Patenting of microorganisms in India: a point to ponder

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The arguments surrounding the merits and demerits of patents shift between the right of the inventor to enjoy the fruits of his labour and his duty towards the society. In the context of microorganisms, the most vital distinction between the legal practices of India and developed countries is that India does not allow patenting of microorganisms that already exist in nature but genetically modified versions of the same microorganisms that result in enhancement of its efficacies are patentable. This article is an effort to throw light on the genesis of patenting and the legalities of patenting microorganisms in India.

Creations of the human brain are called intellect and if they have commercial value they can be classified as property. Intellectual Property thus refers to inventions, industrial designs for article, literary and artistic work, symbols, etc. used in commerce (www.wipo.int). Patenting is the outcome of the works of political economists and philosophers like Locke and Hegel who first argued that intellectual works abstracted from matter can be held as property. Locke based his defence of property in man's labour and his 'ownership' because it involves labour to be created and should be rewarded. Hegel debated that if personality is fundamental to property, then something as personal as artistic expression should certainly be protected as private property. Today, we believe that any new outcome of a man's cerebral labour need to be protected as private property; which can be done by patenting or 'enclosing'[1]. But the word patent has been derived from the Latin word 'patent-em' meaning open. The self-contradiction demands an explanation. The widest possible dissemination of new knowledge makes the greatest economic efficiency. But if everybody is free to access new knowledge, the inventors have little incentive to commit resources to produce it. Intellectual Property Rights (IPRs) temporarily transform knowledge from a public good into a private good so that owners of intellectual property can recoup their expenditure in creating new knowledge. Creative minds and innovative firms have an incentive to engage in inventive activities. This utilitarian argument provides the main rationale for the protection given by patents. A patent can be understood as an IPR relating to inventions and is the grant of exclusive right, for limited period, provided by the Government to the patentee, in exchange of full disclosure of his invention, for excluding others, from making, using, selling, importing the patented product or process producing that product for those purposes. Intellectual property is divided into two main categories: industrial property rights, which includes patents, utility models, trademarks, industrial designs, trade secrets, new varieties of plants and geographical indications; and copyright and related rights, which relate to literary and artistic works. The various forms of intellectual property differ in terms of the subject matter that may be eligible for protection, the scope and duration of protection, and possible exemptions to exclusive rights – reflecting society's objective to balance the interests of producers and users of the intellectual work.

India and TRIPS

On 16 April 1994, India signed the General Agreement on Trade and Tariff (GATT) along with 116 other nations. The agreement also established the World Trade Organisation (WTO) which succeeded GATT and is now policing the implementation of the Uruguay Round Agreement. Under WTO, no country has the option to choose the what part that it likes and abstain from others. The Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement of WTO imposes a number of rules on member countries. The TRIPS agreement ensures that patent protection is available for all the fields of technology including agriculture, energy and healthcare. Also, members can exclude certain inventions from patentability if the exploitation of the invention would be affecting the morality of general public. TRIPS further focussed on patentable subject matter in relation to biological materials. For example (1) Plants, animals, essential biological process of production of plants and animals may be excluded from patenting. (2) Microorganisms per se and non-biological and microbiological processes are patentable[4]. The Patent System in India is governed by the Patents Act, 1970 (No. 39 of 1970) as amended by the Patents (Amendment) Act, 2005 and the Patents Rules, 2003, as amended by the Patents (Amendment) Rules 2006 effective from 5 May 2006.

Matter of microorganisms

Between discovery and invention

The question to be addressed is whether certain substances isolated or derived from naturally occurring living organisms are 'inventions' or 'discoveries'? Logic and sound sense states that one cannot patent a product that occurs in nature in essentially the same form. The product of nature doctrine appears as early as 1889, when, in *Ex Parte Latimer*, the Commissioner of Patents rejected a claim on a new article of manufacture consisting of the cellular tissues of the *Pinus australis* (southern pine) eliminated in full lengths from the siliceous, resinous, and pulpy parts of the pine needles and sub-divided into long, pliant filaments adapted to be spun and woven. In the initial rejection of the claim, the examiner emphasized the identity of the claimed substance and its natural counterpart: The claim and description do not set forth any physical characteristics by which the fibre can be distinguished from other vegetable fibres. Because the fibre claimed is not, and cannot be, distinguished from other fibres by any physical characteristic, the claim was refused. According to the Draft Patent Manual of India (2008)[5] there is a difference between discovery and invention.

