PATENTING OF ORGANISMS:  
THE DISTINCTION BETWEEN LOWER AND HIGHER 
LIFE FORMS.  

Shyamkrishna Balganesh*  

Introduction  

Biotechnology is amongst the fastest growing sectors in today's global economy. It involves the use of living organisms and products obtained from them in industrial processes. It finds application in almost all forms of industrial activity, ranging from the use of yeast in bakeries to the use of micro-organisms that break the hydrocarbon linkage in oil, during oil spills. 

In recent years, biotechnology has advanced to include larger organisms; from hybrid wheat and rice to high-yielding cows and sheep. Needless to say, it has played and will continue to play a very important role in the development of any economy. In spite of this, the sector does not get the required encouragement for greater investment in research and development. This is evident in several patent regimes, in particular, those of developing economies like India. 

The patent regime is supposed to encourage greater investment in research. Research, being collateral to science, advances and develops with the development of the science. A patent regime must therefore, keep up with the advances in science if it is to meet its objective of encouraging innovation. An outdated patent regime would ultimately prove to be to the detriment of the economy in general and a sector it seeks to encourage in particular. In spite of this understanding, several patent regimes around the world are not very keen to make changes in their patent regimes so as to fall in line with the scientific developments. Hence, it is crucial at this juncture to examine more closely the development of the science in question and to see whether patent laws have adapted themselves to this and if so how. 

The patenting of living organisms, which form the very substance of biotechnology, can be traced back to the late 19th century, when in 1873, Louis Pasteur was granted a patent for a variety of yeast1. Patenting of organisms has 

* II Year, B.A., LL.B. (Hons.), National Law School of India University, Bangalore.  
1 US Patent No. 141, 072. A claim was made for “...yeast, free from organic germs of disease, as an article of manufacture.” The patent was the first among a series of several later patents to be granted for vaccines carrying weak or attenuated micro-organisms. For instance, US Patent No. 273,390 (1883) and US Patent No. 197,612 (1877) both granted for vaccines containing pathogenic organisms with other ingredients. See, Iver P. Cooper, Biotechnology and the Law, 2.5-2.7 (1987).
always been an issue that has raised several legal and ethical considerations. Even today, several nations are yet to recognise the patentability of living organisms\textsuperscript{2}. The situation remained considerably fluid until 1980, when the United States Supreme Court, in the landmark decision of *Diamond v. Chakraborty*\textsuperscript{3}, upheld the validity of a patent claim for a living micro-organism which was made in the laboratory. Since then, courts all over the United States and Europe have begun adopting a more liberal view in deciding the validity of patent claims for micro-organisms. However, with regard to patents for higher, more complex life forms the courts have sought to lay down different standards. A few recent, important instances are those of the *Harvard Oncomouse Decision*\textsuperscript{4} and the *Lubrizol Decision*\textsuperscript{5}.

This paper seeks to analyse the fundamental aspects of patenting of living organisms and further, attempts a scrutiny of the differences between lower micro-organisms, predominantly unicellular and higher complex, multicellular organisms, from the standpoint of patentability.

**Basic Issues regarding Patenting of Organisms**

Apart from the usual requirements of patentability required for any invention which are discussed later, patenting of organisms in general raises several other ethical and quasi-legal questions. Most of them stem from an inherent psychological

\textsuperscript{2} For instance the Indian patent regime.

\textsuperscript{3} 447 US 303; 65 L Ed 2d 144; 100 S Ct 2204.

\textsuperscript{4} [1989] O.J.E.P.O. 451, cited from, Trevor Cook et al., *Pharmaceuticals Biotechnology & The Law*, 118 (1991). This was a case relating to a patent claim for a multicellular organism having a specific gene. While the patent faced little objection in the United States, it provoked a major debate in the European Union. The court initially refused to uphold the validity of the patent since it claimed protection over any descendent of the multicellular animal which would necessarily be derived from an essentially biological process of sexual reproduction. On appeal however, the decision was reversed ([1990] O.J.E.P.O 476) and the court accepted the patent claim as a product-by-process claim wherein the claim was only for the product, irrespective of the process employed to obtain it. In Canada however, the court refused to uphold the claim on any ground since, it felt that the novelty was only with respect to the new gene and not the entire mouse as a whole, which could not be manufactured. See infra., n. 37.

