



A Comparative Study on Transgenic Animal Breeding and Patentability Analysis in India: Reference to Animal Husbandry in Biotechnology Industries

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Authors' contributions

This work was carried out in collaboration between both authors. Both authors read and approved the final manuscript.

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ABSTRACT

Transgenic animal breeding or genetically modified animals are useful for various industries like the pharmaceutical industry, the agricultural industry, farming and medical research and development. In modern times the research on biotechnology and gene patent are frequently shows the urgency of development in the area of patent regimes. The United States and other developed country continue to expand their research on genetically-engineered animals and claims the patent protection. The paper aims to describes the process to evolve transgenic animals and the role in food industry. Furthermore, this article draws the development of animal patents in India and the issue regarding patent protection for transgenic animals.

Lastly, this paper concludes the adequate and flexible legal framework to support the patent granting and patent protection for transgenic animals to enhance the scope of research and development in the biotechnology industries.

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1. INTRODUCTION

Now a days the biotechnological inventions are commonly popular to the industries like animal husbandry, farming, medical sectors and pharmaceutical industries. These growing industries in developing countries like India has a huge scope in terms of transgenic animals as well as genetically modified animals breeding. As the farming concept develops from the western countries, it impacts are very powerful across the globe. The scientific methodology turns into the specific gene-orientation as such the genetically modification comes to the picture. It mitigates the starvation and disease like phenomenon to some extends and the need in the globalized world. The transgenic animals quite fruitful for their production of milk, meat and other consumables in the field of commercialization [1].

Moreover, the animal breeding for commercialization has protected under patent regime on the basis of molecular biology, genome sequencing and cloning. The advancements of these technology are subjected to protect for incentivizing the breeders and encourage them. [2] Since, the aim of patent grant is to promote the progress if science and useful arts, transgenic breeding becomes a part of these patentability also. Though there are some other ethical issues, also addressed by many scholars till the date this process of transgenic animal breeding proves to not be futile in research and development [3]. Patentability adherent contends that awarding patents to inventors creates greater motivation for them to produce innovative, practical products. In the Chakraborty case Supreme Court held that living micro-organism are patentable but there are several questions regarding this judgment falls in to place. Organism which is manufactured or composition of matters are entitled to patent [4].

Transgenic animals process: Impact in biotechnology: Genetic engineering means “the artificial manipulation, modification, and recombination of DNA or other nucleic acid molecules in order to modify an organism or population of organisms”. DNA is the primary molecule in living creatures which plays a pivotal role in the realm of biotechnological inventions [5]. Genetic engineering aims to create genetically modified genome in living organisms like animals also. DNA is the smaller units of genes, which has specific features and tends to

be not exactly the same for different animals and creatures in world. Further, genes can be compiled and arranged in different ways and that is how it creates the different DNA sequencing which totally ends a different creature. Recombinant DNA technology produces the manipulation of genes and sequencing. It contributes to the specified traits to the creatures. This non-conventional process leads to encourage the breeders to acquire some specified features like color or shape and size [6]. The breeder promulgates the expected genetic characteristics considering the effective resultant.

Different from the traditional breeding techniques, genetically engineered species creates the additional features by evolving in DNA. Microinjection is popular process which involves certain steps. Firstly, gene which is need to be modified isolated from the original species and then microinjection process has been conducted for the purpose of fertilization of embryo [7]. It stays as a single-cell stage and then the egg is incorporated in the female done species. Finally genetic engineering can profoundly produce transgenic animals with specific gene sequencing.

Benefits of transgenic animals: As genetically-engineered animals are very important for farming, agricultural pharmaceuticals industries and also biomedical research industries. The cost of conducting research and development and investment of time and money is so high before creating the genome setup for a new combination of genome. The inventions are subjected to patentability, through royalties the investments are incentivizes in this arena. Patent protection creates monopoly to the outer world for twenty years under the Indian Patent system. Thus, inventors are highly motivated by the way of doing genetic engineering in the realm of biotechnological inventions in research and development [8]. In the agricultural sector the modification on genetics creates more good quantities food, as the transgenic animals makes advancement of production on their fastest growth. The developing countries are most probably get benefited from this kind of genome modification in the economical zone.

Transgenic animals are useful for medical research also. The diseases like Alzheimer's diseases, human diseases, cancer and AIDS.

The United States has obtained patent on Harvard Mouse, for treatment on cancer [9].

Transgenic animals and genetic engineering: IP protection under patent act: Many of the patent applications in this field fall under the broad category of biotechnology, and the US Supreme Court has developed rules that apply to this technology. In *Brenner v. Manson*, the Court clarified that "any invention not positively harmful to society" did not necessarily imply patent utility, which instead implied usefulness [10]. Monopoly on substances with unidentified activities are the outcome of the scientific study. Animal breeding technologies clearly contributes to the protection in the field of Patentability and improves the economy upon the royalties fixed. The patent protection happens upon the international standard given by TRIPS [11]. The inventions are eligible only if it is novel and non-obvious.

