

Towards Patentability of Essentially Biological Processes

Abhinav Kumar[†]

The WB National University of Juridical Sciences, NUJS Bhavan, Salt Lake City, Kolkata 700 098

Received 12 September 2007, revised 4 February 2008

This paper addresses the issue of patentability of 'essentially biological processes' in India in view of increased importance of biotechnological inventions. The Indian Patent Act excludes the 'essentially biological processes' from patentability in order to be in conformity with Article 27 3(b) of TRIPS. However like TRIPS, the Indian Act does not provide any definition or content of the same. It is understandable in case of TRIPS as due liberty was intended to be offered to the member countries; non-specification by India is baffling. United Kingdom has provided a concrete definition to the term in its Biotechnological Directive and United States through case laws has narrowed the content of 'essentially biological process' considerably. India is in dire need of foreign investment and inventors for the development of biotechnology and such non-specification would act as a strong disincentive for any foreign contribution forthcoming. This paper urges the Government to enact specific amendments to the primary patent legislation for incorporation of definition and content of the term in question distinguishing it from other similar terms like microbiological processes which have been excluded from exclusions.

Keywords: Essentially biological processes, microbiological process, biotechnology, patent, traditional knowledge

The basic concepts of patentability have often been challenged when they have been applied to life forms and biological material as living matter is capable of reproduction. Due to this, issues such as, the extent to which patented plant and animal species can be infringed by biological reproduction remain controversial. In view of its ethical and political volatility, this issue has become a debate with repercussions far beyond its technical aspects.

TRIPS—Primary International Document on Patent Enjoying Overwhelming Support

TRIPS is the primary document framed with the purpose of harmonizing domestic laws of member countries with respect to intellectual property. It mandates certain minimum standards and requirements which every member country has to comply with in conformity with their special needs. Further, TRIPS allows member countries to exclude certain subject matters provided under Article 27.3 from patentability which includes 'essentially biological processes'. However, member countries are at liberty to define such terms and decide on their patentability.¹ It would be pertinent to see whether India has used these liberties in conforming to the requirements of TRIPS in terms of excluded subject-matter.

Indian Patent Act—The Facsimile of TRIPS

Through amendment of 2002 to Section 3 of Indian Patent Act, 1970, India has included almost all the excluded subject-matters that are provided under Article 27.3 of TRIPS. Through the Second amendment to the Patent Act in 2002, the Legislature included Clause (j) to Section 3 which excluded 'essentially biological processes'.² The term 'essentially biological process' has perplexed most scholars in the field of biotechnology and patents. While no effort has surfaced from India to define this term, the European Community and the United States have made an effort to come up with a broad definition for the same.³

Briefly, it has been defined as scientific suspect or a process which requires at least one step of human intervention and which should be decisive for giving the final result.⁴ Therefore, involvement of human effort becomes a seminal criterion for deciding upon the issue of 'essential biological processes'.

Patenting of Life Forms & Essentially Biological Processes

Patentability of 'essentially biological process' mainly revolves around patenting of life forms that may have at least two dimensions. Firstly, there is the ethical question of the extent of private ownership that could be extended to lifeforms.⁵ The second dimension relates to the use of the concept of

[†]Email: abhinavkumar1985@gmail.com

intellectual property as understood in the industrialized world and its appropriateness in the face of larger dimension of rights on knowledge, their ownership, use, transfer and dissemination.⁶ The major justification for the non grant of patent to life forms has been based on the absence of effective system for distinguishing between formal and informal systems of knowledge and system for assessing its impact on public order and morality.⁷

Increasing Importance of Biotechnology

The pertinence of 'essentially biological process' has become more apparent in view of revolutionary changes made in the field of biotechnology. The biotechnology revolution is gaining momentum over the world and reports have indicated that the Indian biotechnology sector is estimated to grow faster than the robust information technology industry in India. 'India's bio-vision' in the future years involves building of a \$5 billion biotechnology business segment and developing a \$4 billion export market.⁸ This could provide employment to 1 million scientists and engineers, besides throwing open a \$1 billion business segment for outsourced research and development.⁹

Impact on Biotechnological Inventions

Article 27.3(b) is the sole provision in the whole of the TRIPS Agreement which is subject to an early revision of four years after the entry into force of the Agreement. As per Article 65 of TRIPS, this period is even shorter than the transitional period (with respect to) contemplated for developing countries. This solution suggests how difficult a compromise on biotechnology-related issues has been and the need for a deeper examination of the matter. As biotechnology has developed in the last 20 years, the subject-matter of the patents generated has evolved from protein sequences or DNA fragments to patents on living organisms including viruses, bacteria, plants and animals. Apart from ethical and political problems involved with such a subject-matter, more technical problems have arisen in relation to the interpretation and scope of such patent claims. As the value of a patent is in the protection that it confers, these issues are the fundamental ones in this field. Recognizing the complexity of the same, atleast the European Patent Office issued a directive on biotechnology to ensure uniformity.

