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Patenting of Higher Life Forms: Justification and Law

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ABSTRACT
Biotechnological applications provide us significant economic and social benefits in areas such as health, agriculture, the environment and industry. Considering its advantages and potent capability innovation in genetic engineering and biotechnology has been extended protection of patent. Almost every international legal instrument has accepted the role of biotechnological inventions in growth of the society. However, when researchers and corporate houses moved for getting patent for higher life forms it was opposed on the ground that it will be in violation of traditional fundamentals of patent laws. Even the claim of patent was denied by patent offices for the process relating to study of growth of cancerous cell in the mouse. This paper is an attempt to assess the effect of patenting of higher life forms and also to identify the philosophical basis thereto. The researcher supports the corollary drawn by European Courts for the patenting of higher life forms.

Introduction

Biotechnological applications may provide significant economic and social benefits in areas such as health, agriculture, the environment and industry.[1] Almost every international legal instrument has accepted the role of biotechnological inventions in growth of the society[2] and world's major economies have recognised the significance of allocating resources to biotechnology and the breadth of potential benefits that the industry brings. Among these benefits is the potential to develop treatments and cures for diseases that plague the world's population as well as a potent tool to food security. However, when an attempt was made to get patent for higher life forms[3] it was opposed on the ground that it is in violation of traditional fundamentals of patent laws.[4] Every patent application is subject to go through two stages before actual patent rights are awarded by the Patent Office. The first of these inquiries deals with criteria of eligibility of inventions[5] that determines what types of inventions can be considered for patent protection. Patent eligibility performs a gatekeeper function. If an invention is not patent eligible, no other provision of the patent law can secure patent rights for that invention.

Recombinant DNA technology[6] makes it possible to selectively modify the genetic material of higher organisms. Genes can be transferred between different species of organisms and between organisms that are not even closely related, for example, bacteria and mice. Existing genes can be cut and spliced to form new gene combinations with new and improved functions. By comparison with selective breeding methods, the ability to combine genetic material from different organisms by recombinant DNA technology provides a more rapid and reliable way to produce organisms with desired traits. Significant advancements towards the ultimate goal have been made through the claim of patent with regard to transgenic animal and transgenic plant. Even the claim of patent was denied

[1] Canadian Biotechnology Advisory Committee, (June 2002), *Patenting Of Higher Life Forms And Related Issues*, Report to the Government of Canada Biotechnology Ministerial Coordinating Committee, p. 2.

[2] *See*, Chapter 16 of Agenda 21 of the Earth Summit 1992. Also refer Article 19 of CBD.

[3] The term "higher life form" is not defined in law. In common usage, it includes plants and non-human animals other than single-celled organisms. In other words, hhigher life forms are those life forms which are multi- cellular complex entities whose identity is characterized and identified on the basis of the multi-cellular composite which makes up the organism.

[4] The subject matter of biotechnology is complex. Many of the products and processes of biotechnology appear in nature, and so, with such origins those products and processes are somewhat familiar to most people notwithstanding their complexity. Indeed, it is the fact that the subject matter of biotechnology is derived from nature that one may question whether there can ever be invention in biotechnology.

[5] 'Patent eligibility' broadly refers to the requirement that a subject matter for which a patent is sought be inherently suitable for patent protection, in the sense of falling within the scope of subject matter that patent law prima facie exists to protect. The term 'patentability', on the other hand, refer to those set of principles that inform the requirements that must be satisfied for a patent eligible subject matter (i.e., an invention) to be granted a valid patent. Principally they are the requirements of novelty, inventiveness (non-obviousness), utility (industrial applicability) and sufficient description.

[6] Recombinant DNA biotechnology involves combining genetic material from different sources thereby creating genetic modified organisms that may have never existed in nature before. *Laboratory Bio-safety Manuals*, WHO, Third Edition 2004, p. 101.

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by patent offices for the process relating to study of growth of cancerous cell in mouse.[7]

Now here the question is whether higher life forms are not patentable because they cannot be the subject of inventions? Or is it a moral/ethical issue? It is to be noted down that the TRIPs Agreement[8] and the Paris Convention on industrial property[9] do not discriminate between any technologies except the rationality incorporated thereto.

