



# Study of Legal Protection of Biotechnological Advancement

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## Abstract:

*In this paper an attempt is made to reflect the emerging social and scientific paradigm of biotechnological research and the need for effective legal protection for such technological advancements. The imperative study of IPR protection has been considered.*

**Keywords:** *Biotechnology, Biochemistry, microbiology, Bioprocessing technology, Hybridoma and monoclonal antibody technology, Cell culture, Recombinant DNA technology, Cloning, Genomic and proteomics, Microarray technology, DNA fingerprinting, patent, bioproduction, Trade mark, servicemark, Geographical indication, Copyright, Patent design, sui-generics, TRIPS, biopiracy, RNA, DNA, cDNA*

## 1. Introduction:

Biotechnology is as old as human civilization and has been an integral part of human life. In traditional parlance biotechnology has been the natural process since many centuries to produce beer, wine, curd, cheese and many other food products. The modern biotechnology extends to all the genetic manipulation, cell fusion techniques and the improvements made in the old biotechnological processes.

The word biotechnology describes the convergence of two fields i.e.: -biology and technology. The creative ability of man is fast advancing in such a direction that it has tried its best in producing many human life and products. Biotechnology has been defined as the integrated use of biochemistry, microbiology and engineering sciences in order to achieve technological (industrial

application of the capabilities of microorganisms, cultured tissue cells and part thereof.<sup>1</sup> It has been also defined<sup>2</sup> as the controlled use of biological agent such as organism or cellular components for beneficial use. This sphere is not only concerned with life forms such as plants, animals and microorganism but also concerned with nonliving or dormant materials such as seeds, cells, enzymes plasmids etc. It assumed popularity in 21<sup>st</sup> century in technological innovation. Following is some of the vistas of modern application in biotechnology.

1. Bioprocessing technology:<sup>3</sup>
2. Hybridoma and monoclonal antibody technology<sup>4</sup>:

<sup>1</sup> [www.biotechnology4u/basic-concepts/biotechnology, Feb, 2013](http://www.biotechnology4u/basic-concepts/biotechnology, Feb, 2013)

<sup>2</sup> Dr. Sanju Thanvi, "Intellectual property and biotechnology" Nov 2012, vol 3, LP, 65.

<sup>3</sup> It is process that uses complete living cells or their components (bacteria, enzymes, chloroplasts) to obtain the desired products. [www.wikipedia/bioprocess, April 2013](http://www.wikipedia/bioprocess, April 2013).

<sup>4</sup> It is used in production of Hybrid cells. These cells are produced by fusing B lymphocytes with tumor cells and they are called myeloma cells. Thus these cells have the capability to produce antibodies due to B-lymphocytes cells and has the capability to divide indefinitely in the culture due to presence of tumor cells. These are cultured in the laboratory using mouse peritoneal cavity and these cells produce monoclonal antibodies and overall it is said to be hybridoma technology.



3. Cell culture.<sup>5</sup>

4. Recombinant DNA technology<sup>6</sup>

5. Cloning<sup>7</sup>

6. Genomic and proteomics<sup>8</sup>

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[www.biotecharticles.com/others-articles/Hybridoma-technology,April](http://www.biotecharticles.com/others-articles/Hybridoma-technology,April) 2013.

<sup>5</sup> This branch has developed from called toxicology and this branch deal with poison .When poison is administered into the living organism. With help of this technique many anti cancer, clinical drugs and pesticides are prepared. By applying the toxicology cell culture is needed in which the cells are grown and maintained at an appropriate temperature and gas mixture (typically 37 degree centigrade, 51%Co2 for mammalian cells) in a cell incubator. [www.toxicologyguide.com/943-cell-culture-technique/April](http://www.toxicologyguide.com/943-cell-culture-technique/April) 2013.

<sup>6</sup> This technology helps in isolate and clone single copy of a gene or a DNA segment into an indefinite number of copies, all identical. This new combination of genetic material or rDNA molecules are introduced into host cells where they propagate and multiply and this is termed to “Genetics engineering”. [www.biotechnology4u.com/basic-concepts/recombinant\\_dna,April](http://www.biotechnology4u.com/basic-concepts/recombinant_dna,April) 2013.