Biotechnology Already Riddled with Difficulties

Biotechnological invention would not be able to accomplish its desired objectives without co-operation and encouragement of inventors and MNC's of

developed countries. It is an established position that development of major sectors gets stymied in the absence of effective laws for protection to foreign investors. The question to be asked is whether we are willing to lose valuable investment in biotechnology due to inadequate laws for patenting of 'essentially biological processes'.

Essentially Biological Processes and Biotechnology

Content of Essentially Biological Processes Provided only by European Union

Article 53(b) of European Patent Convention provides that 'essentially biological processes for the production of plants or animals' are not patentable. It has been recognized that the idea behind such provision is to prevent patenting of natural reproductive processes or non-technical processes such as selective breeding.¹⁰ Beyond the patentability of biological processes, it has also been recognized that this may affect the protection of organisms as such that could be direct products of such processes.¹¹

The patent jurisprudence of the European Community as evolved through case law provides that in order to ascertain whether a process for the production of plants or animals is essentially biological, it is necessary to consider totality of the human intervention and its impact.¹² In addition, a process which comprises at least one essential technical step, which cannot be carried out without human intervention and which has a decisive impact on the final result, is not essentially biological.¹³

The European Patent Office Guidelines to Examiners explain that:

'The question of whether a process is essentially biological is one of a degree depending on the extent to which there is technical intervention by man in the intervention: if such an intervention plays a significant part in the outcome, then that would not be excluded. To take some examples, method of crossing, inter-breeding or selective breeding say between horses, where the intervention involves only selection and bringing together of species sharing certain specific characteristics would be included in essentially biological process. On the other hand, a process of treating plant or animal for improving their growth or productivity, for example, method of pruning tree would not qualify as essentially biological though biological process is involved as the intervention in essence is technical.'

On the contrary, the Biotechnology Directive, a

specialized body of rules for biotechnological inventions, defines 'essentially biological process' as 'a process for the production of plants or animals if it consists entirely of natural phenomena such as crossing or selection.'¹⁴ This definition is different from the content provided by case law as it encompasses a much narrower ambit of inventions keeping in line with purpose and objective of the Directive *i.e.* to promote biotechnological inventions. The Directive bars from patentability only those processes which are solely made up of natural steps such as crossing or selection.

Recital 18 of the Directive implies that the 1998 patent laws of member countries inadequately dealt with biotechnological inventions. It states that, because the patent system provides insufficient incentive for encouraging research into and production of biotechnological medicines which are needed to combat rare or 'orphan' diseases, the Community and the Member States have a duty to respond adequately to this problem.¹⁵ Accordingly, the Directive mandates that 'Member States shall protect biotechnological inventions under national patent law.'¹⁶ They shall, if necessary, adjust their national patent law to take account of the provisions of this Directive' so that '[b]iological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature.'¹⁷

Further, in its final report to the European Parliament and the European Council entitled 'Development and Implications of Patent Law in the Field of Biotechnology and Genetic Engineering', the Commission stated:

'Article 5(2) of the Directive lays down that an element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element. ... The well-known distinction in patent law between a discovery and an invention thus applies fully in the field of biotechnology.'¹⁸

Biotechnology as it is Understood

Biotechnology is application to industry of advances made in the techniques and instruments of research in the biological sciences. It covers many disciplines and, broadly speaking, may be defined as the synergistic union of the biological sciences and

technologically based industrial arts. In other words, biotechnology is utilization of biological processes, through the exploitation and manipulation of living organisms or biological systems, in the development or manufacture of a product or in the technological solution to a 'real -world' problem. As such, advancements made in the biotechnology area have broad and significant impact in pharmacology, medicine, agriculture, and many other fields.

Biotechnology as used for Pharmaceuticals and Drug Manufacture

Biologics are drugs manufactured through biological processes. They are some of the hottest drugs around today and are certainly among the most expensive. Unlike chemical drugs, which typically are comprised of several hundred atoms, biologics are complex proteins that contain thousands of atoms folded over onto themselves.¹⁹ As biologics is not a chemical but a protein, it has to be produced from a living organism. Much of debate has surfaced over the patenting of biologics as they are exact replicas of naturally occurring substances, are not themselves patentable. Any patent involving biologics can be contentious, mainly because many people philosophically disagree with the notion that life can be patented. Companies would seek patents for biologics after they make minor modifications to a naturally occurring molecule, even though it is nearly identical to the natural substance. The US recognizes these patents (the landmark case was *Diamond v Chakrabarty*,²⁰ in which the Supreme Court held that man-made microorganisms were patentable). Other countries, including European Union members, who typically support strong patent protections, have moral objections to the idea of patenting natural substances.²¹

Patentability of Biotechnology

A biotechnological invention would commonly include products, compositions, and processes or methods. Biotechnological products would generally consist of a body of microorganisms, such as , bacteria and fungi, part of microorganism; plasmids, etc., allied products such as, antibiotics and enzymes derived from recombinant DNA, antigens, monoclonal antibodies, hybridoma, artificial organs and novel microorganisms obtained as a result of discovery.²²

