Provisions of the Patents Act, 1970

Unlike the patent laws of most developed and even some developing countries, the current patent law in India, viz. the Patents Act, 1970, does not explicitly exclude or include any biological matter. For instance, the European Patent Convention explicitly excludes the patenting of plant and animal varieties and essentially biological processes for their production, while it explicitly includes the patenting of microorganisms and microbiological processes. No such provision is found in the Indian law. However, there are a number of provisions, which taken together, guide the Indian patent office in accepting or rejecting applications for patents on biotechnological inventions.

What is an Invention?

Under Section 2(j) of the Patents Act, 1970 “invention” has been defined as any new and useful art, process, method or manner of manufacture; machine, apparatus or other article; substance produced by manufacture and includes any new and useful improvement of any of them. The terms “process” or “manufacture” or “substance” have not been defined and therefore could be presumed to include biotechnological processes. However, the practice built up so far is that the manner of manufacture must result in a non-living substance. Thus, a process of preparing a microorganism is excluded from patenting in India, which is an extremely narrow and restricted view. India, like all other countries, grants patents for new, useful and non-obvious inventions.

Section 3 goes on to set out what are not inventions under the law.

Introduction

The application of modern biotechnology to industry and agriculture is a recent development, less than thirty years old. The biotechnology revolution has just begun to touch lives in the developing world. Amongst developing countries, India is one that has immense potential to utilize biotechnology to its advantage to solve some of its most intractable problems of productivity, health and environment. Yet India’s contribution so far to this area, in terms of basic research or commercial applications, has been marginal. NGO activists in India have generally sided with some activists in the industrialized world in opposing advancements in biotechnology, more particularly in agricultural biotechnology. This opposition extends in particular to changing the intellectual property rights (IPRs) regime on biotechnological inventions – the slogan is No Patents on Life. The current patent law in India dates back to the pre-biotechnology era and does not explicitly recognize or exclude the patenting of biotechnological inventions. However, the Trade-Related aspects of Intellectual Property Rights (TRIPS) Agreement, to which India is a party as a member of the World Trade Organization (WTO), requires some level of protection of biotechnological inventions, including of plant varieties. India has to implement most of its TRIPS obligations by end of 1999 and is currently in the process of drafting revised legislation.
The current patent law in India dates back to the pre-biotechnology era and does not explicitly recognize or exclude the patenting of biotechnological inventions.

Exclusions relevant to biotechnology are inventions which are:

• frivolous or which claim anything obviously contrary to well established natural laws;
• inventions whose primary or intended use would be contrary to law or morality or injurious to public health;
• the mere discovery of a scientific principle or the formulation of an abstract theory;
• the mere discovery of any new property or new use for a known substance or of a known process results in a new product or employs at least one new reactant;
• a method of agriculture or horticulture and finally,
• any process for the medical, surgical, curative, prophylactic or other treatment of human beings or any process for a similar treatment of animals or plants to render them free of disease or to increase their economic value or that of their products.

While the first three exclusions are found in almost all patent laws, the discovery of a new property or new use for a known substance is now patentable in almost all developed and some developing countries. Indeed, the first patent given by the US on a living organism was based on the claim that a new property of the bacteria, that of eating oil spills, was discovered through novel and non-obvious process. Similarly, a method of agriculture or horticulture if new, useful and non-obvious would not be excluded from patent grant in most patent laws of the world. Finally, although methods of medical treatment are widely excluded, including in the US, the Indian law extends this to methods that render plants and animals free from disease or increase their economic value or that of their products. These last two are certainly very broad exceptions that would exclude all agricultural biotechnological processes.

What is Excluded from Patent Grant?

In addition to excluding certain inventions on the above-stated grounds, Section 5 of the Patents Act, 1970 excludes the grant of product patents for:

• substances intended for use or capable of being used as food, medicine or drug;
• substances prepared or produced by chemical processes.

Claims for processes or methods of manufacture for such substances are, however, patentable. This, too, has implications for biotechnological inventions as these relate mostly to food and pharmaceutical sectors. More importantly, as noted earlier, processes resulting in living organisms are excluded.