\textsuperscript{5} [1990] O.J.E.P.O. 71; [1990] EPOR 173 cited from, Trevor Cook et al., *Pharmaceuticals Biotechnology & The Law*, 118 (1991). This was a case relating to Lubrizol's patent, which had a process claim for a process of rapidly developing hybrids and producing hybrid seeds and product claims for the hybrid seed which was supposed to be phenotypically uniform. The European Union specifically prohibits a patent for a plant or animal variety; however, for it to be a variety it must exhibit homogeneity and stability. Since these two were lacking in this case, the court held that it was not a patent for a plant variety and therefore patentable. This decision is of relevance mainly because the courts hereafter in similar cases began adopting a sympathetic attitude in interpreting the boundaries of patentable subject matter.
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distinction one tries to make between an object and an animate creature. The idea that a person can manipulate life in a laboratory and claim a patent for the same is something considered unacceptable by a great majority of people. Nonetheless, the fact remains that the problem lies in perception i.e., how one looks at the organism. To a scientist it represents a series of complex biochemical reactions which can be comprehended, while to laymen it may seem as a creation of God, 'living' and flourishing. The concept of patenting living organisms and 'life', as some would call it, has presented courts with several questions and issues.

As stated earlier, many people do hold the view that life and creatures are God-given and a natural part of the biosphere, which no one has the right to control by means of a patent or otherwise. Further, fears also exist that manipulation of life forms will go out of control, resulting in resistant bacteria and viruses. These views, however, leave one major issue unanswered. If an individual is able to get to the bottom of 'life', what precludes him from obtaining a patent to compensate for his efforts? One has to realize that science and technology are progressing very rapidly, and that the law has to keep pace with them if it has to serve its purpose of regulating and maintaining society.

This conservative approach has been ascribed to a theory known as the 'doctrine of vitalism', which believes that organisms are endowed with life which gives them unique powers and capabilities. The doctrine has, however, been rejected throughout the world, owing to the fact that life has been shown to be made of complex, yet understandable physiochemical processes. Closely related to this doctrine was another one, namely that of 'a law of nature'. This doctrine was first

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6 For instance, the amicus brief filed by the Peoples' Business Commission (PBC), in the United States Supreme Court. The brief stated, "...that if patents are granted for micro-organisms, there is no legally viable definition of 'life' that will preclude extending patent protection for higher forms of life..." This goes to show that 'life' is viewed as something beyond human understanding and control, something humans have no right to control, end or manipulate. PBC Amicus Brief Pat., T.M. & Copyright J. (BNA), Feb 7, 1980 at E.1,E-2, cited from, Iver P. Cooper, supra., n. 1 at para 2.37.

7 The very basic objective of a patent right as such, is to encourage innovation. If a person knows that at the end of a series of laborious experiments that last over several years, he will get his due recognition and an exclusive right in the form of a patent, it would undoubtedly encourage such research. One must not forget that there is a *quid pro quo* in a patent system. The patentee has to divulge all his research results and techniques, so that it will facilitate further research and for this, he is granted an exclusive right to prevent others from using his invention. The system is by no means one sided. Further, a patent is just not granted for any invention. The invention must have a beneficial nature; something referred to as 'utility' and is discussed later.

8 The doctrine was rejected in *In re Bergy*, 596 F.2d 952 and also in *Ex parte Schreiner*, 1 Int'l Rev. Indus. Prop. & Copyright L. 136; cited from Iver P. Cooper, supra., n. 1 at paras 2.45-2.46.
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raised in the case of Funk Bros. Seed Co. v. Kalo Innoculant Co. Here, the court held that the inhibitive qualities of a bacteria were inherent works of nature and therefore, not patentable. An analogy was drawn to the heat exuded by the sun and other natural phenomena. Hence, the validity of the patent for the utilisation of the property of the bacteria was rejected. Such a distinction appears at the very outset to be illogical, since, at a deeper level all actions can be said to be dependant on some law of nature. To exclude an invention which has utility simply because it was a discovery of an existent but unknown phenomenon is to say that even if you find something totally new, which has significant utility to mankind, you cannot patent it simply because you found it, you did not invent it. This goes to the very basis of the distinction, which is sought to be made between an invention and a discovery. Why should one be patentable and the other not? Further, showing utility of a discovery is equivalent to ‘inventing a discovery’, crudely speaking.

In this suit, which was one for patent infringement, the respondent had obtained a patent for a mixture of certain strains of micro-organisms of the genus Rhizobium, which converted atmospheric Nitrogen into nitrates in the soil and could therefore be used with certain leguminous plants. Until that time, though it was known that certain bacteria were responsible for the process, the fact remained that each species of the genus was very specific in its infection of leguminous plants. As a result, identification was a problem. Further, a mixture was not possible since the several strains also inhibited the growth of one another and were ineffective. The respondent, through a series of tests found that certain strains of the bacteria were non-inhibitive mutually and could therefore be used as a mixture to avoid the other mentioned difficulties. He had obtained a patent for the mixing of the strains. The appellants had begun selling of a similar mixture and he sought to prevent this. The lower court found in his favour, while the Supreme Court ruled against the respondent.