Biotechnology for Plants

In the advent of plant genome sequencing, efforts have resulted in the patenting of plant DNA sequences by the plant biotechnology industry and public research institutions. DNA sequences are

patentable only when the gene has been isolated and a utility for it demonstrated. Plant patents in US are granted to any person who 'invents or discovers and asexually reproduces any distinct and new variety of plant, including cultivated sports, mutants, hybrids, and newly found seedlings, other than a tuber propagated plant or a plant found in an uncultivated state'. Further, all the provisions applicable to patents for inventions also apply to patents for plants unless otherwise provided by the statute. Similarly in the United Kingdom, the law is clear that just because a product consists of or contains biological material or even if it is a process by which the biological material is produced, processed or used, it is not to be considered as non-patentable.

Biotechnology for Life Forms

The field of medical biotechnology and pharmaceuticals is mainly concerned with the patenting of life forms as most of the research stems from tests performed on life forms. Most industrialized countries allow patenting of microorganisms as long as they meet the criteria of patentability, such as, novelty, utility and non-obviousness. The question shrouding patentability of life forms, again, may be directed towards different kinds of life forms right from microorganisms to clones of animals and humans. Therefore, it can be noticed that there is a robust connection between patenting of biological process and the growth and development of biotechnology. It is in the interest of developing countries to review their laws on patenting of biological process as it has a serious impact on biotechnology and overall development of these countries.

TRIPS and Essentially Biological Processes

The objective of TRIPS is to ensure that the protection and enforcement of intellectual property rights contributes to the promotion of technological innovation and the transfer and dissemination of technology, to the mutual advantage of producers and users of technology knowledge and in a manner conducive to social and economic welfare, and to the balance of rights and obligations. Article 27 of TRIPS has potential benefits to bioprospecting in as far as access to genetic resources, technology transfer and benefit sharing is concerned. For disease conditions with no known therapies, such as, cancers, HIV/AIDS and resistant malaria, it may be classified as technological innovations whose solution may be

derived through bio-prospecting.

TRIPS Controlling Patent Regime of Member Countries

TRIPS substantially regulates domestic laws of signatory countries. It requires that countries should have an effective patent system for virtually all areas of technology²³ which is subject to two exceptions provided in second and third clauses of the provision. First, Article 27(2) provides that members may exclude inventions from patentability where preventing the commercial exploitation of the invention is 'necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment'.²⁴ Secondly, Article 27(3) provides that members may exclude diagnostic, therapeutic and surgical methods for the treatment of humans or animals and plants and animals other than microorganisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, members must provide protection of plants varieties either by patents or *sui generis* system. It would be pertinent to mention that Article 30 of TRIPS ensures that enforcement of such exceptions does not interfere with normal exploitation of patent and legitimate interest of the patent holder.²⁵

Ambit of Article 27 of TRIPS

In Article 27.1, the word 'invention' differentiates between things that are inventions and things that are not. In other words, the agreement sets up a patentable subject matter threshold. Furthermore, it distinguishes between inventions that are patentable and inventions that are not by requiring that patentable inventions be 'new, involve an inventive step and be capable of industrial application'.²⁶ Accordingly, the definition of invention in the context in which it appears in Article 27.1 TRIPS, Article 52 European Patent Convention, Section 1(1) Patents Act 1977 (UK) or the Dictionary in schedule 1 of the Patents Act 1990 (Cth), does not mean that all discoveries cannot be inventions. It means that discovery and invention are not mutually exclusive. In certain circumstances even discoveries can be inventions and Section 101 of the Patents Act USC 35 1952 (US) simply provides a codified formula.

Review of Article 27.3 (b)

TRIPS envisages periodical review of Article 27.3 (b) at a period of every four years. However, the first review that was undertaken in the year 1999 was shrouded with controversy as developed countries

insisted on a review of the implementation and not of the substance and on the other hand, the developing countries demanded for review of substance.²⁷ Further, in the Third Ministerial Conference held at Seattle in 1999, developing countries from Europe submitted a proposal for liberty to prohibit patenting of life and to allow protection of community knowledge.²⁸ They also claimed exclusion on the grounds of conflict between TRIPS and Convention on Biological Diversity²⁹ and with the mandate of World Health Organization.³⁰ However, due to increased complexities, the Seattle Conference remained inconclusive. Paragraph 19 of the 2001 Doha Declaration has broadened the discussion.³¹ It says the TRIPS Council should also look at the relationship between the TRIPS Agreement and the UN Convention on Biological Diversity, the protection of traditional knowledge and folklore.

