

PATENTABILITY OF TRANSGENIC ANIMALS IN INDIA

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ABSTRACT

Biotechnology has become an important part of many research and developmental work since the late 1970's. The term is a mixture of two words 'bio' and technology, which covers various techniques and processes that uses living organisms or a part such organisms to either make or modify products for improving plants and animals or to develop those organisms itself for specific uses. Out of the many techniques that biotechnology covers, recombinant DNA technology has been proved vital in the field of medical science which leads to the creation of what we call "transgenic organism".

Transgenic organisms are those whose genetic make-up has been modified by infusion of assembled genetic material of totally different organisms. This introduces new characteristics into the host organism.

This genetic manipulation, however, raises a plethora of issues relating to morality and patentability controversies all around the world, especially India. Unlike countries like USA and UK, India has not made any explicit alterations or amendments to the existing patent laws to neither provide patent protection to these transgenic organisms nor to the process of their genetic modification.

Under the Patent Act 1970, every invention must pass a two-step test in order to be patentable – namely, it must not fall in any of the categories specifically excluded under Section 3 of the Patent Act and must pass the well-known three-pronged test of novelty, inventive step and industrial applicability. Until adoption of International Convention on Trade Related Intellectual Property Rights (TRIPS) in 2002, India was averse to provide patent protection to biotechnology.

India has thrice undergone amendments to widen the scope of patenting biotechnology. The second amendment in the year 2002 added explanation to 'chemical processes' so as to include biochemical, biotechnological and micro-biological processes under the purview of patent protection. However, where patent is provided to transgenic micro-organisms, higher life forms like animal varieties and its process of formation has been kept out of the purview of patent cover.

This paper aims to bring clarity regarding patentability of transgenic animals in India and find out the rationale behind such a stand.

PART I

EVOLUTION OF PATENT LAWS ON TRANSGENIC ORGANISMS

Biotechnology has become an important part of many research and developmental work since the late 1970's. The term is a mixture of two words 'bio' and technology, which covers various techniques and processes that uses living organisms or a part such organisms to either

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make or modify products for improving plants and animals or to develop those organisms itself for specific uses. Out of the many techniques that biotechnology covers, recombinant DNA technology has been proved vital in the field of medical science which leads to the creation of what we call “transgenic organism”.

Transgenic organisms are those whose genetic make-up has been modified by infusion of assembled genetic material of totally different organisms. This introduces new characteristics into the host organism.

History of Patent laws on transgenic organisms find its root in the American Constitution.² Their constitution states that “*congress shall have power to promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries*”.³ Though, the article does not in express terms say anything about patenting of biotechnology or transgenesis, this provision vests the US govt. with power to grant monopoly rights to the scientific inventors.

This protection and grant of exclusive rights is the threshold of patent Laws. Transgenic organisms being a scientific result, debatably are to be protected under this provision.

The patent act of USA till the 1980’s did not consider living beings as patentable subject matter. During the 1970s and 1980s when the product interaction between biology and technology came into existence, the term biotechnology was officially coined. Transgenic organisms are result of recombinant DNA technology or genetic engineering, which forms the foundation of Modern Biotechnology. In the early 1980s, USA started commercial production of human insulin by making use of recombinant DNA technology and this proved as the beginning of modern Biotechnology.⁴

Researchers classify the development of biotechnology into three ‘generations’. First generation dates back to the ancient period of early man for making use of bacteria, yeasts, enzymes etc. methods of fermentation to produce foods and beverages. Second generation is when cell culture and sterile manufacturing techniques began to be used to develop products like acetone, glycerine, lactic acid etc. Tissue cell culture, Hybridoma technology and Genetic engineering are all developments of the third generation.⁵ Transgenic organism thus, forms a part of this generation.

The development of patent laws on transgenic organisms to a great extent is owed to the US Judiciary. More than legislative framework, judicial interpretations and pronouncements have helped shaped patentability of transgenic organisms. Louis Pasteur was the first one to get patent protection on living organism for inventing ‘yeast’ that is free from organic germs of disease.⁶

² Manu Luv Sahalia, “perspectives Intellectual Property Law: many Slides to a coin”, Delhi, Universal Law Publishing Co. Pvt., 2003,p.i71.

³ Article I, Section 8, Clause 8, USA Constitution.

⁴ Rockman, Howard B., “Intellectual Property law for Engineers and Scientists, New Jersey”: Wiley-interscience, 2004, p.259.