<sup>7</sup> All the individuals derived by asexual reproduction from a single original individual. In molecular biology, a strain of organisms that carries a particular DNA sequence. A plasmid or a phage that carries an inserted foreign DNA to be introduced into a host cells. [www.biotech-now.org/enviromental.ind,April2013](http://www.biotech-now.org/enviromental.ind,April2013).

7. Microarray technology<sup>9</sup>

8. DNA fingerprinting<sup>10</sup>

Visualizing the above dimension of biotechnological developments, the WEO released a list of 10 ways by which the life can be improved through biotechnology. The list is filled with developments related to industrial and environment biotechnology including bio-production of sustainable chemical energy and other materials. Through biotechnology process living organisms such as bacteria, fungus or plants can be used to create fuels, chemicals and many other products. With the help of this not only there was an improvements in providing security to nation’s energy as well as it minimized the dependence on foreign sources.

In 10<sup>th</sup> annual world congress bio-conference it has been found that industrial biotechnology has become the core point of discussion and the issues included:-

-the sustainability of biotech sector and its work towards R&D to commercial deployment as it requires heavy investment.

-the role of industries and that of the govt. is in developing bio-refineries and by product sector.

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<sup>8</sup> The study of the structure and function of genomes. Large scale characterization of the entire protein, complement of cells, tissues, and organisms is called proteomics [www.forumblog.org/feb,2013](http://www.forumblog.org/feb,2013) .

<sup>9</sup> Large number of DNA spots present on a glass slide representative of the total mRNA of a cell, used for detecting expression patterns.

<sup>10</sup> A technique for the identification of individuals based on the small differences in DNA sequences.



-the progress of industries in making the cellulose fuels a commercial reality.

As it has been cited above the faster growth of biotechnology in different area as especially in the area of inventions is to be protected and to restrict the abuse of such inventions is a must. To protect the human intelligence from being manipulated and to make a global image a new law was implemented i.e. The Intellectual Property Right .This law speak about how to protect the intellectual property of the people, their rights through different brigades in IPR:-

-Trademark and service marks

-Copyright

-Patent

-Design

-Geographical Indication

Protecting the Intellectual property rights with regard to biotechnological innovations appears as special and significant issues<sup>11</sup>

<sup>11</sup> Biotechnology is the injection of scientific knowledge into the manufacturing processes by which marketable goods are made out of biological phenomena. It involves the study of method by which living resources (plant, animal, microbial), can be tailored to generate industrial processes and move specimens for use in agriculture, forestry, horticulture, medicine, health and environment. Biotechnology has been defined as, “The application of scientific and engineering principles to the processing of materials by biological agents to produce goods and services”. Biotechnology is the ‘engineering’ of genetic materials towards practical ends, such as medical and veterinary advances,

To protect the intellectual property rights ,the TRIPS (trade related intellectual property) agreement establishes specific standards on the availability, scope and the use of intellectual property rights .Out of the number of articles specified ;article 27(1) and 27(2) is applicable to the area of biotechnology and plant varieties protection. Article 27(1)<sup>12</sup> deal with patents available for any inventions, whether product or process in all fields of technology, provided that are new, involve an inventive step and are capable of industrial application.”All fields of technology” is interpreted to include biotechnology and is granted to all developing countries that are granted by TRIPS to be developing countries and qualify Article 27(2) and (3) which may allow concerned countries some control in areas where there is strong national and public interest. Article 27(2) modifies Article27 (1) “members may exclude from patentability inventions, the prevention within their territory of commercial exploitation of which is necessary to protect public order, public morality, including to protect human, animals or plant life or health or to avoid serious prejudice to the environment provided that such exclusion is not made merely, because of the exploitation prohibited by the law”<sup>13</sup>.

Members may also exclude from patentability diagnostic therapeutic and surgical methods for treatment of humans or animals. Plants and animals other than the microorganisms are essentially biological processes for the production of plants and animals. It also cited out that members shall provide for the protection of plant varieties either by patents or by effective *sui- generics* system or a combination thereof. Time and again it has been

modified crops and improved animal breeds. Applications for patenting were filed for human and animal DNA sequences, or for new gene therapies and medicines or for both.

<sup>12</sup>TRIPS Agreement, N.K Acharya “Text book on Intellectual Property Rights”3<sup>rd</sup> edition.