A discovery adds to the amount of human knowledge by disclosing something already existent, which has not been seen before, whereas an invention adds to the human knowledge by creating a new product or processes involving a technical advance as compared to the existing knowledge. A scientific theory is a statement about the natural world. These scientific theories are not considered patentable, no matter how radical or revolutionary an insight they may provide, because they do not result in a product or process. However, if the theories lead to a practical application in the process of manufacture of article or substance, they may be patentable[6]. A claim for formulation of abstract theory is not patentable. For example, the fact that a known material or article is found to have a hitherto unknown property is a discovery and not an invention. But 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[6]. For an invention to be patentable, the Indian patent law requires the invention to be new, to have an inventive step (non-obvious), industrially applicable (utility) as well as repeatable. Substances such as microorganisms if to be treated as new should be judged by the given criteria. The requirements of inventive step constitute one of the most complex questions in the field of biotechnology. It is a mandatory requirement of the patent law to provide detailed information of the invention to be protected. This is commonly referred to as 'sufficiency of disclosure'. In the field of biotechnology the requirement of the condition of sufficient disclosure poses specific problems because the inventions in this field involve living entities (biological material). Such materials are difficult to describe in words. It is significant to note that, to meet the test of 'sufficiency of disclosure', a practice that the inventor has to deposit the sample of the living entity involved in the invention with an authorized depository authority has been developed for biological inventions[7].

Deposition of microorganisms: A patentee has to disclose the invention completely in the patent document so that a person skilled in the art can repeat the invention and satisfy all the claims with the help of information provided in the patent document. In case of microbial inventions, the repeatability is an issue. The British Government in 1973 proposed that the World Intellectual Property Organization (WIPO), Geneva, Switzerland should take the initiative to study the feasibility of a single deposit fulfilling the need of depositing culture in other countries where patent applications are filed. A formal body was put up by the recommendations of an expert committee in a conference held in Budapest, Hungary during April 1977 and a treaty was adopted called the 'Budapest Treaty on the international recognition of the deposit of microorganisms for the purpose of patent procedure'. The treaty came into effect in 1980. In India the Microbial Type Culture Collection and Gene Bank (MTCC) was recognized by WIPO, as an International Depository Authority (IDA) on 4 October 2002, thus becoming the first IDA in India, seventh in Asia and thirty-fourth in the world. The deposit of microorganisms under the Budapest Treaty is recognized to fulfil the requirement of patent procedure in 55 member countries. MTCC, a national facility established in 1986, is funded jointly by the Department of Biotechnology and the Council of Scientific and Industrial Research, Government of India.

Interpreting the law

The Indian Patents Act, 1970 has been amended with effect from January 2005 to comply with the TRIPS agreement. The main provision of the Act is to allow the grant of product patents in the field of chemical, pharmaceutical, food and biotechnology. Patentable biotechnological inventions can be broadly categorized as: 'Products in the form of chemicals, microorganisms, plant extracts, fermented material; processes/methods for using useful products and compositions/ formulations of product such as vaccines, proteins, hormones'. Thus, TRIPS and the Indian Patent Law clearly state that microorganisms are patentable. India has allowed patenting of microorganisms but the Patent Act does not provide a definition of the term 'microorganisms'. This has led to many debates regarding patentability of microbes. Further, the act does not allow patenting of plants and animals per se, essentially biological processes for the production of plants and animals, and the method of treatment of humans and animals. Inventions pertaining to microorganisms and other biological materials were subjected to product patent in India, unlike many developed countries. But with effect from 20 May 2003 India has started granting patents in respect of invention related to microorganisms, though India was not obliged to introduce laws for patenting microorganisms per se before 31 December 2004.