Biotechnological Processes are Included

Despite all these exclusions from patentability, biotechnological processes that do not result in living organisms and are not agricultural or horticultural methods or are not aimed at improving the economic value of plants and animals, are patentable. In this narrow band of inclusions would fall processes that use living organisms to improve either industrial or environmental products.

Indeed, from 1972 to 1990, a total of 1049 process patents were filed on biotechnological inventions, of which about 28.5% were filed by Indians. These include processes for the manufacture of vaccines and other medicines, food additives and biogas as well as for the treatment of effluents and wastewater. However, only six of these patents were cited, an indication of the low quality of these patents.1

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Under Section 48, however, the rights of the process patentees extend only to the use of the process. The patentee has no ground to challenge a product that was made using the patented process outside the country and then imported into the country, or, in the case of an identical product produced in the country, to make the defendant prove that he was not using the patented process.

TRIPS Requirements

India, however, has to amend its patent law to meet its obligations under the WTO TRIPS Agreement by the end of 1999. TRIPS calls for the availability of patents, whether for processes or products, in all fields of technology. However, at the time of the negotiations on TRIPS in the Uruguay Round of multilateral trade negotiations, the US and the EU differed on their approaches to patenting of biotechnological inventions. While the US believed that ‘anything under the sun made by man’, except for human beings, was patentable, the EU was grappling with strong internal resistance to patents on living organisms. Since the debate had not yet been settled in Europe, it was agreed to retain a minimal agreement while committing to revisit this provision within four years from the entry into force of TRIPS i.e. by 1999.

Article 27.3(b) of TRIPS incorporates this minimal agreement. It allows the exclusion of plants and animals, and essentially biological processes for their production, from patent grant but obliges the protection of microorganisms and microbiological or non-biological processes for their production. While there is uncertainty on the definitions of certain terms such as ‘non-biological’ organism’, confining this term to viruses, algae, bacteria, fungi and protozoa and excluding genes and gene sequences. Others view the term as extending to genes and even to plants and animals and call for its deletion from the text.

It is important to note that India is in compliance with the three universally recognised criteria of patentability now incorporated into Article 27.1 of TRIPS, viz. novelty, non-obviousness and industrial applicability or utility, which also apply to biotechnological inventions. Most importantly, even under TRIPS discoveries of products found in nature do not constitute an invention and are thus excludable from patent grant. However, the distinction, relevant to patentability, between the ‘discovery’ of something that exists in nature and the ‘invention’, or the creation of something new involving a pre-determined degree of human effort or intervention, is, in practice, difficult to make in the field of biotechnology. TRIPS gives no guidance on this, thus giving a certain degree of flexibility to India and developing countries in formulating their laws to avoid the patenting of products of nature.
Under 27.3(b) of TRIPS, if plants are excluded from patent protection, at least an effective *sui generis* system must be put in place for the protection of new plant varieties. In other words, plant breeders’ rights (PBRs) are to be protected despite the optional exclusion from the patenting of plants. Countries can also opt to give both options for the protection of plants. Unlike in the other subjects under TRIPS, there is no mention of adherence to the pre-existing international convention or to any specific details on scope of coverage, term of protection and limitations to such protection.

TRIPS in Article 28.2 extends the rights of process patentees to the product directly obtained from the patented process. Thus patented microbiological processes would give their owners product-patent-like rights over the products produced directly with the use of these processes. TRIPS also calls for the reversal of the burden of proof in the case of infringement of process patents, thus greatly strengthening the protection afforded to process patents. Can WTO members choose to exclude such rights if the products resulting from microbiological or other technical processes are plants and animals? The answer is not clear. Nevertheless, even with a minimalistic interpretation of these provisions, TRIPS obliges the grant of patents on microorganisms, microbiological and non-biological processes and products thereof, while excluding altogether only plants and animals and essentially biological processes for their production. Again, plant varieties have to be given some form of effective protection.

TRIPS also allows adequate safeguards against abuse of the monopoly rights granted such as compulsory licenses to third parties, use by government for public non-commercial use, price controls and parallel imports. These policy instruments should be adequate to counter any adverse effects on prices or on access to technologies. However, it must be noted that a policy of cooperation may be better than confrontation as sometimes patented technologies cannot be worked efficiently without the cooperation of the right holder.