<sup>13</sup> <http://www.public-perception> –issues in Agricultural and environmental biotechnology, September 1, 2013.



asserted that, the presence of large-scale generic drug industry in the developing countries has adversely affected the interests of drugs and pharmaceutical manufacturers investing huge amount money for research and development. It is always easy to pirate a process unless the product is protected it is not possible to protect the invented processes.<sup>14</sup> Further, proponents of product patenting have always insisted that for the purpose of economic development, to improve technology and to recoup the investment made on R & D, so product patenting is as a must. However, those concerned with welfare of the poor and the oppressed have vehemently argued against product patents taking in to account and the possible impact of product patenting on health, safety and welfare of the people.

Firstly, for centuries, indigenous peoples in many countries have developed herbs, seeds and plants for use as food and medicine. TRIPs gives foreign MNCs the right to take traditional indigenous seed varieties developed by small farmers, improve them with slight generic alterations, and patent them. In order to use them, the people who originally developed them must buy them back at exorbitant rates. It is sometimes described as bio piracy.<sup>15</sup> There has been an epidemic of farmer suicides in some parts of India that used to be prosperous agricultural regions before “the ecological and social disaster” caused by bio-piracy.<sup>16</sup>

Secondly, the product patenting, conferring property rights would allow a few MNCs of technologically rich states to control access to food, medicine and drugs.

Thirdly, it has been claimed that intellectual property rights are well protected by WTO at the expense of human beings is well seen by having an eye on their price chart.

Fourthly, product patenting through TRIPs necessarily commercialise certain aspects of social

life that should belong to non-commercial sectors. For the purpose of preventing over commercialisation of food supply and health care Indian law contain certain general principles of working of patents. But there are doubts as to their efficacy to regulate monopolistic behaviour of economically powerful patent holder.<sup>17</sup>

Fifthly, some critics have asserted that product patenting would strengthen western monopoly over technology and 20 years term would discourage research and development in third world even though there is an assumption that the patent system would assist technology transfer.<sup>18</sup>

Another example of intellectual property protection regime is the development of crop varieties which are protected through “plant breeder’s rights or PBRs<sup>19</sup>. The PBRs ensures that the plant breeder who developed a particular variety gets the exclusive rights for marketing the variety. Agriculture for the first time was included in the trade related intellectual property rights (TRIPS) and TRIPS is a major concern for developing countries. The following two major steps were taken in consideration of PBRs:

(a) The Food and Agriculture Organization (FAO) have an International treaty on plant genetic resources for food and agriculture. This treaty consists of particular classes which refer to operation of farmer’s rights.

<sup>17</sup> [www.lawyersclubindia.com/articles-1/](http://www.lawyersclubindia.com/articles-1/) April 2013

<sup>18</sup> Ibid.

<sup>19</sup> PBRs Act 2000-statement and object-1.In order to provide for the establishment of an effective system for the protection of plant varieties.2.right of farmers and plant breeders .3.to encourage the development of new varieties of plant and to right of farmers in respect of their contribution at any time in conserving, improving and making available in plant genetic resource for the development of new plant varieties. <http://www.plantauthority.gov.in/pdf,September,2013>

<sup>14</sup> Philip W.Grubb, Patents for Chemical, Pharmaceuticals and Biotechnology, (Oxford: Oxford University Press, 2000), p.219.

<sup>15</sup> A.K Rajaraman, Adv Madras High Court 'Product Patenting: Promises and Perils' ICI, vol 3, Nov 2012.

<sup>16</sup> Ibid



(b) The 'Plant Varieties Protection and Farmer's Rights Act 2001 agrees for the right of farmers, breeders, and researchers. The protection is provided by making compulsory licensing of rights, and inhibiting the import of plant varieties consisting of 'genetic use of restriction technology' (GURT) e.g. terminator technology of Monsanto.

Following conditions should be fulfilled to grant protection to the new varieties:

- a) The new variety must always be new i.e. it should not have ever been exploited commercially.
- b) It should be biologically distinct and possess different characters.
- c) The new variety of the plant must have uniform characters.
- d) The distinguishing character of new variety must be stable for generations.
- e) The new variety should have taxonomic validity i.e. systematic position, generic and species names etc.