Microorganisms patenting was earlier considered to be a product patent, the period of protection was five years from the date of grant or, seven years from the date of filing of application for patent. Now grant of patents for microbiological inventions is for a period of 20 years from the date of filing. The most vital distinction between the legal practices of India and developed countries is that India (or developing countries) does not allow patenting of microorganisms that already exist in nature as the same is considered to be a discovery according to the provisions of the section 3(d). But genetically modified versions of the same microorganisms that result in enhancement of its known efficacies are patentable. The grant of patent in respect to microorganisms depends upon the regulations concerning the requirements for the deposition of microorganisms under the Budapest Treaty of which India has become a member, and accessibility of that microorganism from the depositories. According to the provision (ii) to section 10(d) the microorganism if not being described fully and particularly and is not available to public, the said microorganism is to be deposited before the International Depositary Authority under the Budapest Treaty 2002. Amendment of the Indian Patent Act added explanation to chemical process, which states – chemical processes include biochemical, biotechnological and microbiological process. Areas involving microorganisms are also patentable in India. For example, a synergistic composition containing the microorganism, which is either new or known, and a process using microorganisms to produce a substance can both be patented. Also, the process of biosynthesis of a new microorganism is patentable. Microorganisms that are lyophilized as an end product are patentable. In order not to defy TRIPS by a blanket direct exclusion of microorganisms from patenting, Pillai *et al.*[8] suggested that Indian approach should be

more 'definitional' and 'interpretative'. India can adopt a narrow and limited definition of 'microorganisms' to exclude everything other than 'microscopic' organisms including only algae, bacteria, fungi, protozoa and viruses. Alternatively, they could adopt an expansive definition of microorganism to include within its scope all 'biological materials' containing genetic information and capable of reproducing or being reproduced in a biological system, similar to the European Patent Examination Guidelines. The Chinese Patent Examination Guidelines can also be adopted whereby patentability of microorganisms be restricted to only algae, bacteria, fungi, protozoa and viruses or should be extended to DNA fragments, genes, peptides and proteins. In the absence of clear definition of microorganism and microbiological process in the TRIPS agreement, the country needs to draw a distinctive line between the product of human intervention leading to novelty and those freely occurring in nature.

Dimminaco case: a case in the point: Although the Indian Patent Act, 1970 does not permit patenting of microorganisms, per se, this particular case at Calcutta High Court is a case to understand the intricacies of patenting. Dimminaco Case 2 clarified the position relating to patentability of biotechnology inventions, particularly in a case where a process of manufacture of vaccine involving a living end product was involved. Swiss company Dimminaco A.G. filed an application for an invention relating to a process for the preparation of Bursitis vaccine, which was capable of protecting poultry against infectious Bursitis infection, and with isolation and preparation of novel virus useful for preparing such vaccines. The Controller of Patents had rejected the claims on the following ground that – the Examiner found that the 'claim' did not fall within Section 2(1)(j) of the Patent Act, 1970, and therefore could not be called an invention. Calcutta High court has addressed the issue of whether a process involving microorganisms that are living as an end product can be patented. Prior to the case, the applicant had requested a patent for the process of creating a vaccine to protect poultry from infectious bursitis. The Controller of Patents determined the process was not an invention because the end product produced by the process contained a living organism, and thus was not patentable. The applicant appealed the Controller's decision in the Calcutta High Court. The Controller claimed a patent is given only for a process that results either in an article, substance or manufacture, and a vaccine with a living organism is not an article, substance or manufacture. The court used the normal dictionary meaning of manufacture, because it was not defined in the Patents Act, and determined manufacture is where 'the material in question after going through the process of manufacture has undergone any change by the inventive process and it becomes a material which is different from the starting material'. The court determined this meaning does not exclude the process of preparing a product that contains a living substance from patentability. The court found that no statute precluded a living end product from the definition of manufacture. Also, the court decided that 'since the claim process for patent leads to a vendible product, it is certainly a substance after going through the process of manufacture'. The court ultimately concluded that 'a new and useful art or process is an invention', and because the process is new and useful, it 'is apparently patentable under section 5 read with section 2(j)(i)' of the Patents Act. The court determined that 'where the end product is a new article, the process leading to its manufacture is an invention.' Although the definition of invention has been amended, this change may enhance the court's invention argument, because now the elements of manufacture, article, or substance are no longer required. Rather, the new definition merely calls for a new, non-obvious and useful product or process.