⁵ Dr. Sreenivasulu, N.S., Dr. Raju, C.B., “Biotechnology and Patent Laws”, 1st edition, (2008),p 5.

⁶ Us Patent No: 141,072 granted in year 1873

Another remarkable matter was the case of *Diamond vs Chakraburty*⁷ where he wanted patent claim for a genetically modified micro-organism capable of eating crude oil spills. He claimed patent on both process and product. It was for the first time when the question arose that if living organisms could be also patented. In this case the US patent office though granted process patent for the technique of producing such bacteria, but rejected patent over the bacteria so produced. Supreme Court on appeal by 5:4 majority held that the US constitution and section 101 of US patent law is wide enough to cover even the living organisms under its purview. The reading of clause 8 of US constitution that “the congress shall have power to promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries” very well equips the state to provide patent protection in respect of all inventions which promotes the progress of science. Secondly, interpreting section 101 of US patent law the word ‘composition of matter’⁸ was to encompass all living matters too which have been genetically modified through biotechnology. The bacterium produced of Dr. Chakraburty⁹ was not a natural occurring organism it was a result of human ingenuity and intellectual labour that led to its creation. Hence, even the bacteria so produced was later on granted patent.

After this judgment all the lower life forms of life were recognised as patentable subject matter. The position of animals which are considered as higher life forms were still not very clear. Patentability of genetically modified animals i.e. the transgenic animals was not recognised on grounds of non-obviousness (lack of innovation). In the case of *Ex parte Allen*¹⁰ oyster, a genetically modified animal, was rejected patent on the ground that, animals are natural creation and no individual can own it by way of patenting it. However, such claim for animal genetic material and tissue culture kept on pouring the Patent office. As a result finally, the US patent office issued a statement clearing its stand on patentability, to grant patent protection to all life forms, modified genetically which occur non-naturally¹¹. And in the year 1988, Harvard’s ‘onco-mouse’¹² became the first animal to get patent. It was a transgenic organism which was genetically modified by infusion of a gene known as ‘onco gene’ that made it susceptible to cancer. This mouse was proved useful in cancer testing.

And now the stand of US on patentability is that anything under the sun made by man is patentable. Thus, they adopted have a very liberal approach to cover almost everything under the ambit of their patent law.

After US had liberalised its policy on patentability in the field of biotechnology particularly, of transgenic organisms, European Union soon felt the need to welcome the same.

⁷ (1980) US SC 447 at 303

⁸ Describe section 101.

⁹ *Supra* 6.

¹⁰ 1987 USPO 2d 1425

¹¹ *Supra* 4, p27, “The patent office now considers non naturally occurring, non-human multi-cellular living organisms, including animals to be patentable subject matter within the scope of subject matter under the United States Patent Statute”.

¹² T 19/90 (1990) OJEP0476, Tech. Bd App;(1991) E.P.O, R.525, Ex.D.

There are three major conventions which have contributed significantly towards the development of substantive law on patenting biotechnology in the EU. Paris Convention of 1883 for protection of Industrial property was the first such convention. It provided protection of all industrial properties like, trademarks, designs, logo and patents. 'Industrial product' was given a wide interpretation to include all manufactured product and by-product.¹³ And the production process of mostly all these products especially that of the agricultural sector had biotechnology inherently involved. Production of wines and beer biotechnology are few to name. Hence, even when biotechnology was not explicitly mentioned was interpreted to be covered.¹⁴

The second convention to shape patentability of biotechnology was the Strasbourg Convention¹⁵. This aimed at harmonizing patent law in terms such as novelty and inventive steps¹⁶. The third convention allowed patent for any type of invention which was susceptible to industrial application and which involves an inventive step. It even allowed the grant of patent to living organisms if there were created by way non-biological processes¹⁷. Hence, to this, extent transgenic organisms were very much thought to be included.

The first and foremost case which opened the door to the patenting of biotechnology inventions in European Union came in the late 1969. In this case the patent claim was on the method of breeding doves with red plumage.¹⁸ However, The German patent office rejected patent on the ground that the method adopted for breeding was not repeatable. The methods which essentially involves biological processes were non-repeatable, hence non-patentable.

In EU, the lower life forms just like in USA were recognised as patentable subject matter much before the higher life forms began to. Patent on transgenic animals were mostly controversial in EU because of the exception clause under Article 53(a) of the EPC¹⁹ which prohibited grant of patents if the invention is found against the public order and morality. Also, 53(b) of EPC was interpreted to exclude animal varieties.²⁰ Sufferings caused to such animals and possible threat to the environment were the prime concern of EU Patent office while deciding the grant of patents to these transgenic animals.