Recently Utility patents for both plant and animal genetic materials, have been allowed in some countries like USA and other member countries. This forbids the use of patented material for further breeding. The farmers are allowed to use and save the seeds for cultivation only after paying a fee to the patent holder.

Some concerns have been voiced regarding the implications of IPR on the genetic diversity and the conservation of genetic resources. IPRs will directly or indirectly affect the food security and distribution around the globe, biological diversity and ecological balance, employment avenues in the poor and developing countries, and the use of new and effective agricultural practices.<sup>20</sup>

Looking at the core point of discussion of TRIPS agreement regarding the area to be patented

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[www.biotechnology4u.com/biotechnology\\_patent/April.2013](http://www.biotechnology4u.com/biotechnology_patent/April.2013)

,yet it has to be discussed in more details to give a legal protection from being manipulated or pirated by any other person is as follows:-

#### **Patenting Biotechnological Products:**

A question, therefore, arises as to whether patent protection can be obtained for inventions in the area of biotechnology, which usually relates to and / or involves living things. Furthermore, what is the position of substances like microorganisms or other biological materials present in nature? Do they fall under the category of discovery or invention? If they are considered inventions do these materials fully satisfy the important patentability criteria of novelty, as they are already available in nature? As in the case of other technological fields, the requirement of satisfying the criterion of inventive step (non-obvious) constitutes one of the most complex questions in the field of biotechnology. The consideration of industrial application is yet another obstacle for securing patents for inventions in biotechnology.<sup>21</sup>

Another problem in protection of inventions in biotechnology is the difficulty of satisfying the mandatory requirement of the condition of 'sufficient disclosure'. This is due to the fact that inventions in this field relate and / or involve, as explained above, living entities (biological materials). Such materials are difficult to describe in words. Therefore, it is important to know clearly how inventions in biotechnology are accommodated within the general framework of the patent system.<sup>22</sup>

Patents are viewed as vital to protecting the commercial interests and intellectual property rights in biotechnology. Patents are limited rights based on a claim that a new technological invention has been created and fully communicated to the public. Patents can cover new products, processes that creates these new products, new processes for producing existing products and new processes generally. While patenting of a biotechnological invention it is important that it meets the 3 criteria's laid down by

<sup>21</sup> <http://www.jstor.org/stable/440987>

<sup>22</sup> <http://www.TheHindu.com> Protection of biotech invention.htm/Feb, 2013.



the TRIPs to meet patentability, namely -which are new or novel, involves an inventive step or not obvious and capable of industrial application.<sup>23</sup>

-It has been estimated that thousands of patent applications were made in respect of micro organisms, plants and for human and animals DNA sequences.

In essence, the India Patents Act gives only very limited protection to research-based pharmaceutical companies. Patenting of human material in the form of gene sequences is considered to be wrong as it amounts to commercialization of life. Failure of the basic patent principles to cater to the needs of genetic inventions has given rise to ambiguities for companies concerned with biotechnology.

#### **Gene Patenting**

“Gene patenting” is a broad term referring to the patenting of genetic sequence such as DNA and RNA and to alternate forms of DNA such as cDNA (complementary DNA)<sup>24</sup>. Gene patents are a part of the broader category of biological patents.

Patents are being granted to genes despite there being many arguments for keeping the genes in the public domain. A patent cannot be granted on a gene as it naturally occurs. Isolation of the gene is required for it to be patentable. The patent offices have treated genes as a new chemical compound and have granted “composition of matter” patents. Thus a patent granted on an isolated and purified DNA composition confers the right to exclude others from any method of using that DNA composition for up to 20 years from the date of filing. However Human Beings are not patentable as human multi-cellular living organisms are not a patentable subject matter under section 101<sup>25</sup>.

The courts have upheld claims on altered sequences, but courts and lawyers' opinions have been mixed on upholding the use of natural sequences and particularly the sequence itself. Patents on genes have only been granted on isolated gene sequences with known functions, and these patents cannot be applied to the naturally occurring genes in humans or any other naturally occurring organism.<sup>26</sup>

#### **Patenting of Micro-organisms and Cells:**

The insertion of recombinant DNA into a host micro-organism that was held in 1973. During this period the scientists realized the huge potential involved in directing cellular machinery to develop new and improved products and processes. So with this technology the process of patenting living organism came into existence<sup>27</sup>. The sciences dealing with molecular biology, genetics, biophysics, cell biology and immunology have for the last few years made startling advancement and opened up vast possibility for the development of new and novel technologies. The grant of patent for engineered micro-organism meant grant of product status to that micro-organism, which revolutionised the field of biological research.<sup>28</sup> The member countries have no options meaning that the protection should be by way of grant of patents.