Further, in the case of *The Netherlands (supported by Italy and another) v European Parliament and another*, a challenge was made The European Biotechnology Directive 98/44/EC³² which was passed by the European Parliament in 1998 for standing in violation of Article 27 of TRIPS. It was argued that the Directive was removing rights of Member States to exclude from patentability 'plants and animals other than microorganisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes' as provided by Article 27(3)(b) TRIPS. The point at issue, then, was that the Directive was inconsistent with Article 27(3)(b) of TRIPS.³³ The Court, however, held that in narrowing the scope of excludable patentable subject matter, the Directive was not inconsistent with TRIPS because the European Community was merely exercising an option provided by Article 27 (3)(b) of TRIPS, and not therefore acting contrary to an obligation imposed. However, as Article 27.1 TRIPS does impose a specific obligation, it follows that the Court's conclusion that 'the Community legislative framework itself is not illegal'³⁴ is questionable.

Indian Patent Act and Essentially Biological Processes

India is one of the first few countries to have its patent law in place which was evolved on the basis of its socio and economic conditions-a law that would support its closed-door economy.³⁵ However, after the advent of TRIPS it became imperative for India to incorporate its essential provisions in its domestic law

on patents. In view of those provisions, India made the second amendment to the Indian Patent Act in the year 2002 to include Clause (j) to Section 3 which excluded 'essentially biological processes'.

Dimminaco Case

On 15 January 2002, the Calcutta High Court delivered a landmark judgment in *Dimminaco AG v Controller of Patents and Designs & Others*, which is set to change the landscape of patents and life forms in India. Dimminaco AG had filed a patent application for the process of manufacture of a vaccine. The end product contained living organisms in the form of a virus. Under the Patents Act, 1970, life forms cannot be patented, but the Court held that the process of manufacture was patentable, merely because the end product contained a live virus which did not inhibit the process of manufacture from being patented. The Court held that there is no statutory bar to accept a manner of manufacture as patentable even if the end product contains a living organism. Justice Ashok Kumar Ganguly observed that 'if the end product is a commercial and vendible entity, and for that, presence of living virus/microorganism in the end product cannot be a bar to its patentability'. This case has most definitely paved the way for further research and development on life forms and essentially biological process.

Opposition of Patenting of 'Essentially Biological Processes' on the Grounds of Morality

According to Section 3 (a) & (j) of Indian Patent Act, there is a serious overlap between clause relating to essential biological process and public morality.³⁶ Non-grant of patent to 'essentially biological processes' has been defended on the ground that ownership and control over life forms and naturally occurring biological processes would affect public morality and order.³⁷

Morality Standing against Essentially Biological Processes

Indian Patent Act or any other existing law does not provide any definition to the term 'morality'. The European Union has endeavoured to describe morality as 'the concept of morality is one which is related to the belief that some behaviour is right whereas other behaviour is wrong, this belief being founded on the totality of the accepted norms which are deeply rooted in a particular culture.'³⁸ This definition seems to be reasonable and suitable.

Article 6 of the Biotechnology Directive of European Union which prohibits grant of patent on

the ground of public order and morality clearly specifies groups of techniques which not should be prohibited.³⁹ Countries like United States and Canada do not even recognize exception of morality and public order. However, the Indian Patent Act does not provide any content for limiting the patentability on the ground of morality. If we agree with the definition provided, it can be seen that morality is an ever changing process and therefore, due regard has to be given to comprehensive content which should be amended according to change in the structure of the society. As both the clauses remain vague and uncertain, opposition should not be entertained on grounds of morality.

Comparative Study with Other Countries

European Community

As discussed earlier, Article 53(b) of the European Patent Convention and Biotechnology Directive excluded patentability of production of plants and animals through essentially biological process. It would be pertinent at this juncture to review case law that has surfaced in the Union.

The Novartis Case⁴⁰

Novartis, a renowned company in biotechnological research filed a claim for patent for a transgenic plant which was able to synthesize one or more lytic peptides together with one or more chitinases.⁴¹ The Enlarged Board of Appeal while deciding on claim 24 laid down three broad parameters which included issues:

- (1) the process should contain no 'essentially biological' steps but should only comprise clearly identified non-biological process steps;
- (2) to adopt the approach whether or not a process is to be considered as 'essentially biological' has to be judged on the basis of the essence of the invention, taking into account the totality of human intervention and its impact on the result achieved. The consequences of such an approach would be that 'a process for the production of plants comprising at least one essential technical step, which cannot be carried out without human intervention and which has a decisive impact on the final result does not fall under the exceptions to patentability under Article 53 (b) EPC first half sentence'. The Board felt that the outcome of such an approach would be relatively uncertain;
- (3) the most favourable approach to the applicants, was to regard the presence of one clearly

identified 'non-biological' process step as sufficient to escape the exclusion of Article 53. The comment was made that this was not the approach so far adopted by the Boards of Appeal.

The Technical Board contrary to the proposals held that human intervention in case of transgenic plant was substantial if compared to Lubrizol case⁴² and hence, the process was not 'essentially biological'.