Every action that takes place is ultimately regulated by some law of nature. Movements of machines, at the basic level are due to the law of gravity, electricity is due to the movement of electrons in atoms; this however, would not preclude the patenting of a new machine or the patenting of a new process of generating electricity.

A patent for a micro-organism may at a very basic level be of two kinds. It can be for a genetically manipulated micro-organism or on the other hand for the isolation of a new micro-organism. While utility is a prerequisite in both cases and is a less contentious issue, the issues of novelty and non-obviousness are far more contentious ones.

If a micro-organism, previously unknown is isolated from nature and utility is found for the same, then the primary objection that is raised is that the organism was discovered and not invented and therefore not patentable. The micro-organism however can meet the three requirements of patentability; it is novel since it was previously unknown to the public and in this sense is not yet a part of the existent prior art, utility as mentioned already exists and thirdly with regard to non-obviousness, since the isolating of the new organism and finding utility for it is through extensive research and to this extent involves ingenuity, a clear inventive step is present and it is therefore not obvious to a person skilled in the art. With regard to a micro-organism that is genetically manipulated in the laboratory, the first two requirements of novelty and utility are clearly present. In this case too a distinct inventive step exists and is much more apparent than in the previous case. Thus, if the requirements of patentability are interpreted liberally and reasonably, they most definitely will include micro-organisms.
At this point, it is apt to discuss the basic statutory requirements of patentability. Patent regimes all over the world\(^\text{12}\) as also the recent TRIPS agreement, require an invention to be novel, involve an inventive step and have utility, sometimes referred to as "industrial application".

The concept of novelty requires that the invention must be new. 'New' here, has a specific meaning attached to it. It is not the same as abject or absolute novelty. The requirement is that the invention should not be made available to the public in any form or should not exist in the prevailing state of art at the time of filing for the patent. If such an invention is prevalent among the public, it is part of the 'prior art' and therefore would lack novelty. As a result it would be not be patentable. So, the invention must be new, in the sense that it is not known to the public or 'published'\(^\text{13}\).

The requirement of inventive step is also referred to as the requirement of non-obviousness. This means that the invention should not be obvious or natural to a person having sufficient knowledge in the art. It should be non-obvious and must require an inventive step, an innovation arising out of some ingenuity. This concept has always been an ambiguous one\(^\text{14}\).

The previously mentioned objections of 'law of nature' and 'product of nature' are founded on these two requirements of patentability. Micro-organisms are part of nature, freely found and are therefore not new, not an invention. Further, since they exist out there, they are obvious to the diligent researcher and definitely


\(^{13}\) The term published here does not refer to mere literary publication. It includes any form in which the information is made available to the public. Nevertheless, this includes prior research publications, prior patent applications, prior patents and even practices prevalent among the public. As regards novelty, the invention may even be said to be published when it is demonstrated to prospective buyers. On the other hand, disclosure of the invention in confidential terms or in secrecy is not considered equivalent to publication. See, *C.I.P.A Guide to the Patent Acts*, 32-33 (1990).

\(^{14}\) Several tests have been suggested by courts to assess non-obviousness. One such test was suggested in *Graham v. John Deere*, 383 US 1, where the US Supreme Court set out the conditions to be looked into;

a) The scope and content of the prior art has to be determined.

b) The differences between the prior art and the claims at issue are to be ascertained.

c) The level of ordinary skill in the pertinent art has to be resolved.

d) Based on this, the non-obviousness has to be ascertained.

The concept of non-obviousness was introduced in the United States in 1952 and since then has been a major criterion for judging patentability. However, all these tests involve a great deal of subjectivity and discretion on the part of the courts. See generally, 60 Am. Jur. 2d § 22-43.
not dependent on any inventive step. However, these arguments have two major flaws. As regards, the micro-organism not being new, no patent law draws any distinction between 'old' and 'new'. Novelty means knowledge of the public, something, which a new micro-organism will possess. Also, if micro-organisms were obvious and parts of nature, why does such elaborate experimentation go into the process of identifying new organisms and their characteristics?

With regard to the requirement of non-obviousness, the question that has arisen before the courts on some occasions has been whether modifications in products of nature, which result in products of utility, are patentable. The courts seem to have adopted the view that if a product of nature is altered substantially, resulting in a drastic change from the original product, the object is patentable and not otherwise.