#### **Patenting Pharmaceuticals:**

The pharmaceutical industry is one of three technology-based industries in which the patent virtually equals the product. While only a small - and declining - number of new chemical entities are approved annually, thousands of patents are applied for to protect variants of existing products, processes of manufacture or, where admitted, second indications of known pharmaceutical products<sup>29</sup>. Since patents confer exclusive rights regarding the production, sale and use of the patented subject matter, they can be used to restrain competition and set prices higher than those that would have existed if

<sup>23</sup> P.kVasudev, "Patenting biotech products-complex issues" Economic and political weekly, vol35, No.42.

<sup>24</sup> [http://www.ama.assn.org/ama/pub/physician\\_resource](http://www.ama.assn.org/ama/pub/physician_resource).

<sup>25</sup> Ildi, <http://www.ipsuستراليا.gov.au/get-the-rights-ip/patents/about-patents/what-can-be-patented>.

<sup>26</sup> American Medical Association Report  
<sup>27</sup> <http://www.lexorbis.com>, Feb13,2012.

<sup>28</sup> <http://www.lexorbis.com/pdf/patenting-micro-organism.pdf>, April30,2005

<sup>29</sup> <http://www.pharmainfo.net/reviews/patent-system-pharmaceuticals>, April02,2013.



competitive products were available. This is the very purpose of the patent system, which is generally justified as necessary to encourage investments to develop new products and processes. Concentration of manufacturing takes place in pharmaceuticals industry as well as in the other branches of industry and it is characterized by the joining of firms. However, there are several specific features in patenting pharmaceutical products. Enforcement of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement) made it compulsory to establish in all World Trade Organization (WTO) Members patent protection on pharmaceutical products and their manufacturing methods as well as patent protection of drugs. WTO Doha Declaration is an essential stage in patent protection of pharmaceutical products establishing the legal basis and compulsory licensing system. In 2005, the European Commission completed the Regulation of the European Parliament and the Council on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems<sup>30</sup>.

#### **Patenting Biological Materials:**

A biological patent is a patent relating to an invention or discovery in biology. It can be a composition of matter, a method for obtaining or using one or more thereof, or a product combining such things. Even when a natural biological substance itself is patented (apart from any associated process or usage), this has been permitted in the United States as long as they are sufficiently "isolated" from their naturally occurring states. Prominent historical examples of such patents on isolated products of nature include adrenaline, insulin and vitamin B<sub>12</sub>. New plants and seeds are also patentable. Isolated and manipulated cells - even human cells - can also be patented. There has been much patenting of genetically modified organisms. This includes bacteria, viruses, seeds, plants, and even non-human animals. For example, a genetically modified mouse, dubbed the Oncomouse (type of laboratory mouse that has been genetically modified using modifications to carry a specific gene called an activated oncogene), that is

useful for studying cancer, was patented by Harvard University<sup>31</sup>.

#### **Patenting of plants:**

Plant patents encompass newly found plant varieties as well as cultivated spores, mutants, hybrids and newly found seedlings on the proviso that they reproduce asexually. It is the propagation of a plant to multiply the plant without the use of genetic seeds. Modes of asexual reproduction in plants include grafting, bulbs, apodictic seeds, rhizomes and tissue culture. Specifically excluded from protection under the Plant Patent Act are tuber-propagated plants and plants found in an uncultivated state. In some countries (including the United States, Australia and Europe) plants can be covered by patent claims provided that the patent applications are able to meet all of the necessary standards and requirements that exist in that country for patentability. According to the TRIPS provisions of the WTO Agreement, it is essential for member countries to provide, in the area of biotechnology, at least protection for microorganisms *per se* if they satisfy the novelty, inventive step and utility requirements of the patent law and for the protection of plant varieties. In the case of plant varieties, there are options, namely, either by patents or by a sui generis system. India has opted for the latter.