The scholars favouring patentability of transgenic animals, argued that, some amount of environmental risks are obvious to take place in any kind of invention. All these effects are to be weighed against the positive benefits which public at large will reap.²¹ There were different interests involved which required an unbiased balancing; one, there was the basic interest of

¹³ International Legal Instruments of Intellectual Property Rights Law, Dept. of Business Laws, Vol. I & II, National Law School of India, Bangalore, 1998.

¹⁴ Article 1, sub clause (3) of the Paris Convention on Industrial Property Rights.

¹⁵ Starbourg Convention on patent for invention, 1963.

¹⁶ Lislei Restanio, Steven E. halper, and Dr. Eric, "Patenting DNA-related inventions in the European Union, United States and Japan: A trilateral approach or a study in contract?", ULCA Journal of law and Technology, 2003.

¹⁷ Article 53 (a) European Patent Convention

¹⁸ Adelman et al.(1998), p.335

¹⁹ *Supra note 14.*

²⁰ See, exceptions to patentability under Art. 53 of the EPC.

²¹ See. W.R. Cornish, Cases and materials on Intellectual property, London : Sweet and Maxwell Limited, Third Edition, 1999, p.84 a

mankind to remedy widespread deadly diseases; two, the environment was to be protected against the uncontrolled dissemination of unwanted genes, and three, that cruelty to animals should be not done. Invention of transgenic animals like the 'Onco-Mouse' of USA that proved useful in cancer treatment, contributed immensely towards the development of anti-cancer treatment. Therefore, if there's any invention that can be proved useful to the mankind, should ideally be not denied patent.²²

Secondly, it was argued that what is prohibited under article 53(a) of EPC is 'animal variety' and transgenic animals do not constitute an animal variety. Transgenic animals are formed by way of infusion of genetic material which by no means can be said to be a biological process. Transgenic animals are a result of microbiological process, which is not excluded from patenting.²³

Both the arguments were ultimately accepted by the Board and the EPC now encompasses patents to transgenic animals produced through biotechnology. The stand of Europe currently is that living matter produced through biotechnology such as micro-organisms, plants, animals and related inventions, involving cells, genes and DNA are indisputably patentable. However, EU did not legislate explicit provisions on patenting of biotechnology. It has only widened the interpretation of existing patent law so as to circumscribe patent on biotechnology within the existing legal framework. Meanwhile, in 1998 EU adopted a directive on the legal protection of biotechnological inventions which came into effect on 2000. This was a major breakthrough in the evolution of patenting of biotechnology. Under this directive every member state is required to protect biotechnological inventions and it also provides necessary changes and required modification in patent laws on biotechnology of its member states. At the same time it excludes various biotechnological inventions on grounds of public order, morality and ethics. Transgenic organisms however, are patentable inventions even under this directive.

PART II

PATENT LAWS ON TRANSGENIC ORGANISMS IN INDIA

In India when patent Act 1970 came into existence, biotechnology has already made its mark around the world. The Indian Patent Act of 1970 mandates that every invention in order to get patent protection has to satisfy three universally accepted requirements of patentability namely, novelty, inventive step and usefulness.²⁴ The framers of the Indian Patent Act did not seem to forethought of patenting living beings produced out of the non-biological process.²⁵ Biotechnology, particularly transgenic organisms were kept out of the sight of patent laws until India ratified convention on Trade Related Intellectual Property Rights (TRIPS).²⁶ Soon after ratification, India brought some significant modifications in all its

²²Supra note 9, p48

²³Bar of patenting of essentially biological process does not cover microbiological processes; See Supra note10

²⁴ Section 2of The Indian Patent Act, 1970.

²⁵ Earlier to the amendments made to the Act in 1999, 2002, and latest by 2005.

²⁶ TRIPS is a multilateral agreement on intellectual property rights. It provides for universal law on intellectual property rights. As far as biotechnological patents are concerned the convention gives respect to the

intellectual property including patent laws and headed towards patenting of biotechnological inventions.