*Greenpeace UK v Plant Genetic Systems N43V*⁴³

The decision delivered by Technical Board of Appeal in Plant Genetic System remains one of the most important progresses for patenting of essentially biological process in plants. In 1990, the European Patent Office (EPO) granted European Patent No. 0 242 236 to Plant Genetic Systems NV (PGS) in respect of processes and products relating to the herbicide 'Basta'. The patent gave rights over genetically engineered plant cells, and, thereafter, over all subsequent seeds and plants derived from the engineered cells. In 1992, Greenpeace filed an opposition under Article 100(a) of EPC, to the patent on the grounds that it violated both parts of Article 53 of the EPC. This was heard in 1993 by the Opposition Division, which upheld the patent.⁴⁴

The Board looked at the distinction between non-technical processes (or essentially biological processes), technical processes and microbiological processes.⁴⁵ Using the judgment in Lubrizol, the Board reiterated that the question of whether a process is to be regarded as microbiological or not 'has to be judged on the basis of the essence of the invention taking into account the totality of human intervention and its impact on the result achieved'.⁴⁶

The Board held that step of transforming plant cells or tissue with recombinant DNA may fall within the ambit of 'microbiological process' however, regeneration of plant has to fall within the ambit if 'essential biological process' and hence, the claim 21 was not allowed.

The Plant Genetic System case seems to take a more restrictive approach to the possibility of encompassing excluded material. For the pro-patenting life lobby it reaffirms that living material can be validly patented, but it carries with it the caveat that where it can be shown that the material is such that it would be regarded as 'abhorrent' then it could be denied a patent. Equally if the material is such that it would 'seriously prejudice' the environment, then the patent will fail, this having to

be more than a mere possibility at the time the patent is being prosecuted but a sufficiently substantiated, actual consequence of its exploitation.⁴⁷

United States

In the United States, only inventions that meet the statutory requirements of being new, useful, and non-obvious, can be patented. Inventions or discoveries, such as naturally occurring organisms, laws of nature, natural or physical phenomena and abstract ideas, cannot be patented. A patent in United States lasts for 17 years.⁴⁸ However, for patent claims for a human drug product, medical device, food or color additives that have been reviewed for commercial availability or use by the US Food and Drug Administration (FDA), the patent is extendible for another five years.⁴⁹

Diamond v Chakrabarty: A Landmark Judgment in the Patent History of United States

The leading case in the United States which touched on the patentability of biotechnological processes and products is *Diamond v Chakrabarty*.⁵⁰ In this case, a microbiologist had genetically engineered a bacterium capable of breaking down multiple components of crude oil, a property possessed by no naturally occurring bacteria, and therefore believed to have a significant value in the treatment of oil spills.

The United States Supreme Court ruled that such live, human-made microorganisms are a patentable subject matter because they constitute either a 'manufacture' or a 'composition of matter' within the meaning of the patent statutes. The court further stated that Congress contemplated that the patent laws should be given wide scope, and the relevant legislative history supports a broad construction while laws of nature, physical phenomenon, and abstract ideas are not patentable, respondent's claim is not to a hitherto unknown natural phenomenon but to a non-naturally occurring manufacture or composition of matter and product of human ingenuity having a distinctive name, character and use.

This judgment offered a huge boost for biotechnological invention in the region especially in the light of the observation of the Court which provided that any invention under the sun is a patentable subject matter.⁵¹ This case subsequently opened the doors to biotechnologists and other researchers whose creativity produced products and processes that were registered and given patents. It

also liberalized the scope of the definition of patentable inventions in American patent jurisprudence, usher in an era of patentability of biotechnological inventions.

Subsequent Cases Showed Leniency Towards Naturally Occurring Substances and Biological Processes

Following strict interpretation of non-patentability of 'essentially biological processes', invention of natural compounds like protein and DNA should not be patentable as they naturally occur in nature. However, the United States has created few exceptions to the same in order to encourage biotechnological inventions. Under US patent law, they can be patented only if they are new and purified.⁵² For DNA molecules, a separate category of patent has been created, namely 'composition of matter'. The USPTO has justified patenting of DNA molecule on the grounds of utility.⁵³

In case of plants, the question of patenting of naturally occurring substances does not arise as special protection to new varieties of plants (both sexually and asexually reproduced) has been extended by the Plant Patent Act, 1930 and Plant Variety Protection Certificate (PVPC) in the Plant Variety Protection Act, 1970.⁴⁷ Moreover, plant is a valid patentable subject-matter in United States.