Summing up, it may be said that there are many gray areas in respect of securing protection for inventions in biotechnology. In spite of this position, there is ample scope for the protection of inventions falling within the area of biotechnology.

#### **Patenting of Animals:**

Research in the field of biotechnology has been taken a step towards patenting of animal's. Through various works it has been found that animals are being patented in some countries. The first animal being, onco-mouse, for the treatment of cancer. But in many countries like India animal patenting has been considered immoral and unethical.

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<http://www.issues.org/17.4/barton.htm>, August 25, 2013. John.H.Barton "Patenting Agriculture, September, 2013

<sup>30</sup> *ibid*



It has been clearly opposed by American Anti -Vivi Section (hereafter AAVS). In animal law section deals purely with animal's utmost security and protection measures. It has been cited out that wild animals can never be utilized for any kind commercialization. Patenting of animals can be done only on transgenic animals<sup>32</sup>. Recent survey states that nearly 660 animals are already patented such as chimpanzees, monkeys, mice, rabbits, dogs, cats, and pigs that have been "altered" in some way, creating an incentive to profit from hurting animals. AAVS is of the opinion that it is an unethical and inappropriate use of the patent system to issue patents for sentient beings. A patent was recently granted for rabbits whose eyes are intentionally damaged to serve as a model for "dry eye" conditions in humans. AAVS has submitted a challenged to the U.S. Patent and Trademark Office for issuing the rabbit patent, requesting that the patent be repealed.

AAVS previously challenged patent issued to Texas A&M University for beagles who were severely sickened and whose lungs were then purposefully infected with a mold in order to test new human drugs on them. That challenge resulted in a victory for the beagles when the patent holders dropped all claims to the patent<sup>33</sup>. Transgenic animals are just one in a series of developments in the area of biotechnology. Biotechnology has transformed the way in which we understand processes such as engineering and manufacturing. Genetic manipulations at the level of DNA have also changed long held views as to what is considered to be animal, plant and human. In turn, these changes have made it more difficult to evaluate the ways in which animals are used and have obscured distinctions between pure and applied research.

A representative, but non-inclusive, list of purposes for which transgenic animals have been used indicates the wide ranging application of this biotechnology:

- in medical research, transgenic animals are used to identify the functions of specific factors in complex homeostatic systems through over- or under-expression of a modified gene (the inserted transgenic);
- in toxicology: as responsive test animals (detection of toxicants);
- in mammalian developmental genetics;
- in molecular biology, the analysis of the regulation of gene expression makes use of the evaluation of a specific genetic change at the level of the whole animal;
- in the pharmaceutical industry, targeted production of pharmaceutical proteins, drug production and product efficacy testing;
- in biotechnology: as producers of specific proteins;
- genetically engineered hormones to increase milk yield, meat production; genetic engineering of livestock and in aquaculture affecting modification of animal physiology and/or anatomy; cloning procedures to reproduce specific blood lines; and
- Developing animals specially created for use in xenografting.<sup>34</sup>

The successful cloning of Dolly underlines the fact that innovative developments in animal science are part of the mainstream of biotechnology. In addition, the use of xenografts, at least at the public health level makes animal and human welfare inseparable. The evaluation of animal and human welfare as it may be affected by biotechnology is a complex issue. One of the elements most notable in this process is the absence of an informed sense of the processes involved. ACCs share the responsibility for educating members on relevant aspects of animal care and use. Education concerning transgenic animal care and use is of particular importance, involving the careful consideration of the reasons for manipulating the genome of any organism as genetic engineering is a sensitive social issue<sup>35</sup>.

<sup>32</sup> <http://www.animallawsection.org/animal-patents.15thMay.2013>.

<sup>33</sup> <http://www.stopanimalspatent.org/faq.html>, 15th May, 2013.

<sup>34</sup> <http://www.people.ucalgary.ca/~browder/transgenic.html>, 16th May, 2013.

<sup>35</sup> <http://www.animallawsection.org/animal-patents.15thMay.2013>.





A thorough discussion of biotechnology issues, including transgenic animals is needed, particularly to develop some consensus as to the relative value of benefits to be obtained from the use of transgenic animals. One of the more challenging questions is how to account for the interests of the animals involved.