India has thrice undergone amendments to widen the scope of patenting biotechnology. The second amendment in the year 2002 added explanation to 'chemical processes' so as to include *biochemical, biotechnological and micro-biological processes* under the purview of patent protection²⁷. This by and large, thus, include within its explanation, transgenic living beings such as micro-organisms, animals, plants, etc. Also, till this amendment was made the term 'invention' only included processes and not product. Now, both product as well as its process of formation are patentable in all the fields including science and technology²⁸. Just like USA and EU, even in India animal varieties formed essentially by way of biological process or living beings existing naturally without involvement of any human interference is not patentable. This means that only a non-natural process that involves some technical application to a natural process is patentable in India.²⁹

In March 2005, in order to meet its obligation, India amended its patent law to recognize the Budapest Treaty. As a result of this treaty section 5 of the original act was omitted to give patent on methods or processes to manipulate living beings genetically or to produce genetically engineered living beings.³⁰

Thus, emergence of patenting both transgenic organisms as well as their process of creation can be traced back to TRIPS agreement and amendments thereafter. However, only transgenic micro-organisms are patentable and stand of India on patenting of non-naturally produced plants and animals is still not very clear.³¹

This is so because on one hand, section 3(j) of the amended act includes provisions that prevent patenting of plants and animals as a whole or in part thereof. The Section further prevents patenting of 'biological processes for production or propagation of plants and animals'. Any treatment of animals which renders them free of disease or increases their economic value (or that of their products). E.g. A method of treating sheep for increasing wool yield is precluded. Even Section 3(i) prohibits patenting process used in medicine and treatments of human beings and animals, both either as part of treatment and for increasing their economic value or the economic value of their products. Such provisions makes it appear that India is still not ready to provide patent cover to higher transgenic life forms.

And then on the other hand in the *Dimminaco* case, Calcutta High Court, clarified that "*if the end product is a commercial and vendible entity, the presence of the living organism in the end product cannot be a bar to the patentability of the process*".³²

developments in the United States and European Union. It mandates all the member states to provide patents on biotechnological inventions.

²⁷ Explanation to section 3 of the Act as amended in 2002 in light of Article 27 of TRIPS.

²⁸ See definition of "invention" under patent Act, 1970.

²⁹ Section 3 of Patent Act after amendment in 2002.

³⁰ Patent Act as amended in march 2005.

³¹ *Supra note 9*, p155

³² (2002) I.P.L.R. 255 (Cal)

Even in the *Monsanto case*³³ Intellectual Property Appellate Board (IPAB), overturned the Indian Patent Office's objection that plant cell shouldn't be granted patent for it is hit by section 3 of patent Act and was an essentially biological process. The IPAB held that the plant cell in the claimed process was transformed as a result of human intervention in the manner claimed in the application, and was therefore patentable.

PART III

WHY SHOULD INDIA PATENT TRANSGENIC ORGANISMS?

One of the primary purposes for the developed countries behind granting of patent protection is to encourage investment in the field of research and development, and to promote scientific innovations by way of incentives. "Incentives include monopoly power and royalties."³⁴ "For animal patents in particular, an additional goal is to promote research and development in understanding and combating disease."³⁵ "Also, issuance of animal patents will promote industry-wide disclosure of important biotechnology research developments"³⁶.

Unfortunately many developing countries like India have been reluctant to grant patent to transgenic animals.

We need to realise that to allow patent on transgenic animals is the need of hour, because it is an indispensable tool for screening of novel molecule to various diseases. The primary applications for transgenic animals are in the pharmaceutical, agricultural, and medical research industries. These industries are imperative to the development of India, as two of the largest problems faced by the developing countries are starvation and disease. Protecting animal patents for the promotion of the pharmaceutical industry can promote the availability of medicines, because many pharmaceutical products are produced by transgenic animals. Promoting the availability of these animals will lead to increased availability of pharmaceuticals. Developed countries with a wealth of resources in pharmaceutical manufacturing will be more willing to invest in the pharmaceutical industry of developing nations if they are likely to earn profits. This investment will enhance the growth and efficiency of the pharmaceutical industry, thereby enlarging the availability of pharmaceuticals in India.

Genetically-engineered animals serve several purposes in the pharmaceutical industries. First, many animal proteins are used as vaccines to treat illnesses. These proteins may be more easily available through transgenic animals. Genes containing the protein may be inserted

³³ A. Samuel Oddi, *The International Patent System and Third World Development: Reality or Myth?*, 1987 DUKE LJ. 831, 834 (1987).

³⁴ Edwards B. *Patenting Transgenic Animals*. 2001, at <http://mipr.umn.edu/archive/v2n1/edwards.pdf>, accessed on Aug. 27th, 2018.

³⁵ Judith Curry, *the patentability of genetically engineered plants and animals in the U.S. and EUROPE: a comparative study* (1987); michael b. landau, *multicellular vertebrate mammals as patentable subject matter under 35 u.s.c. § 101: promotion of science or and open invitation for abuse?*, 97 dick. l. rev. 203, 216-17 (1993).