The "transgenic" animals[10] that are produced are used in medical research, in pharming and as farm animals with improved nutritional value, reproductive efficiency, and growth rate and disease resistance. Transgenic technology can also potentially be used to preserve animal species. The ability to produce and patent transgenic animals has led many to question whether the creation and patenting of inventions that are alive should be permitted.[11]

The real issue with respect to patents for higher life forms is, if a claim is directed to a genetically modified "higher" life form, can it be said, or is it possible that such a claim exceeds the scope of the invention by going further than the protection to which the inventor is entitled. . The Problem with Patenting of Higher Life Forms

Since patenting of higher life forms is likely to have direct impact on fundamentals of patent and human rights, its patentability has been debated and from the very beginning. Till today the debate about the propriety of patenting and balancing of competing interests thereto continues to be matter of concern. It has been questioned for its social relevancy. High prices of patented drugs are considered as main obstacle against concern of access to medicine. A patent does not, however, grant its holder the right to market or even use the invention. This is because some applications of the technology may pose risks to human or animal health or to the environment, challenge the capacity of current approaches to protecting health and the environment, and/or raise other serious social and ethical questions that must be addressed. The issues included concerns about the commoditisation of life, equitable sharing of the benefits that come from biological inventions, the preservation and use of traditional and local knowledge, animal welfare, concentration of ownership and resulting lack of competition, possible abuses of economic power and access to genetic resources. The common man and society puts a duty on government to provide the benefits and offer protection from the risks. But whether putting a complete ban on granting of patent is imparting duty by government?

However, most of the social and ethical concerns arise either in the research stage leading up to a patent application or in the commercialization stage following the grant of a patent. A variety of mechanisms other than the patent system exist for addressing such concerns. Moreover, in cases of a serious and compelling ethical or social concern arising from the commercialization of the invention, it could be revoked[12] or its operation could be suspended.[13] Even the TRIPs agreement provides that granting of patent to an invention could be restricted on the ground of invention seriously prejudice to invention.[14]

Trans- National Practice of Higher Life Forms Patenting US Patent System

In 1980, in 'Chakrabarty'case , the US Supreme Court held that patentable subject matter under the Act included 'anything under the sun that is made by man' and that protection covers living non-human matter so long as the material would not be found in the wild.[15] Since 1980, the Act has been interpreted by the USPTO to provide patent protection for genetically engineered plants[16], non-human multi-cellular organisms and even human genes transplanted into non-human mammals, such as the Harvard 'Onco-Mouse'. In the late 1980s, the USPTO promulgated a rule delineating non-human cell lines as patentable subject matter, and the patent practice rules specifically contain instructions and reference to regulations regarding depositing cell lines as proof of invention. Thus, because of 'Chakrabarty' and the 'Onco-Mouse', the USPTO has granted patents to higher life forms, so long as, the Act's other requirements are met. At present, under the US patent system there is no legal impediment to patenting higher non-human life forms or their related genes, processes and methods.[17]

In *Ex parte Allen*, case the Board of Appeals refused to grant a patent on a process to make more edible oysters by putting them under pressure. The Board said the claims in question were obvious, but it also said that the mere fact that a multi-cellular animal was involved was not a bar to patentability.[18] On April 21, 1987, the PTO announced that it would accept applications for "non-naturally occurring nonhuman multi-cellular living organisms, including animals." The PTO stated that, to be patentable, the animals must be "given a new form, quality, properties or combination not

[7]Dennis, J.K.P. (2008) 'Divergence in patent systems: a discussion of biotechnology transgenic animal patentability and US patent system reform', *Int. J. Private Law*, Vol. 1, Nos. 3/4, pp.268-269.

[8] Article 27(1) of the agreement mandates that patent will be given for process and product of every new technology involving industrial applicability and inventive steps.

[9] Article 1 provides that patent can be granted for manufactured industrial product as well as natural products.

[10] A transgenic animal is one which through recombinant DNA technology, the process of transplanting a gene from one organism into another organism, deliberately carries a foreign gene in its genome.

[11] Susan J. Friedman, "Patenting Life: Issues and Controversies", Washington State Bar Association *Animal Law Section Newsletter*, Vol.1, No. 3, Fall 2003, p.1, available at: http://www.speckmanlaw.com/SLG%20Materials/IP%20Materials/Patenting%20Life.pdf, (visited on 23.08.10).

[12] Every patent laws contain provision for revocation. *See*, S. 64 of the Patent Act 1970.

[13] GMO regulation of 1989 empowers central government to withdraw marketing rights of any GM food if any new information pertaining to it comes latter.

[14] Article 27.2 of the TRIPs Agreement.

[15] *Diamond* v. *Chakrabarty*, 447 U.S. 303, 309 (1980)

[16] See, *J.E.M. Ag Supply* v. *Pioneer Hi-Bred Int'l,* 534 U.S. 124, 146 (2001) ('newly developed plant breeds fall within the terms of [35 U.S.C.] § 101'); *Ex parte Hibberd*, 227 U.S.P.Q. (BNA) 443 (Bd. Pat. App. & Interferences, 18 September 1985) (genetically engineered maize plants and seeds).