The final requirement of patentability is utility or industrial application. This does not mean commercial exploitability. It only seeks to prevent frivolous

15 This could possibly mean rethinking the entire concepts of 'novelty' and 'non-obviousness'. Novelty, in the traditional sense as it is used refers to the addition of something new into the existent art. The subject matter of the patent must therefore, not be known to the public prior to the publication. With advances in biotechnology, by manipulating a few gene sequences in a micro-organism it is possible to create practically new organisms. The major problem therefore is whether the new organism will fit into the traditional notion of novelty since it is only a modification of the known organism, however major the modification is, and therefore may form part of the prior art. The modified organism would also not fit into the category of improvement patents in the true sense. Hence, what is imperative is to adopt a new standard to determine novelty with regard to micro-organisms. One such approach could be to disregard the presence of the organism in nature and to look at the extent of novelty within the modified organism. Whatever approach is adopted, one thing is for certain; the traditional notion of novelty must either be completely modified or expanded considerably.

Similarly, the concept of non-obviousness too has to be re-thought. The traditional notion requires the subject of the patent claim to involve an inventive step. The very idea of 'inventive step' has led to objections being raised with regard to micro-organisms that they are not invented but are either discovered or are modified products of nature. The very concept has remained ambiguous for several years and courts are yet to come up with a truly objective set of guidelines to judge obviousness. Currently used guidelines do not consider the amount of experimentation that goes into producing or alternately isolating a new organism. The criteria should therefore be modified to include a judging of the amount of experimentation that is involved with regard to the patent subject matter and the degree of difference between that which is existent in the prior art and that which is claimed in the patent. These ideas need to be seriously reconsidered.

16 In American Fruit Growers v. Brogdex Co., 283 US 1, the court refused to hold valid a patent claim for an orange which had been modified so that its skin included a borax rind that made it resistant to mould decay. However, the court adopted the near opposite stand in Steinfur Patents Corp. v. William Beyer, 62 F. 2d 238, cited from, Iver P. Cooper, supra., n. 1 at para 3.25, and held that successfully bleaching furs and utilising them to be coloured differently was a patentable modification of a product of nature.

17 It is not necessary that the invention for which a patent is claimed should be marketable for it to possess utility. It must have 'industrial application' in the relevant field. While commercial success is a notion that is taken into consideration by courts in determining utility, it is not an absolute criterion. Thus in the case of Eibel Process Co. v. Minnesota & O. Paper Co., 261 US 45, the court said that commercial success was weighty, but not conclusive evidence of utility.
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patents, which do not have any use or application. This requirement has been recognised however, even in the patenting of micro-organisms. Patents are not granted for all micro-organisms, just because the organism is novel. It must have some useful property or function\(^1\).

However, it must be noted that in recent times, courts have begun giving a more liberal interpretation to these concepts and have acknowledged the fact that no definite standards can be set. The requirements vary from case to case depending on the exact circumstances. In the process they have begun looking at micro-organisms as patentable inventions\(^2\).

**Problems regarding Patenting of Organisms**

As stated, courts have indeed begun looking at micro-organisms as patentable subject matter. In spite of this, several practical and theoretical difficulties do exist, in filing and prosecuting a patent application for a micro-organism.

Several options are available to a patentee when filing a patent claim for a micro-organism. The claim can be filed for;

(a) the process of producing the organism
(b) the new organism produced by the novel process\(^2\)
(c) the new organism *per se*
(d) the process of using the organism
(e) the product obtained from the organism\(^2\)

Among these the most common claim is that stated in (d); for using the organism to obtain something\(^2\). Here the claim is not for the product obtained, but

\(^1\) Thus, just because a mutant variety of a micro-organism, which has the same properties as existent micro-organisms, is created, a patent will not be granted. The micro-organism so created must have some *utility*, some advantages over the existent micro-organisms. It may have advantages in the industry such as in the manufacture of vaccines and antibiotics; or it may be easy to produce in large quantities for research and other purposes.

\(^2\) Several nations like India do exclude all living forms from patentability. However, a distinct attitudinal change is perceivable. Some nations like Korea have started including life forms under patentable subject matter. The TRIPS agreement too, under Article 27 (3) (b) requires all signatories to provide patent protection to micro-organisms. This is clear indication of the changing attitude. See generally, Jay Yang, *Korea Revises Standards for Biotech Inventions*, IP Worldwide, January/February 1999, at pp. 28-29.

\(^2\) The *Polypeptide Expression Case*, [1989] O.J.E.P.O. 275, cited from, Trevor Cook et al., *Pharmaceuticals Biotechnology & The Law*, 123 (1991), where the claim was for a new bacteria produced from a process of introducing a plasmid into it.

\(^2\) As in the case of patents for certain antibiotics, vaccines and more specifically Vitamin B-12.