However, in case of animals, the position is not that well-established. In *Ex Parte Allen*,⁵⁴ where the applicant sought to patent a method of inducing polyploidy in oysters as well as the resulting oysters as products-by-process. Following the reasoning in *Diamond v Chakrabarty*, the USPTO concluded that such organisms were eligible for patenting. Shortly after the *Allen* decision, the USPTO issued a notice declaring that it would consider non-naturally occurring, non-human multicellular living organisms, including animals, to be patentable subject matter within the scope of the Patent Act.⁴⁷

Germany

In Germany, during the first half of this century, the Imperial Patent Office (Kaiserliches Patentamt), the Reichspatentamt and the German Federal Patent Court (Bundespatentgericht) refused applications for animal breeding. However in 1969, the Federal Supreme Court (Bundesgerichtshof) adopted a more liberal view of the law in the *Red Dove*⁵⁵ decision and made it clear that inventions in the field of biology were not, in principle, excluded from patent protection. The Court identified three sorts of

biological inventions: those which affected the course of biological events by means other than animate matter; those which affected inanimate matter by biological means; and those in which both the means and the final result are within the field of biology, this last embracing the results of animal breeding.⁵⁶

Despite the Red Dove decision in 1969, the position in Germany (and many other countries, particularly European countries) began to change in 1963 with the advent of the Strasbourg Convention, which provided that the signatories were permitted not to grant 'patents for plant or animal varieties or essentially biological processes for the production of plants or animals'.⁵⁷ It appears that the sole reason for including this provision was to avoid the need for delegates to have to consider the problems of biological inventions in the context of the Convention, leaving the whole matter for discussion in some other forum.

Conclusion

It can be conveniently concluded that biotechnology has acquired a great importance and increased significance in the growth and development of a developing country like India. However, a vague understanding of an important term such as 'essentially biological process' for the mere purpose of complying with strict regime like TRIPS can prove fatal for the country's development in a long run. It is suggested that the Indian Patent Act should provide definition and content to 'essentially biological process' as provided by other member countries before excluding it from patentability.

It is submitted that member countries should be given the liberty to exclude from patentability plants, animals, microorganisms and parts thereof, and any processes making use thereof or relating thereto. The effect of this formulation would be that WTO members will retain the right to exclude patentability of plants and animals, without the condition of providing protection for microorganisms, microbiological processes, non-biological processes and also plant varieties.

On this point, it has been suggested that since Article 27.3(b) refers to 'plants and animals' and not to any particular class thereof (such as 'varieties', 'races' or 'species'), this reference should be read to include both naturally occurring plants and animals and parts thereof, as well as those which have been genetically modified (i.e., transgenic)⁸.

Whilst this option does not disallow patents on life, it maintains a measure of national sovereignty over patent law and biological resources. The attractiveness of this option lies in the fact that it will be a logical position to defend, since many developing countries have legislation which does not allow for patenting of plants and animals. The strategic advantage of this option is that it would provide the developing countries with a convenient fall-back position, that is, no change to the Article 27.3(b) text.

References

- 1 United Kingdom in response to the provisions of TRIPS regarding biological process has observed in Recital 18 of Biological Directive, 'the patent system provides insufficient incentive for encouraging research into and production of biotechnological medicines which are needed to combat rare or 'orphan' diseases, the Community and the Member States have a duty to respond adequately to this problem', Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998, The Legal Protection of Biotechnological; In Article 1.1 of the same Directive, they observed, 'Member States shall protect biotechnological inventions under national patent law. They shall, if necessary, adjust their national patent law to take account of the provisions of this Directive'5 so that '[b]iological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature.' Inventions, Official Journal L 213, 30/07/1998 P 0013-0021.
- 2 Patent (Amendment) Act, 2002, No. 38 of 2002.
- 3 Lex Orbis, Patent system examined, Newsletters, International Law Office, 9 January 2006, 11; Stim Richard W, *Intellectual Property: Patents, Trade Marks And Copyrights*, 2nd edn (West Legal Studies, US), 2002, p. 432; Grubb Philip W, *Patents for Chemicals, Pharmaceuticals and Biotechnology: Fundamentals of Global Law, Practice and Strategy*, 1st edn (OUP, London), 1999; Explanation to Article 5 of EU Directive provides, 'Essentially biological processes' could include transformation and transfection, processes used in creating transgenic organisms.'
- 4 Plant Genetic Systems/ Glutamine synthetase inhibitors, [1995] EPOR 501; Article 53 (b) of the European Patent Convention; Mae-Wan Ho & Terje Traavik, No scientific basis for patenting under TRIPS Article 27.3(b), Third World Network, 12 May 2007, 21-24.
- 5 Sullivan Clark G, How personalized medicine is changing the rules of drug life exclusivity, *Pharmacogenomics*, 5 (2004) 429.
- 6 Shiva Vandana, WTO, patents on lifeforms and amendments in India's patent law, <http://www.zmag.org/sustainers/content/2005-04/07shiva.cfm> (17 July 2007).
- 7 Gitter Donna M, International conflicts over patenting human DNA sequences in the United States and the European Union: An argument for compulsory licensing and a fair-use exemption, *New York University Law Review*, 76 (2001) 1623, 1625; Portman Robert M, Legislative restriction on medical and surgical procedure patents removes impediment to medical progress, *Baltimore Intellectual Property Law*