[17] 'Following the issuance of the Onco-Mouse patent in 1988, the floodgates opened and all manner of transgenic fauna (rats, rabbits, fish, sheep, pigs, cows to name a few) have now been patented'.

[18] 846 F.2d 77 (Fed. Cir. 1988).

present in the original article existing in nature in accordance with existing law.[19]

When the US Supreme Court was grappling with the boundaries of patentable subject matter in 'Chakrabarty', Harvard College's Dr. Phillip Leder led cancer efforts culminating in a mouse cell line found to be more susceptible to cancerous growths and tumors (neoplasms). This was due to the insertion of an activated onco-gene into the mouse's DNA at an embryonic developmental stage, preferably the oocyte stage to 'ensure that the onco-gene sequence will be present in all of the... cells... of the transgenic animal'. This 'Onco-Mouse' was a breakthrough in the field of cancer research, since it could serve as a test subject for various remedies and treatments, and possibly yield cures for cancer. As a result of 'Chakrabarty', Harvard was able to obtain patent protection for the 'Onco-Mouse' itself (the '866 Patent), and later two processes of using such mice in research (the '571 Patent and '803 Patent). using such mice in research (the '571 Patent and '803 Patent).

A foreign gene onco was inserted into the mouse by genetically engineering, which made it susceptible to cancer. The mouse was useful in cancer testing. The patent office granted patent on the ground that the invention is non-naturally within the purview of patentable subject matter.

This is now the classic example of a claim directed to a genetically modified higher life form. This patent includes claims to any non-human animal into which "any onco-gene or effective sequence thereof" has been introduced. Notwithstanding that the disclosure portion of the specification only describes experiments and results conducted in the mouse in respect of the *myc* gene (one of a number of so-called "onco-genes"), and lists thirty-three additional onco-genes and mentions that primates such as the Rhesus monkey could also serve as a transgenic animal, this claim includes all mammals (except humans) and all onco-genes, and all future generations of the animal containing those onco-genes. After getting patent for the first 'Onco-Mouse', Harvard sought international patent protection by filing essentially identical applications in Canada, Europe and Japan.

European Union System

Article 53(b) of EPC provides that European patents are not available for plant or animal varieties and essentially biological processes for the production of plants or animals. Rule 23 C of the E.U. Regulation provides that plants and animals are patentable if the technical feasibility of the invention is not confined to a particular plant and animal variety. Genetically modified animals and plants have been held to be patentable as they fall outside the scope of animal and plant variety.

In Europe patentability of transgenic animal has been approved by Technical Board of Appeal in Onco-mouse case.[20] The case related to a genetically altered mouse, which involved inserting an activated onco-gene to develop cancer in the mouse. Here Board held that the wording of Article 53(b) indicates that all animals are not excluded from patentable subject matter because the usage of both the terms animal varieties and animal in the same provision illustrates that the legislature did not intend to exclude all animals from patentability. As rodents and mammals form a taxonomical unit higher than any animal variety.[21] The EPO determined that Article 53(b) did not constitute a per se ban on the patenting of animals, and that the 'Onco-Mouse' was not in any case an animal variety that would fall within the exclusion. Turning to the Article 53(a) issue, the EPO developed a utilitarian balancing test to determine morality issues under the Article. The test 'aim[s] to assess the potential benefits of a claimed invention against negative aspects', and it permits the consideration of negative effects such as 'animal suffering,... environmental risks and of the feasibility of using non-animal alternatives', and a 'wider range of positive benefits to human kind than... substantial medical benefit'.[22] As far as the 'Onco-Mouse' was concerned, the EPO carefully weighed the suffering of the mice and possible risks to the environment, against the invention's potential usefulness to human kind and the medical community. The Office concluded that the usefulness of the mouse in furthering cancer research outweighed the moral arguments about the suffering caused to the animals.