\(^2\) Some examples are: US Patent No. 4,634,670, wherein the claim was for a process of producing a cellulose, using micro-organisms of the genus *Trichoderma*; US Patent No. 4,328,312, wherein the claim was for producing a peroxidase using the micro-organisms of the genus *Mycothecium*.
for the novel approach of using the organism to achieve it. Well known examples include the utilisation of micro-organisms to produce vitamins, enzymes or antibiotics. Objections have however, been raised with regard to this form of patents too, saying that what was being patented was nothing more than a process of nature. Fortunately, courts have been reluctant to give any great significance to this defence.

The greatest problem however, arises in attempting to patent the micro-organism per se. If a micro-organism is to be claimed in a patent, it essentially means that the micro-organism should be defined. Therein lies the difficulty. Further, the micro-organism should be described in such a manner that people skilled in the science should be in a position to reproduce or obtain the organism.

One approach has been to describe the organism in terms of its name, morphology and biochemical characteristics. This is not sufficient to totally describe the organism. So a new method which was evolved was that of depositing a strain of the micro-organism claimed with a certified depository. However, the problem still persists; the question whether the claim is for the strain deposited and descendants of it or any other micro-organism that is substantially similar. However, not much judicial consideration has arisen over this issue. A third, more practical, method of claiming a patent on micro-organisms is by claiming the organism based on its utility; the so-called ‘functional definition’. Whatever is the method of claiming, the problem is still not solved. For instance, if a person claims to have isolated a new variety of micro-organisms or to have genetically produced a new variety, how can one be certain that the variety can be reproduced in exactness for

23 In the case of Cameron Septic Tank Co. v. Village of Saratoga Springs, 159 Fed. 453, the claim was for a new process of treating sewage using bacteria. The court rightly interpreted that what was being claimed was not the process of anaerobic decomposition but the process of anaerobic decomposition using bacteria and hence held the claim to be valid. In Guaranty Trust Co. v. Union Solvents Corp., 54 F. 2d 400, a similar view was taken and the defence of ‘process of nature’ was openly rejected. See, Iver P. Cooper, supra., n. 1 at para 2.4.

24 Further, to bring about co-ordination among the collection agencies, the Budapest Treaty was signed by several nations in 1977.

25 For instance, US Patent No. 3,003,925, which claims the use of a new species to produce a glutamate or UK Patent No. 952,820, which claimed a strain of an organism which produced tetracycline. It must be borne in mind that in India, though the Patent Act of 1970 does not explicitly prevent the patenting of micro-organisms, patent offices are reluctant to grant patents claiming organisms by bringing micro-organisms under the list of unpatentable subject matter as enumerated under Sec. 3 (a) of the Indian Patent Act. Patents, which have been granted regularly so far in relation to micro-organisms, are those for the process of using the organism or for the process of producing or isolating the organism. See generally, Sudhir Ahuja, IP Treaties Show Little Effect in India, IP Worldwide, January/February 1999, at pp.21-24.
which exact conditions would be required. This problem has been encountered very frequently in German courts.

Thus, we see that courts have progressed from a time where they considered micro-organisms unpattentable due to their animate nature to a stage where they have started recognising methods of collecting new organisms and storing them. However, this attitudinal shift has not been uniform. Several nations, like India, do not openly allow patenting of micro-organisms, nor are they members of the Budapest Treaty. No doubt patenting of micro-organisms has several technical and legal problems as have been discussed; however, this does not justify the complete exclusion of their patentability. These nations should draw on the experiences of the courts of the USA, UK and the European Union, to answer queries and ethical questions that prevent them from allowing the patenting of organisms. It is never too late. Hopefully, the TRIPS agreement will at least partially result in a unified system of patent protection for micro-organisms.

Going Beyond Micro-organisms to Higher Life Forms

If one thought that the problems associated with patenting of micro-organisms were complicated, then the problems of patenting higher life forms are enormous. This however, is understandable and, to a certain level, justified. Even today, very few nations openly allow patenting of all higher life forms.

In the USA, the patenting of higher life forms can be traced back to Ex Parte Allen. In this case, the court held that polypoid oysters per se were patentable subject matter. However, the major controversy and international response arose later, in the patent today infamously known as the Harvard Oncomouse Patent.

26 See, R.S. Crespi, Patents: A basic guide to patenting in Biotechnology, 95-96 (1988).

27 The distinction between animate and inanimate was negated in the case of Diamond v. Chakraborty, 447 US 303 and also in the German case of Ex parte Schreiner, 1 Int’l Rev. Indus. Prop & Copyright L. 136, referred to at supra., n. 8.

28 The European Union (EU), in its new Directive on the Legal Protection of Biotechnological Inventions, has attempted to solve several of the older controversial questions such as biodiversity and ethical considerations. It now allows patenting of micro-organisms. India and other countries which do not allow such patenting as of now, should follow this example; they should look at the decisions of the US and UK courts to solve the traditional problems associated with patenting of life. See generally, Ian Judge and Mathew Frankel, European Parliament Approves Biotech Directive, IP Worldwide, September/October 1998, at p.3.