³⁶ *ibid.*

into the fertilized egg of a host species. As a result, the milk from the transgenic animal will contain that protein, which may then be extracted from the milk and used as a pharmaceutical. For instance, in Japan, silkworms produce a vaccine for hepatitis³⁷. India could benefit greatly from improved pharmaceutical production capability. Second, pharmaceuticals companies use transgenic animals that are prone to certain diseases to test various drugs in order to determine their effectiveness. Transgenic animals are also used for biomedical research. Using transgenic animals, scientists are studying how cells operate. Also, scientists are learning about human diseases, and treatments for illnesses such as Alzheimer's disease, cancer and AIDS.

Coming to problems like food shortage and starvation, protecting animal patents for the promotion of the agricultural industry will promote food supplies, reducing starvation in India. "Transgenic animals are able to produce healthier food in greater quantities than normal animals, with reduced nutritional requirements".³⁸ This leads to increased food production since it costs less to produce more food from these animals. And this increased productivity could have great benefits for starvation in India. However, it is believed that industrialized countries that presently have the ability to create these animals would only make these animals available to developing countries if they receive profits in return. Protecting animal patents for medical research will promote the health of citizens through an understanding of disease and the means for treating disease. Scientists within a developing country might be able to use transgenic animals to gain an understanding of illnesses specific to that country. But again, the industrialized nations are only likely to let the developing countries use their inventions in order to enable them to gain such an understanding if the invention receives patent protection. Furthermore, the local knowledge base of scientists in India can increase if they are able to observe and learn about such inventions. Since patent laws are the only laws which favour full disclosure of an invention, India won't be able to gain knowledge necessary to create transgenic animals unless transgenic animals along with their formation process is patented in India. Therefore, not only can the patent laws allow scientists to target their research to diseases specific to that country, but patent laws can also promote the flow of information to a developing nation like India.

In the light of such facts it is desirable that transgenic animals should be granted patents provided they are in consonance with the TRIPS agreement.

PART IV

THE OTHER SIDE OF PATENTING TRANSGENIC ANIMALS

The potential of transgenic organisms is undoubted but the other side of it is destructive in nature. One of the most debated over disadvantage of it is that of sufferings caused to animals in manipulating. The process of genetic modification is fairly expensive with huge

³⁷*Ibid.*

³⁸*Supra note 34.*

investments requirement. Weighed against the success rate of such processes, it is only 15% of it.³⁹

The process is expensive also because of longer gestation period, higher maintenance and litter size cost of the recipient animals. There may be high mortality rate and other deleterious effects on animals used by researchers to create transgenic breeds. It has been observed that transgenic pigs having enhanced growth rate and efficient feed conversion exhibit reduced reproductive performance and may suffer from arthritis and dermatitis etc. Also, large number of recipients is required for embryo transfer because of low transgenesis rate. The irregular release of genetically manipulated organisms into the environment also leads to some serious environmental threats.

It is against this background that individuals argue against the patenting of transgenic animals.

It is also argued by some scientists that patents actually act as a deterrence to scientific innovation; the licensing fees that these patent holders charge for any scientist work concerning animals might prove as a discouragement to the smaller academic labs with more limited resources than larger profit-making companies. And this infact was originally the case with Oncomouse where the initial licensing fees were approximately \$5,000, and these were lowered over the years to zero dollars for non-profit universities.⁴⁰ Time and energy are taken away from scientific innovation, and instead are spent on negotiating the payment of licensing fees. Research shows that 20% of scientists delay disseminating their research findings to the public to file their patent,⁴¹ which abstain other scientists from using their results to make other advancements. If the benefits of such invention of transgenic organisms could not be reaped by the public at large then, the very purpose for which transgenic organisms are favoured would be hindered. Some people see a forthcoming danger that accompanies transgenic technology by allowing companies to patent specific genetic manipulations that raises many ethical, legal, and policy questions about whether genetic sequences themselves can be patented.

Out these arguments the most controversial hindrance for patenting transgenic animals are the ethical sentiments involved.

India, being a country where ethics and morality are held higher than anything, laws on patenting transgenic animals become the biggest challenge in India. For Indians, plants and animals are gift of nature and some varieties are even considered as a form of God. And patenting of such plants and animals would be no less than patenting and owning God.⁴² Such an idea would be not encouraged in the interest of public order and morality at was the similar stand of India taken in not giving private rights over natural things.