Moreover, The Enlarged Board of Appeal of Europe came to the conclusion in G 1/98 that a correct interpretation of Art. 53(b) EPC does not exclude the granting of patents for transgenic plants, where specific plant varieties are not identified, even if the claims embraced inter alia plant varieties. The Enlarged Board took the view that Art. 53(b) EPC defined the borderline between patent protection and plant variety protection. The extent of the exclusion for patents was the obverse of the availability of plant variety rights. Since plant variety rights were only granted for specific plant varieties and not for technical teachings which could be implemented in an indefinite number of plant varieties, it was not sufficient for the exclusion from patent protection in Art. 53(b) EPC to apply that one or more plant varieties were embraced or might be embraced by the claims of the patent application.[23] In *Novartis Transgenic plant*[24] case European technical board of appeal held that genetically modified plants are patentable subject matter and observed that genetically modified plants were not conceived at the time of drafting, and do not fall within the scope of exclusion to patentable subject matter.[25]

In interpreting the term "animal varieties" the board in this decision emphasised the narrow interpretation to be given to the provisions of Art. 53(b) EPC. Keeping in view that for animals - unlike plant varieties - no other industrial property right was available, the board decided that the exception to patentability under Art. 53(b) EPC applied to certain categories of animals but not to animals as such. It thus constituted no bar to patentability for subject-matter which was not covered by any of the terms "animal varieties", "races animals" or "Tierarten".[26]

The definition of animal variety (or species or race) by reference to taxonomical rank would be consistent with the position in relation to plant varieties and also in the interest of legal certainty. It would allow assessment under Art. 53(b) of EPC as interpreted by Rule 23C (b) of EPC to be made by considering whether the technical feasibility of the invention was not confined to a particular animal variety (or species or race).

Canadian Patent System

In Canada, the Patent Office describes higher life forms as "multi-cellular differentiated organisms (plants, seeds and

[19] 1077 OG 24.
[20] 3.3.2. [1990] E.P.O.R. 1950
[21] *Id* at. 508 and 512

[22] However, The EPO has not accepted and used the same utilitarian test to address another transgenic mouse patent application: the Upjohn bald mouse case.
[23] *Supra* note 47, p. 42.
[24] 3.3.4. [1999] E.P.O.R. 123.
[25] *Id.* at para 91.
[26] *Id*. at 43.

animals)" and does not consider them to be patentable.[27] This interpretation of Canadian patent law was challenged in the "Harvard mouse" case. Harvard's patent prosecution attempts in Canada proved less fruitful. Canada allows patents on genetically engineered plants and simple organisms. However, Harvard received preliminary and final rejections from the Canadian Intellectual Property Office (CIPO) to the patent application's claims that read on the 'Onco-Mouse' itself. Even, Supreme Court of Canada observed that it was contrary to Canadian public policy to allow the patenting of higher life forms, and held that a transgenic animal did not fall within the meaning of 'invention' in the Canadian Patent Act as it was neither a 'manufacture nor composition of matter'.[28] The court interpreted the term 'manufacture' as a 'non-living mechanistic product or process', and interpreted 'composition of matter' as ingredients or substances that have been combined or mixed together by a person.[29] Justice Bastarche acknowledged that the Canadian Patent Act's scope of patentable subject matter was broad, but that it was not so broad as to include 'anything under the sun made by man'.[30] The majority determined that the 'Onco-Mouse' was not an 'invention' for purposes of the Canadian Patent Act and deferred to the legislature to include higher life forms within the meaning of 'invention' if it so desired.[31]

Indian Patent System and Higher life Forms

India became a member of the World Trade Organization on January 1, 1995.[32] As a member, it was required to comply with the Trade Related Aspects of the Intellectual Property Systems (TRIPS) agreement. The TRIPS agreement requires member countries "to provide adequate standards and principles concerning the availability, scope and use of intellectual property rights and effective means for the enforcement of these rights."[33] Prior to TRIPS, India's patent system had been regulated by the country's Patents Act of 1970 (Patents Act). To begin making India's law consistent with TRIPS, the Patents Act was amended in 1999, 2002 and 2005.

Indian Patent Act also provides that subject matter can be patentable only if it is an invention. An invention under the Act is "a new product or process involving an inventive step and capable of industrial application." This definition was added in the 2002 amendment and is TRIPS compliant. The terms "inventive step" and "capable of industrial application" are defined under the 2002 amendment. An inventive step is "a feature that makes the invention not obvious to a person skilled in the art." The definition given for "capable of industrial application" does not provide additional meaning; however, commentators have said the term is synonymous with "useful."
Prior to the amendment, the Supreme Court of India determined the requirements for a patentable invention. Under the previous law, an invention was "any new and useful art, process, method of manufacture, machine, apparatus or other article, or any substance produced by manufacture." Under this definition, the Supreme Court held that an invention was required 1) to meet the test of "new" and "useful," meaning "novel" and "utility," and 2) to be the inventor's own invention, rather than a "mere verification of what was already known before the date of the patent."

Patentable Inventions

In India legislature is silent about the patenting of multi-cellular or higher forms of life. Although Section 3 of the Act makes clear that plant, animal and essentially biological processes are not patentable. Section 3© of the Indian Patent Act provides, "the mere discovery of a scientific principle or the formulation of an abstract theory or discovery of any living thing or non-living substances occurring in nature is not patentable"

It is quiet clear that it does not prohibit any invention which is result of human intervention, where living beings has been used initially for conducting experimentation.