30 US Patent No. 4,736,866 granted in 1988. Researchers at the Harvard University, using methods of genetic engineering, were able to introduce a specific gene into the genome sequence of a mouse as a result of which the mouse was unduly susceptible to cancer. The patent was sought not only for the process, but also for all non-human mammals having the said oncogene in their genome.
The US Patent and Trademark Office (USPTO) granted a patent for all non-human eukaryotic animals having a non-natural gene. Subsequently, a similar patent was sought in Europe. This however, faced numerous objections and in the process several issues of ethical, legal and environmental concern were raised. Many individuals felt that if patenting of multicellular organisms was allowed, the day would not be far when people would artificially begin to clone humans with desired characteristics. Further, it was also feared that it would result in a drastic modification of natural creatures, as many of them would be in danger of being wiped out or drastically modified. Thus, several eugenic issues and issues related to biodiversity were voiced.

These views, however, disregarded the benefits that would accrue from such research. The output of crops could be enhanced, the yield of milk multiplied, the longevity of dairy animals altered, the nutrition of meat increased, so on and so forth. The possibilities are innumerable. If cows, which could go without water for several days, could be created, could not the food and water shortage in Africa be alleviated to a certain extent? If disease resistant cattle were introduced in third world nations, could not poverty be alleviated to a large extent? To facilitate research in these directions, patents for protecting and rewarding hard work are necessary. The previously mentioned fears are however, not without any truth in them. So, what should be sought is a balance between the two, to have the best of both worlds. On one hand you should have disease resistant high yielding cattle, and on the other all the naturally occurring cow varieties, in equal numbers. But is such a scenario a possibility? Could a legal model seek to achieve such a situation?

If a balance has to be struck, it is essentially about striking a balance between public and individual interests. While a completely conservative approach could prove disastrous for the biotechnology sector, a completely open and free policy would prove to the detriment of the environment, and ultimately, the people. The policy that ought to be adopted, should lie between the two. This can be achieved

31 It was feared that people would start choosing the qualities they wanted in their children, thereby leaving nothing to nature. This would also be against the interests of the human race, eugenically. This issue has raised another very crucial debate; whether to allow cloning of human beings or not. This debate involves ethical and legal considerations. The ethical consideration involves the fact that if human life could be controlled and produced in the laboratory, every couple would opt for a perfect child, thereby leaving little to chance. Further, if identical clones were created, the value of life would definitely be questioned, with people knowing that if one life is lost, another of an identical nature could be re-created. The legal consideration, which is closely related, relates to human rights. By being able to control life in a laboratory and expose it to changes, the individual would be under the control of other humans. These issues are yet to find acceptable solutions. See generally, The Ethics of Human Cloning, at (visited on 14th March, 1999) <http://www.houston.isd.tenet.edu/hspva/academic/Science/Thinkquest/gail/text/ethics.html>.
by selective regulations, prohibiting certain forms of patents; a rational and judicious approach. Further, a policy must be open to change in accordance with the development of the science concerned.

A better understanding of what a policy should envisage can be got by looking at the position of biotechnological patents in different countries.

**United States of America**

Very similar to the approach it has adopted in all other sectors, the USA is also very free about patentable subject matter in the biotechnology sector. This is characterised by the fact that it is the only country to date, to openly allow and grant patents for advanced and higher life forms. As can be expected, this liberal approach followed by the US courts and the patent offices, has resulted in a great boom in the biotechnology sector. The courts have come to follow what is today known as the ‘hand of man’ approach. This means that if any matter is sufficiently manipulated by human ingenuity, irrespective of its nature, it is patentable. Needless to say, the courts never make any distinction between lower life forms and higher ones. They only go on the openly exclude patenting of human organisms, which is one of the very few restrictions on the subject matter of patentability.

This approach however, completely disregards ethical and environmental concerns, many of which are genuine. The effects of such a capitalist approach will have to be seen over a long period of time and will probably not be discernible in the immediate future.

**Canada**

In comparison with the approach of the USA, the Canadian approach could be termed ‘conservative’. The courts here appear to not be ready to take bold,
innovative decisions. In the case of *Re Application of Abitibi Co.*, the court relied on *Diamond v. Chakraborty* and allowed a claim for a micro-organism. In a subsequent case, however, the court refused to allow a patent claim for a plant variety. In the more recent case of *President and Fellows of Harvard College v. Commissioner of Patents*, the court refused to validate the patent claim for the Harvard Oncomouse. In its ruling it very clearly stated that higher life forms were not patentable subject matter since they could not be reproduced in exactness. Whether the court liked it or not, it had made a distinction between lower and higher life forms.