³⁹ *Supranote 29, p 234.*

⁴⁰ https://web.wpi.edu/Pubs/E-project/Available/E-project-082212-140656/unrestricted/Savan_and_Jeffrey_IQP_Final.pdf

⁴¹ *Ibid.*

⁴² *Supra note 34, p222*

Animal rights also seem to be violated when genetic manipulation and selective breeding are to be carried out on animals in order to produce transgenic animals. The process involve manipulating animals for human ends as if the animals were nothing more than human property, rather than treating the animals as being of value in themselves.

Recent action to allow animals to be patented reinforces the idea of animals as human property, rather than beings in their own right.

Keeping this ideology, The Patent Act of 1970 in consonance with the TRIPS agreement added that any “*invention or its exploitation which is against public order and morality and that may cause serious prejudice to the health of human being and animals or plants cannot be patented*”.⁴³ Further, even when under sub-clause(i) of section 3(b) plants and animals are excluded from patenting on ethical grounds, India being a member to TRIPS,(which provides patent on micro-organisms and such other living inventions produced through microbiological or non-biological or biotechnological process) is now encouraging patents on micro-organisms and other living inventions produced through biotechnological processes, however patenting of transgenic animals like we discussed are still to be encouraged.

PART V ANALYSIS AND CONCLUSION

The number of applications for patents filed during 2016-17 was 45,444 showing a marginal decrease of about 3% in the filing figure of 46,904 in 2015-16⁴⁴. During the year under report, filing of applications in majority of fields of invention has shown modest to high growth except in the fields of Chemicals, pharmaceuticals, Food, Bio-technology, Bio-chemistry, Micro-biology, Agro-chemical, Textile, Polymer and Metallurgy, which witnessed a decrease in filing as compared to the last year.⁴⁵

TRENDS OF FILING AND GRANT OF PATENT APPLICATIONS IN VARIOUS FIELDS OF TECHNOLOGY -2016-17

Filed in no.	Field	Granted
19640	Electrical, Electronics and related Subjects	2860
14540	Mechanical and Allied subjects	2546

⁴³ Section 3(b)

⁴⁴See 44th Annual report 2015-2016 &2016-2017 published by The Office of The Controller General of Patents, Designs, trademarks And Geographical Indications; and Annual report for the year 21016-2017.

⁴⁵*Ibid.*

9510	Chemistry and Allied subjects	3883
1754	Biotechnology, Micro-biology and Related Subjects	558

Table 1 ⁴⁶

The above table reveals, that in totality 9,847 patents were granted during 2016-2017 out of which 1,315 were granted to Indian applicants. The number of patents in force was 48,765 as on 31st March 2017, out of which 7,660 patents belonged to Indians. Out of the total granted patents, 3883, patents were granted to applications relating to the Chemical and related fields, 2546 to Mechanical, 2860 to Electrical and only 558 to Biotechnology.

Number of patents granted in Biotechnology from 2012 to 2017

Year	Biotechnology
2012-2013	144
2013-2014	220
2014-2015	262
2015-2016	185
2016-2017	333

Table 2⁴⁷

The above table shows that there has been steady increase in grant of Patent from the year 2012 to 2017. However, whether there has been any increase or fall in patenting of transgenic organisms is not revealed. The evolution of patent law on biotechnology inventions is not smooth but confusing in India. There is still a need to streamline the same with necessary adjustments relating to transgenic animals in the existing laws. Patent procedure is complicated and cumbersome in India. It takes more than 5 years to grant patent. Also another reason for biotechnology to not boost as rapidly as other field have in terms of patent could be lack of expertise of the patent office which makes the assessment and evaluation of patent application claiming genetic manipulation difficult. Enforcement mechanism of biotechnology involving genetic engineering might find it difficult to dispose such patent infringement suits owing to the complexity and technical nature of such inventions.

Thirdly, for granting compulsory licences of biotechnology patent is not uniform even for the member states of TRIPS agreement.

⁴⁶ See 44th Annual report 2015-2016 & 2016-2017 published by The Office of The Controller General of Patents, Designs, trademarks And Geographical Indications; and Annual report for the year 21016-2017.

⁴⁷ Ibid.

Fourthly, there is still a fear in mind of Indian Patent Office that if patent on transgenic organisms is encourages then there's a fair possibility to produce a transgenic Human being by abusing biotechnology in violation of public order and morality.

Hence, India's stand seem quite unclear when it comes to patenting transgenic animals.