Transgenic animals in developed countries on patentability: Developed countries are more proficient on patent laws so that the encouragement on scientific inventions and useful arts. It is very evident that animal patents are important for economy of the nation and provides research and development in scientific innovation [12].

Monopoly and getting royalties are the main purpose of granting patent. Additionally, it involves with the larger sector of the biotechnological industries. Historically, Patent is the largest form of IP and has the root grounded in the US and abroad legislation. US legislations grant patent for inventions that are useful, novel and non-obvious. Before living organisms are not patented but after Chakrabarty case Supreme Court observed that microorganism can be patented within the meaning of s.101 [13]. Edible Sterile oyster is patentable for years. For an instance, A virus-resistant mouse is useful to treat disease, patented by the Ohio University.

European Patent Convention (EPC) stated patentable subject matter can be inventions which is new, involves with inventive steps and which has industrial application. Europe patent system grants transgenic animal patent. European patent legislation makes their law little wider to interpret on a case-by-case basis.

Transgenic animal patent protection in India: India does not grant transgenic animal patent so

far, Chakrabarty case has witnessed the rigid legal framework in the Indian legislation and their interpretation. Country like India do not grant adequate patent protection for transgenic animals, Piracy is the main reason for Indian market and economy. Local piracy has done on very lowest cost which harms the actual research and development cost [14]. Developing countries are not very interested on patent protection, somehow the countries which are progressing in their biotechnological inventions being denied for getting patent. Moreover, granting patent means granting a monopoly, local business could not compete with them. Some other factors also include that the higher cost and non-availability is a big issue altogether. Domestic player should be introduced in global market, but paying royalties to the technology developer sometime curtails the possibilities for domestic industries [15]. Indian Patent system recognizes the need for invention as well as the need for development in the animal husbandry or other pharmaceuticals industry. The trade system also plays a pivotal role in this scenario. The patent regime can not be working as a one-man army platform, the entire trading web is connected through the economical situation.

Patenting invention will increase availability of invention in the country and piracy will not a be factor for investing money in the particular invention from foreign investors. For an example the more animals are available conducting research is possible for pharmaceutical companies, biomedical [16]. Above all, though, patent laws' enabling provisions mandate complete disclosure of an innovation; hence, by granting patent protection for an invention, developing nations would have access to technological knowledge. Developing nations can use this material to learn about different technologies that support their own development and expansion.

Subsequently, India can reduce transaction and enforcement costs by granting patent protection [17], that is, the USA or other nations may use unilateral measures, such as sanctions, if India does not provide sufficient patent protection. The LDC may incur higher costs as a result of sanctions than from the original patent protection. Such unilateral action could serve as an effective disincentive to attempts at piracy. Patents might encourage foreign investment in a least developed country (LDC), which would spur growth. Given the high level of speculation and significant expenditures associated with research

in the biotechnology sector, investors must be persuaded to take a big financial risk by offering substantial earnings expectations. In the absence of substantial profits, the majority of investors will lack motivation to participate [18]. Also, the pharmaceutical, agricultural, and medical research sectors are the main industries that use transgenic animals. These sectors are essential to the growth of LDCs since hunger and disease represent two of the biggest issues facing emerging nations. Since many pharmaceutical products are made using transgenic animals, protecting animal patents for the benefit of the pharmaceutical business can increase the accessibility of medications. Enhancing the accessibility of these animals will result in a rise in the availability of medications [19]. If there is a chance of profit, developed nations with ample resources for pharmaceutical manufacturing will be more inclined to invest in the pharmaceutical sector of underdeveloped countries. The pharmaceutical industry will grow and become more efficient as a result of this investment, increasing the amount of medications available in LDCs [20]. Preserving animal patents in order to advance the agriculture sector will increase food supply and lower the rate of starvation among the least developed countries.

Ethical issues regarding transgenic animals:

The patenting of genes and animals has given rise to numerous ethical and societal concerns [21]. Among them are: 1) Patenting genes or animals will destroy the natural world and enable humans to act as "gods"; 2) Patenting will result in more animal suffering; 3) Patenting will decrease animal genetic diversity and endanger species; 4) Patenting will devalue animal life and hence human life; 5) The commercialization of academic research is accelerated by patenting; 6) Patenting will make industrial farming techniques more prevalent and threaten traditional farming practices. Animals were first tamed by humans, and skilled breeders and geneticists turned them into productive species. Undoubtedly, boundaries have been (and still need to be) established to define acceptable and undesirable behaviour. For instance, the majority of individuals and governments have come to the conclusion that, although cloning animals is permissible (at least when used for study), cloning humans for any cause is wrong and should be avoided. Concerns about animal rights and welfare are nevertheless fundamental to both livestock production and biomedical research [22].