- Journal*, 4 (1996) 91, 98.
- 8 James C, Global Review of Commercialized Transgenic Crops: 2001, International Service for the Acquisition of Agri-Biotech Applications (Briefs No 24, Ithaca, NY) 2001, p. 210; *Innovative Environmental Biotechnologies: From Research to Application*, edited by S Natesh and S Govil (Department of Biotechnology, New Delhi), 2003, 53-70.
 - 9 Nishith Desai Associates, Biotechnology-legal and ethical issues, <http://www.lawthinktank.com/BIOTECHNOLOGY%20-%20Phase%201%20Report%20-%20January%204-2002.pdf> (1 June 2007); Thirvenugam B C, Biotech industry: IPR and other legal issues, *Biospectrum*, 13 June 2005, 7-13.
 - 10 Adcock Mike and Llewelyn Margaret, TRIPS and the patentability of microorganisms, *Bio-Science Law Review*, 3 (2000/2001) 91.
 - 11 The direct products of a patented process are protected; Article 64(2) of EPC and Article 8(2) of the Directive 98/44 on the legal protection of biotechnological inventions, United Kingdom.
 - 12 Plant Genetic Systems/Plant cells [1995] EPOR 357.
 - 13 Plant Genetic Systems/Plant cells [1995] EPOR 357 for plants and (Harvard/Oncomouse) [1990] EPOR 501 for animals.
 - 14 Article 2(2) and 4(1) (b) of the Directive 98/44 on the legal protection of biotechnological inventions, United Kingdom.
 - 15 Recital 18, European Biotechnology Directive, 98/44/EC.
 - 16 European Biotechnology Directive, 98/44/EC, Article 1.1.
 - 17 European Biotechnology Directive, 98/44/EC, Article 3.2.
 - 18 Final Report from the European Commission to the European Parliament and the Council, Development and Implications of Patent law in the Field of Biotechnology and Genetic Engineering, Commission of The European Communities, Brussels, Com 2002, 545.
 - 19 Kleinberg Michael and Mosdell Kristen Wilkenson, Current and future considerations for the new classes of biologicals, *American Journal of Health System Pharmacy*, 61 (2004) 695; Feick Katja, Patent expiries and the prospect of cost savings to underline the popularity of generics and biogenerics in Europe, Business Briefing: *Pharmagenerics*, <http://www.touchbriefings.com/pdf/955/ACFB3AC.pdf> (25 June 2007).
 - 20 447 US 303 (1980).
 - 21 Gitter Donna M, International conflicts over patenting Human DNA sequences in the United States and the European Union: an argument for compulsory licensing and a fair-use exemption, *New York University Law Review*, 76 (2001) 1623, 1625. A good example of moral objections making their way into public debate is the European Parliament resolution on the patenting of BRCA1 and BRCA2 (breast cancer) genes, <http://www.cptech.org/ip/health/biotech/eu-brca.html> (3 July 2007), in which it 'reiterates its call on the European Patent Office 'to ensure that all... patent applications in Europe do not violate the principle of non-patentability of humans, their genes or cells in their natural environment.'
 - 22 Giant Group, The invention patent of biotechnology, <http://www.giant-group.com.tw/ep&t/ep&t4.htm> (3 August 2007).
 - 23 Article 27 (1) of TRIPS states: '... patents shall be available for any inventions, whether products or processes, in all fields of technology, provided they are new, involve an inventive step and are capable of industrial application.'
 - 24 Adelman and Baldia, Prospects and limits of the patent provision in the TRIPS Agreement: The case of India, *Vanderbilt Journal of Transnational Law*, 29 (3) (1996) 507-533.
 - 25 Article 30 entitles a member country to provide limited exceptions to the exclusive rights: '...provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.'
 - 26 Duigan Miranda and Dowling Michael, Threshold test of manner of manufacture in Australia – What next? *Patent World*, September 1998.; Padbury Mary, Inventiveness Apart from novelty and inventive step – The High Court decisions of manner of manufacture in Philips and Ramset, *Australian Intellectual Property Journal*, 9 (1998) 161.
 - 27 Abbott F M, The enduring enigma of TRIPS: A challenge for the World Economic System, *Journal of International Economic Law*, 1998, 498; Cullet P, Revision of the TRIPS Agreement concerning the protection of plant varieties: Lessons from India concerning the development of a sui generis system, *Journal of Intellectual Property Law*, 1999, 328.
 - 28 Council for Trade-Related Aspects of Intellectual Property Rights, Review of the Provisions of Article 27.3(b) Summary of Issues Raised and Points Made, Paper IP/C/W/369 (August 2002), http://www.wto.org/english/tratop_e/trips_e/ipcw369_e.doc (13 September 2007); Sykes Alan O, TRIPS, pharmaceuticals, developing countries, and the Doha solution, *Chinese Journal of Interational Law*, 47 (3) (2002) 27.
 - 29 The developing countries stated that CBD stipulates that IPRs must be supportive of Convention objectives while TRIPS lacks reference conservation, sustainable use or fair and equitable benefit sharing.
 - 30 The developing countries raised the claim that 'essential drugs' should be left out as it is specifically addressed by World Health Organization.
 - 31 C Correa, TRIPS and the protection of community rights (signposts to sui generis rights - Resource materials from the International Seminar on sui generis rights) 1997; Downes D, The Review of Life Patenting under TRIPS, CIEL Revised Discussion Paper, 1998.
 - 32 *The Netherlands (supported by Italy and another) v European Parliament and another (supported by the European Commission)* [2002] All ER (EC) 97.
 - 33 Eisenberg Rebecca S, Re-examining the role of patents in appropriating the value of DNA sequences, *Emory Law Journal*, 49 (3) (2000) 783.
 - 34 European Commission, Communication from the Commission to the European Parliament, to the Council and to the European Economic and Social Committee Life Sciences and Biotechnology—A Strategy for Europe Progress Report and Future Orientations, 2003, 96.
 - 35 Thirvenugam B C, Biotech industry: IPR and other legal issues, *Biospectrum* (13 June 2005) 12.
 - 36 Hormone Relaxin Opposition [1995] OJ EPO, 338; *Harvard College v Canada (Commissioner of Patents)* [2002] SCC 76 (21 May 2002).
 - 37 T 19/90 (Harvard/Oncomouse) [1990] EPOR 501; European