Moreover, Patent Manual of India reads that 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.[34]

However, Manual of Patent Practice and Procedure (MPPP)[35] take the position that any "living entity of natural origin" is not patentable, nor is any "living entity of artificial origin such as transgenic animals and plants or any part thereof."[36] A "living entity of artificial origin such as a micro-organism or vaccines is considered patentable".[37] Thus a transgenic higher life form is not patentable in India as per patent manual language, but nowhere in the Act it qualifies that Transgenic plant and Transgenic Animal can be treated as plant and animal on equal footing and hence they are non patentable. Rather, legislature has inserted new section for 'New Invention', which might cover the case of higher animals. It reads, "Any invention or technology which has not been anticipated by any document or used in the country or elsewhere in the world before the date of filing of patent application with complete specification, i.e. the subject matter has not fallen in public domain or that it does not form part of the state of the art."[38] However, if we apply the logic of *Dimminaco* case and

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[27] Canadian Manual of Patent Office Practice, *Ch. 16, section 16.05 Living Matter and section 16.04*, Examples of Non-Statutory Subject-Matter.

[28] Harvard College v. Canada (2002) 4 S.C.R. 45 (Can.).

[29] Id. at 153–155.

[30] Id. at 158.

[31] Id at 166

[32] Understanding the WTO: The Organization, available at: http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm (visited on 12.01.11)

[33] Article 72 of the TRIPS Agreement Provides that

[34] Draft Manual of Patent Practice and Procedure, 2008, Patent Office Kolkata, para 4.4.1., p. 56.

[35] India Patent. Office, Manual of Pat. Practice & Proc. (2005), p. 4, available at: http://patentoffice.nic.in/ipr/patent/manual-2052005.pdf.
Like the U.S. Manual of Patent Examining Procedure, the Indian MPPP does not have the force and effect of law. Rather, it is an internal document intended to provide guidance to patent examiners. The contents of this manual including the guidelines are merely for the purpose of illustrations and not meant for legal purposes. In case of any conflict, legal provisions of the Patents Act will prevail".

[36] *Id*. at 141

[37] *Ibid.* The MPPP position that a living micro-organism or vaccine is potentially patentable subject matter is consistent with the landmark decision in Dimminaco A.G. v. Controller of Patents, Designs & Trade Marks, (2002) I.P.L.R. July 255, 269 (Calcutta H.C).

[38] Section 3 (l) , The Indian Patent Act, (subs by Act of 2005).

jurisprudence of *Diamond* case then certainly every development in the area of biotechnology due to human intervention and more than mere discovery will be covered under the domain of new invention. Hence transgenic animal and transgenic plant are covered and should be patentable in India.

Non-Patentable Invention

The Clause 3(j) of the Patent Act 1970 states "plants and animals in whole or any part thereof other than microorganisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals as non-patentable invention". This provision differs from the patent laws of countries like the US, the European Union, and Japan who follow liberal patent standards and where patents are also granted to genetically modified animals and plant varieties.[39] This exception of non-patentability is allowed as per TRIPS Agreement provided member countries provide alternate effective system for protection of plant varieties patentable subject matter in India. In accordance with the available flexibility in the said agreement India has chosen to exclude seeds as well as varieties and species of plants and animals from patentability, and provides sui generis system of protection for the above stated subject matter under the Protection of Plant Varieties and Farmers' Rights Act, 2001. Regarding animal no definition is given under Indian patent Act hence it is not clear that whether it includes transgenic animal or not.

Contrary to Indian position definition of variety of European system does not qualify such restriction regarding transgenic plant in its definition.[40]

Conclusion

We should take note of global means of balancing competing patent interests to reframe the way in which higher life technology is addressed in the intellectual property arena. Considering that under the TRIPs Agreement, there is no general exclusion of inventions in the sphere of animate nature. On the contrary, we read in Article 27 that WTO members *may* exclude from patent protection *plants* other than *micro-organisms* as well as *essentially biological processes* for the production of plants (again, other than microbiological ones). It is advisable to accept the jurisprudent of European Court that while granting patent interest of the society shall be criteria. If majority of society will be benefitted by the research it should be protected under patent system.

[39]Sujit Bhattacharya, "Patenting in Biotechnology", *DESIDOC Bulletin of Information Technology*, Vol. 27, No. 6, November 2007, p. 35.

[40] R. 23b (4) of the EPC.