**European Union**

The approach that comes closest to a balance between the two interests is the one adopted by the European Parliament in its new Patent Directive. This is one of the few policies that have open regard for ethical and environmental concerns. It however, also seeks to encourage investment in the biotechnology sector. The directive very clearly allows patenting of micro-organisms and processes related to them. The directive also allows patenting of transgenic plants and animals. However, with regard to patents on plants and animals, it permits them so long as they do not relate to an entire variety.

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36 *Pioneer Hi-bred Ltd. v. Commissioner of Patents*, [1987]3 F.C. 8, cited from, supra., n. 34 at p.164. This was a claim for a variety of soybean and it was rejected by the court on the grounds of unreproducibility.

37 T-275-96 (unreported) discussed in Brian Gray, supra., n. 35.

38 In arriving at this decision the court sought to answer four questions:

*Is it appropriate to examine the degree of the inventor's control over the creation of the claimed invention?* The court held that while absolute control was not essential, a reasonable degree of control was a must. That was found lacking in this case. Only the gene could be controlled, not the entire mammal.

*Is it appropriate to distinguish between laws of nature and human intervention?* The court held that most biotechnological inventions were a combination of the two and a distinct line could not be drawn.

*What is the relevance of the test of reproducibility in the present instance?* The court held that only the existence of the oncogene was reproducible, while the variations in the other characteristics of the mice were many. It considered the test quite appropriate in this case.

*Is it appropriate in determining whether something is patentable subject matter to make distinctions between higher and lower life forms?* The ruling felt that this was a matter to be decided by the legislature. However, by its very decision, the court had made the distinction.


40 See Article 3.1.

41 See Article 4.2.
The directive also has clauses, which allow the exclusion of certain items from patentability in the interests of public morality. This is basically an ethical consideration. Techniques of altering and cloning humans are explicitly prohibited. This model also seeks to protect the rights of farmers, in the event of patenting of animals and plants. On the whole, the model seems to strike a comprehensive balance. It however, has its own drawbacks.

A Possible Solution

The three models looked at in the preceding part serve as excellent examples of patent regimes wherein the limits as to the extent of patenting organisms are to different degrees. These models can be contrasted with the approach of nations like India, where patenting of life forms is still disallowed.

What then would be the best approach? While completely opening up the patent regime to include all forms of organisms indiscriminately would be too liberal an approach, completely excluding patenting of life forms would be too narrow an approach and could in the long run prove disastrous for biotechnological research. Therefore, the approach should preferably be mid-way between these two and should be extremely judicious.

It would seem that the best alternative to the extremist positions is selective allowing and disallowing of patents on life forms. At the very outset, it must be conceded that a selective approach can never be purely objective and therefore a standardisation may not be possible at an early stage. However, certain fixed guidelines can be followed in selectively allowing patent claims. If this selective approach is followed, then drawing the distinction between lower and higher life forms could be done away with too.

Fundamental to this approach should be the question; whether the claimant has ostensible control over the organism claimed in the patent. The importance of this requirement lies in limiting the claim of the invention to that which is really novel. This is especially so in cases where the claimant has genetically manipulated an organism and however, has claimed a patent for the entire organism possessing the genetic manipulation. The concept of control has to be determined from the extent of homogeneity and stability in the organism claimed. If all the organisms

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42 For instance, the exact meaning of 'plant or animal variety' is an issue, which is yet to be settled. Further, it is upto the judiciary to decide whether a biological process is essential and therefore unpatentable or not.


44 The idea of ostensible control was used by the Canadian court in the Harvard Oncomouse Case, supra., n. 37. There, the court held that since the patentee could not exhibit apparent control over the organism, the patent was invalid.
of the said kind are uniform and can be reproduced with a great degree of homogeneity, then it would demonstrate sufficient control and would satisfy this requirement.

Subsequently with advances in science, the day is bound to arise when it would be possible to control every single character of the organism in a laboratory, by deciphering the genome sequence. In such cases, if through homogeneity in the offspring and stability in the characters, the inventor is able to demonstrate substantial control over the organism, then the claim should not be disallowed merely because it is a multicellular organism. Thus, the guideline of control serves a two-fold purpose; on one hand it prevents frivolous broad patent claims and secondly, it prevents a rigid line of demarcation between higher and lower life forms.