As noted previously, the court determined the vaccine was new and useful, and made no discussion about the end product containing living material in reaching this conclusion. However, other changes to the act may change the case's outcome. For example, section 3(j) was added to the Patents Act after this case and now essentially excludes biological processes for production or propagation of plants and animals from the definition of invention. In that case, the court cautioned that claims for patentability should 'be considered by the controller on the principle of section 3' of the Patents Act. The main issue in contention between the parties was whether the phrase 'method of manufacture' used in section 2(1) (j) could be said to include a live organism. The court, in its positive affirmation, has held that the dictionary meaning of 'manufacture' did not exclude from its purview the process of preparing a vendible commodity that contains a living organism. Thus, the court in this case has identified the 'vendibility' test as the most effective test to determine whether the process of manufacture ought to be patented or not[7].

The future concerns

The TRIPS agreement was criticized on two issues. It threatens the right of poor countries to manufacture or to import cheap generic versions of patented drugs. This is particularly immoral at a time when AIDS epidemic and other diseases are so rampant. Poor people cannot afford the exorbitant prices the pharmaceutical giants are charging for patented drugs. Secondly, TRIPS forces all members to accept indirectly a medley of new biotech patents covering genes, cell lines, organisms and living persuaded into accepting these 'patents on life'[9]. Biotechnology is booming in India especially in the pharmaceutical and food sector. Patent is still the most viable system of the protection of biotechnological inventions. Human rights approach to intellectual property takes what is often an implicit balance between the rights of inventors and creators, and the interests of the wider society within intellectual property paradigms and makes it far more explicit and exacting to be consistent with the established human rights standards, envisaged in various international convents. Thus, there is an imperative for adopting a human rights approach to the intellectual property regime so as to facilitate and promote scientific progress and its application, and do so in a manner that will broadly benefit members of the society on an individual, corporate and international level. It also implies a right of access to the benefits of sciences, again on both an individual and collective level[7]. One of the potential solutions lies in compulsory licensing of some patents which have applications in potential life saving medical care and where emotions run deep and political pressures are great. Innovative compa-

nies will be able to receive a return on their investment in research and development, and be encouraged to do so whereas consumers will have access to the technology at reasonable prices and lives will be saved and good health achieved[10].

The application of microorganisms in food is a million dollar industry today. Since genetically modified microorganisms (a criteria that lends the human intervention angle to satisfy one of the criteria to make the organism patentable) is not permitted to be used in the food industry, the only source for improving the textural and sensory properties of food is by isolation of new strains of bacteria that deliver these properties. One need not mention the time, effort and money involved in this excercise. In the Dairy industry, lactic cultures are used for the preparation of fermented products and cheese whose consumption rates are increasing at a rate of 10% annually. Suppressing the growth of these fermented products is the growth of functional foods containing probiotic cultures. These are bacteria that when consumed in sufficient quantity confer some beneficial attributes to the host. The probiotic strains used in these products have been isolated after decades of research work followed by clinical trials to prove their probiotic attributes. Most of these strains are patented in the European Union and the United States (where isolation of a new strain of bacteria is patentable). As a result, these companies are marketing these products containing these microorganisms. However, the same protection for these bacteria is not available in India. This is not encouraging enough for the academia and industry in India to isolate potential probiotic strains due to the absence of patent protection. Some of the probiotic products launched in India are by companies which use strains that are catalogued by leading international culture suppliers or by foreign companies that have these strains. One may also run the risk of being accused by other nations of being insensitive to the issues of promoting multilateral trade and hence of being subjected to sanctions which may prove to be more economically ruinous in the long run[11].

Summary

Patenting life forms bring with them overbearing issues of religious and ethical values. In today's competitive and globalized world, biotechnology revolution is affecting industry and growth in a big way. It would, thus, be in our national interest to document, protect and modify new microorganisms isolated from various parts of our country and find their new and improved industrial uses. However, in the clash between socialist and capitalist centric ideologies, the betterment of the society as the prime objective should be borne in mind before our regulatory bodies arrive at a conclusion.

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