- patent application no. 89913146.0, The Upjohn Company of Michigan, filed on 17 November 1989.
- 38 Patant Genetic Systems/Plant cells [1995] EPOR 357.
- 39 ticle 6 includes '(a) processes for cloning human beings; (b) processes for modifying the germ line genetic identity of human beings; (c) uses of human embryos for industrial or commercial purposes; (d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.'
- 40 1999] EPOR 123 (EPO).
- 41 Claim 24 of the final claim included a method of preparing the transgenic plant by preparing two or more transgenic plants encoding the relevant sequences by an unspecified method and crossing them using conventional breeding techniques which concerned the question of falling of claim within the ambit of 'essentially biological process'.
- 42 LUBRIZOL/Hybrid plants [1990] EPOR 173.
- 43 [1995] EPOR 357 (EPO).
- 44 'Opposition may only be filed on the grounds that: (a) the subject-matter of the European patent is not patentable within the terms of Articles 52 to 57.
- 45 LUBRIZOL/Hybrid plants [1990] EPOR 173, 27.
- 46 It followed from this that where an invention is the result of a technical step which is essential to its production, which would not occur without human intervention, and this step has a decisive effect on the end product then Article 53(b) would not apply. Where a technical step has occurred but it relates to a previous generation of plants and protection is being sought for a subsequent generation which is not the direct result of the technical step but of traditional breeding, then the subsequent generation cannot be regarded as the result of the technical process and Article 53(b) will apply.
- 47 Roberts, News Section [1995] 6 EIPR D 188.
- 48 Manual of Patent Examining Procedure § 2105, 8th edn, 2001; JEM AG Supply Inc v Pioneer Hi-Bred Int'l, Inc, 534 US 124 (2001).
- 49 Office of Technology Assessment, Biotechnology in a Global Economy, Congress of the United States (1991) 56-94.
- 50 447 US 303 (1980).
- 51 *Diamond v Chakrobarty*, 447 US 309 (1980).
- 52 Evans Christopher, Intellectual property and wealth creation, RSA LECTURES 1 (March 2001) 24; Utility Examination Guidelines, 66 Fed Reg 1093 (2001).
- 53 Utility Examination Guidelines issued by USPTO which states, '(1) An excised gene is eligible for a patent as a composition of matter or as an article of manufacture because that DNA molecule does not occur in that isolated form in nature; or (2) Synthetic DNA preparations are eligible for patents because their purified state is different from the naturally occurring compound.'; Notification issued by USPTO which states 'An inventor's discovery of a gene can be the basis for a patent on the genetic composition isolated from its natural state and processed through purifying steps that separate the gene from other molecules naturally associated with it. If a patent application discloses only nucleic acid molecular structure for a newly discovered gene, and no utility for the claimed isolated gene, the claimed invention is not patentable. But when the inventor also discloses how to use the purified gene isolated from its natural state, the application satisfies the 'utility' requirement....Like other chemical compounds, DNA molecules are eligible for patents when isolated from their natural state and purified or when synthesized in a laboratory from chemical starting materials.'
- 54 2 USPQ 2d 1425 (Bd Pat App & Inter 1987).
- 55 1 IIC 136 (1970).
- 56 Nott Robin, Plant protection for plant and animals, *European Intellectual Property Review*, 14 (3) (1992) 79-86; Greengrass Barry, The 1991 Act of the UPOV Convention, *European Intellectual Property Review*, 12 (1999) 466.
- 57 Article 2(b) of Strasbourg Convention on Unification of Certain Points of Substantive Law on Patents for Invention, 1963.