This guideline too, will most definitely have its own demerits. These demerits however are not without remedies. For one, whether reproducibility with homogeneity and stability are true indicators of control and whether further analysis is necessary. These two criteria however are subject to expediencies to be adopted by the different patent regimes. Thus, one regime may find external homogeneity sufficient, while another may look at genotypic homogeneity. These immediate modalities should however be left to the patent regimes to decide upon and both the methods, though they have their own disadvantages can be used to ascertain control. Another factor is that absolute control may not always be possible and to disallow a patent merely because one nucleotide is different may be a little too harsh. Thus, the control must be 'ostensible' and reasonable.

45 For instance, in the case of the Harvard Oncomouse, the novelty was with regard to the introduction of the 'oncogene' into the genome of the mouse. The claim however, was for the entire organism possessing the manipulation and further, for all multi-cellular organisms possessing the said gene. When the manipulation was with regard to a single gene, then how can the claim be for the entire organism over which actual control would be truly impossible. Though a new gene would be controllable, the novelty is not with respect to other characters like colour, nature of the fur, etc, which were beyond the control of the inventors. Thus, a claim of this sort should be disallowed and the narrow claim should be permitted such as a claim for the 'new gene capable of being inserted into all multi-cellular organisms'. The concept of control here is strictly confined to control over the characteristics of the organism and does not extend to control over the activity of the organism. Thus, the claim in the Harvard Oncomouse patent, for all multi-cellular organisms possessing the gene would fail, because the genes controlling other characteristics in the organisms would be beyond the control of the inventors, as described in the specification.

46 External homogeneity may be due to other reasons and may not necessarily reflect identical organisms. Thus, in cases where the novelty is with regard to a few genes the organisms produced may be identical. In such cases, courts should use their discretion and in the event of prima facie control over the organism being absent, the patent should be disallowed. To ascertain prima facie control, the courts should look at what is novel in the genome and what is claimed. Examination of genotypic homogeneity to ascertain control may prove to be extremely tedious and extremely time consuming.
Another aspect, which the selective allowing process should look into, is the process of excluding specific organisms from the realm of patentability owing to social, ethical and economic circumstances prevalent. For example, a major controversy has arisen whether cloning of human beings should be allowed and if it is, if patents for the same should be permitted. This has led to patent regimes like the USA banning patents on humans. Similarly, if the economy of a nation is greatly dependent on a particular species of animals for its development, then that species should be excluded from patentable subject matter. This must therefore, depend on economic and ethical standards prevalent in society. The exclusion should not be a blanket one so as to exclude an entire category; it must be situation based and most importantly should be narrow and justifiable.

The entire process of selective allowing of patents on life forms may seem lacking in objectivity. Objectivity however, can arise only after the system gets used to the new approach. It must be done on a case-to-case basis. It thus serves as a form of ‘selective control’; whereby freedom is granted in a majority of areas, while reasonable restrictions are placed on a few areas.

Conclusion

Based on the previous discussion, it is seen how the concept of patenting living organisms is at the very outset very tricky and unpalatable to several. This is possibly the major reason why nations like India have not allowed it. It is however, suggested that such an approach is not the solution. Biotechnology being one of the fastest growing sectors and to completely disregard that sector would be to the detriment of the economy. While it is conceded that the issues relating to higher life forms are extremely complicated and are often based purely on ethical considerations, it is felt that issues relating to patenting of micro-organisms are not as complicated. Conveniently enough, for nations that have not yet provided for such patent protection, the problems and solutions have been dealt with by the developed countries. Hence, one can selectively draw on the experiences of those nations to develop a suitable method of patent protection for micro-organisms.

This would not mean completely disregarding national requirements. A judicious, but open approach is necessary to provide patent protection in the biotechnology sector. The distinction between lower and higher life forms should not be one of a rigid line of demarcation. Selectively, the distinction should be

47 For instance, under the TRIPS agreement, member nations are allowed to exclude certain matter from the list of patentable subject matter in the interests of national and public morality. In addition to this, temporary exclusion should also be permitted in the interests of economic independence of the nation. It however is emphasised that these provisions should not be misused but should provide only reasonable restrictions.
brought about through the process of ‘selective exclusion’ as described in the
previous part and used by the Canadian court to disallow a patent for the Harvard
Oncomouse. A standardised system of distinguishing between patentable and
unpatentable life forms must be developed. The traditional, anachronistic attitude
of staying away from the problem by excluding all forms of life forms from
patentability must go. It must be realised at the very outset, that law has to be
susceptible to changes in society for it to have any relevance. The changes however,
should be made after a cost-benefit analysis and in the present instance, the change,
which is to include life forms within a patent regime, would undoubtedly have
more advantages than disadvantages.

Thus, it would be appropriate to conclude by saying that the distinction
between higher and lower life forms is a necessary evil. One cannot afford to have
it as absolute, but at the same time one cannot afford to do away with it.