However microorganisms under the umbrella of 'biological materials' should be treated individually. This is because microorganisms are distinct from other life-forms and the intricacies in treating them along with other life-forms or their molecules (like DNA) cannot be predicted now.
3. It is better to group viruses, prions (for probable applications in future), archaebacteria, eubacteria, actinomycetes, photosynthetic microbes, yeasts, filamentous fungi and mushrooms, protozoans, Micronematodes (for probable applications in future) into microorganism with a clear definition of each category.
4. It is essential to develop a system of classification of microbial processes and products. This will enable to identify the items suitable for patenting with a view to safeguard the interest of the nation. This will also be helpful for the patent examiners to identify whether the patent filed is eligible for patenting or not.
5. Patenting of a single microorganism is mostly encountered so far. But, we should think about the situations where patenting of microbial consortia, microcosms, etc. will be sought in due course of time.
6. It is important to notify an IDA in our country at the earliest, as our country has already become a member of the Budapest Treaty.
7. We should develop means of deriving benefits from patented microorganisms isolated from India and being used elsewhere using the provisions of CBD.
8. We should think of documenting and protecting our traditional knowledge on the use of microbes.

For example, the microbial system of making foods like Idly, use of certain puff-balls of fungi for wound healing purposes, the preparation of arisum (a microbial fermentation product) of certain herbal extracts in Siddha, etc. It is suitable that this knowledge must be linked into the Traditional Knowledge Digital Library (TKDL) which was primarily proposed and evolved for higher plants by Mashelkar⁵. TKDL has now started functioning at the National Institute of Science Communication (NISCOM), New Delhi.

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