TRIPS obligations generally enter into force for developing countries by 2000. However, countries that do not allow product patents have been given time, under Article 65 of TRIPS, up to 2005 to introduce such patents. However, for pharmaceuticals and agricultural chemicals, patent applications have to be accepted from 1995 onwards and exclusive marketing rights, i.e. rights very similar to patent rights, have to be granted for a period of five years or until the grant or rejection of a product patent. In the case of microorganisms or other biological material not treated as pharmaceuticals or agricultural chemicals India can take advantage of the delayed introduction up to 2005. However, process patentees will have product-patent-like rights over products directly obtained from microbiological or non-biological processes from 2000 onwards. India can also continue to exclude plants and animals and only allow PBRs on plants. Is it possible that the TRIPS obligations will be revised soon as already envisaged in Article 27.3(b)?

### Possibility of TRIPS Revision

Built into Article 27.3(b) of TRIPS is a provision for this clause to be reviewed four years after the date of entry into force of the WTO i.e. any time after 1999. At the time of the TRIPS negotiations this was a compromise, as the US wanted no exclusions for biotechnological
inventions, while the EC and many other developed and developing countries were comfortable with the EPC language. It was expected that with the passing of the European Biotechnology Directive that there would be united pressure on developing countries from US, Europe and Japan in the TRIPS Council in 1999 for accepting, under Article 27.3 (b), the patentability of all eligible biotechnological inventions, including plants and animals. Some research-based agricultural biotechnology companies in the US are particularly interested in plant patents as they argue that breeders’ rights, with breeders’ exemption and farmers’ privilege, are not sufficient to recoup their investment on R&D. While farmers’ privilege to use saved seed may, to some extent, be restricted by the use of hybrids or in the future, possibly by using other Genetic Use Restriction Technologies (GURTs), breeders cannot legally or technically be protected under plant variety protection laws that permit other breeders to derive new varieties from the protected one. Today, genetically engineered crops make up a large portion of agricultural production in developed countries and is projected to grow even more rapidly, replacing traditional varieties.

However, developed countries, backed by the international business community, are reluctant to re-open the debate on Article 27.3(b). One reason could be that some view this as risky as it would endanger the advances already made in Europe in this area, even while the public debate has not been fully settled there. Others may believe that the wording of TRIPS can be subject to an interpretation under WTO disputes as given in the recent European Biotechnology directive. Some experts in the US and EU believe plant variety protection is appropriate for plant varieties while genes and genetic processes should be granted patents, where eligible, thus preserving farmers’ privilege to re-use saved seed. Moreover, as many developing countries would only just have changed their laws to implement this provision of TRIPS, it may be considered premature to review this so early.

One more reason for such caution could be the preparations being made by developing countries to demand changes in TRIPS. Given the controversy on the grant of patents based on indigenous knowledge, a suggestion has been made that developing countries demand that the US and other countries that follow such a system, undertake an obligation under TRIPS to amend their patent laws to allow for prior knowledge of an invention revealed by public sale or otherwise. Others go further and suggest that patent applicants who base their inventions on traditional knowledge should name the indigenous community as co-inventor. Another suggestion is that genes, even if patented, upon isolation, remain free for use by all. Demandeurs for strengthened IPR protection may have reason to fear further weakening of the TRIPS text in any premature review. For some time to come, India can expect the TRIPS text on biotechnological inventions to remain unchanged.

Conclusion
At present India grants only process patents for certain biotechnological inventions. However, India’s adherence to the WTO will entail changes in its patent law by 2000. Although there is no need for India to go beyond TRIPS and grant patents for plants and animals in the near future, India will need to patent microorganisms and microbiological processes and products directly obtained therefrom. Sui generis plant variety protection can also take advantage of the flexibility currently allowed to include farmers’ privilege and breeders’ exemption. However, new technological advances may make farmers’ privilege redundant and local innovative breeders may themselves demand the limiting of breeders’ exemption. Some developing countries have already seen the wisdom of going on to the next stage of granting patents for plants, genes and animals and many others may do so, once domestic research capabilities in biotechnology improve. India should also do so once it gains confidence that IPRs can be used to encourage domestic innovation in this crucial technology.

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