The field of transgenic animal biotechnology is likely to become of increasing importance as the techniques develop further and are applied to many more animal species. Welfare and ethical concerns will also continue to evolve. Consequently, education together with thoughtful ethical decision-making will remain the keystone of the review of transgenic protocols.

#### **Patenting of Cosmetic processes:**

It has been observed under Australian Law, that cosmetic processes and methods for improving or changing the appearance of the human body or of parts of it are not of a like kind with medical, prophylactic or therapeutic processes or methods, and can therefore be the subject matter of a patentable invention. Thus it was held that a process for improving the strength and elasticity of keratinous material, especially human hair and fingernails, is a proper subject matter of a patent<sup>36</sup>.

#### **Conclusion:-**

The legal protection regime of biotechnology invention contemplates that whoever Involves in the act of piracy i.e. illegal use of any others work and without permission is to be Punished. There is a danger of bio piracy as well as threat to society of bio wars which is more Hazardous than the nuclear wars and it has to be abated.

There is an immense need that every individual or the inventor should be protected of trade secrets. But to enforce trade secret is very difficult than to Patent. Based on US constitution, the Patent Act, which is codified under Article title 35 of the United States codes, regulates the requirement for obtaining a patent. Section 101 of the Title requires that

“whoever invents or discovers any new and useful process, machine, manufactures of composition of matter may obtain a patent therefore subject to the condition and requirements of this title. This section sets out the three general requirements namely – novelty, usefulness and non-obviousness for obtaining patent”. Apart from this general condition which we have studied above there are no further statutory requirements for patentability.<sup>37</sup> The Patent (amendment) Act, 2005 in India<sup>38</sup> also contains general principles applicable to the working of all patented inventions. To secure the inventions not only it included and encouraged a patentee to merely import the patented article, but also to see that patent rights contribute to technological innovation, and to transfer and to disseminate technology for the mutual advantage of producers and users of technological knowledge in a manner conducive to social and economic welfare. The Act also ensured that the benefit of the patented invention is available at a reasonably affordable prices to the public and for grant of compulsory licenses in respect of patents for the reasonable requirements of the public. The ultimate goal of any intellectual property system is the advancement of science and technology as a means of securing overall social and economic development. By conferring exclusive rights on inventors, the true goals of any intellectual property system are actually the advancement of science and technology. It is expected that if additional rights are conferred upon inventors, it would induce further inventions, enabling giant strides in the development of technology, ultimately benefiting society.

It can be seen from the above that the intellectual property law by protecting the rights of an inventor in his invention which actually ensures the progress and growth of science and technology as a means of securing economic and social development.

Even though there is patentability there is an urgent need to make the patent system efficacious on an equitable basis and to promote technology specific

<sup>36</sup> <http://www.australianlawsection/publication/7-exclusion-patentability/May,2013> .

<sup>37</sup> Ms. Geetika Walia, 'software patenting – a challenge' March, 2013 vol-4 LPP-34

<sup>38</sup> <http://www.nipo.in/images>, Sep, 2013.



training to patent officials, in order to inculcate the spirit of IPR.<sup>39</sup>

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[3] A Good Year Again, *Biospectrum*, June 14, 2006, at 23-30

[4] Aaron S. K. & Jason K., "Biomarkers Unbound—The Supreme Court's Ruling on Diagnostic-Test Patents, *New England Journal of Medicine* (May 24, 2012).

[5] *About the Personalized Medical Coalition*, Personalized Medical Coalition (June 19, 2012)

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[8] Annual Report (1998) of the TRIPS Council

[9] Arriola S.R., "Biotechnology Patents After Festo: Rethinking the Heightened Enablement and Written Description Requirements", 11 *Fed. Circuit B.J.* 919.

[10] Atkinson RC, Beachy RN, Conway G, Cordova FA, Fox MA, Holbrook KA, Klessig DF, McCormick RL, McPherson PM, Rawlings HR III, Rapson R, Vanderhoef LN, Wiley JD, Young CE (2003). Public sector collaboration for agricultural IP management. *Science* **11**: 174–5.

<sup>39</sup> <http://www.wipo.int/abouttip/en/about-patentable.htm/April2013> .

[11] Bainbridge D.I., "Intellectual Property", (2002), p. 373.

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