People who think that animals have "rights" will probably be against patenting any technology that comes from studying animals. The most frequently given instances include transgenic animals, such as the original transgenic pigs, where certain animals experienced health issues. Animal rights activists also view as immoral the production and patenting of specialized lines of rats that are predisposed to particular diseases for use in scientific research [23]. However, patenting is significantly less of a problem if people think that animal rights are less important than human rights but that animals still deserve to be treated with care and welfare.

International agreements: discourse of bilateral agreements:

Historically, the United States has employed various processes such as unilateral measures, bilateral agreements, and multilateral accords to obtain agreements with its trading partners [24]. The greatest short-term solution for guaranteeing patent protection for transgenic animals is bilateral agreements. Eventually, the bilateral agreements might be integrated into multilateral agreements. Direct discussions make up bilateral agreements, which, if required, should be supported by economic sanctions. The benefits of bilateral agreements include a higher likelihood of short-term success due to the reduced number of interests that need to be taken into account and discussed. Bilateral agreements provide flexibility in addressing different challenges with diverse ideas 3) Through bilateral accords, the US and a certain trading partner can come to a settlement. Therefore, these countries might be more open to signing multilateral accords in the future [25]. Bilateral accords are sometimes criticized for being at odds with the long-term goals of global trade. Bilateral agreements involve two countries, which leads to a disjointed trading system.

Multilateral agreements, which involve numerous nations, are supported by this rationale. However, because just two countries' interests need to be taken into account rather than the interests of many, bilateral agreements are far simpler to accomplish in the short run. Long-term interests may also be taken into account during bilateral discussions, and these accords may be included into a multilateral agreement with a longer duration. However, the bilateral meeting needs to be the initial action item [26]. Numerous bilateral agreements have been successfully negotiated by the US. Taiwan, for instance, has modified its copyright regulations to impose harsher sanctions on pirates." Additionally,

Taiwan passed a new patent legislation. Furthermore, Korea's intellectual property laws have undergone a number of upgrades. At last, Brazil has increased the scope of its software protection [27].

Corresponding agreements on treaties:

Multilateral agreements are an option in place of bilateral ones. The US and several economic partners participate in multilateral agreements. Multilateralists argue that there are various reasons why multilateral accords are preferable [28]. First of all, proponents contend that because multilateral accords involve numerous countries rather than just one, they are more effective. However, international accords take a long time to complete. Certain aspects of a multilateral agreement may be met with resistance from a number of countries during negotiations [29]. Customized bilateral contracts with these nations could indulge in participation and bring them to the benefits of global agreements. By using bilateral accords as a first step, these nations may eventually be more open to taking part in multilateral negotiations [30]. The Biodiversity Treaty, the World Intellectual Property Organization (WIPO), and the GAIT negotiations are a few instances of problematic international agreements. UN agency called WIPO was established to deal with matters pertaining to intellectual property, including attempts to harmonize patents. The majority of developing nations support WIPO, notwithstanding some reservations about the wide variety of inventions that are protected [31]. However, developed nations continue to reject WIPO because of its rules, which would, among other unfavourable developments, force the US and other nations to stop patenting plant and animal types. The laws pertaining to forced licensing also gave rise to arguments. The United States would have to make a lot of adjustments to the current patent system if the WIPO proposals were passed. WIPO is still not complete [32].

An international agreement known as the Biodiversity Treaty was created to safeguard species of plants and animals that are facing extinction. The United States declined to sign the pact, despite it being available for signature during the Earth Summit in Rio de Janeiro in June 1992. Fears that the deal will limit biotechnology development in the US led to the refusal [33]. Furthermore, because the deal did not grant any inventions, it would interfere with the biotechnology industry's access to US patent

protection. Assessing the significance of animal patents was another area of disagreement in this multilateral accord.

GATT is conceivably the most promising multinational accord. In the Uruguay Round of the GATT negotiations, the ideas pertaining to intellectual property were opposed by the LDCs, while the industrialized countries supported them. The proposed dispute resolution methods were especially well-liked by the industrialized nations, as they differed from those found in any other multilateral agreement [34]. From any of these international accords, no consensus has been reached. As a result, the US should seek bilateral agreements in the near future, particularly with regard to animal patenting.

Key findings:

1. Restructuring Indian Patent system: Since, the Indian Patent system is quite adequate in terms of granting patentability. International standards of originality test are followed by Indian Patent Registrar, although the Indian judiciary is reluctant to grant frequently patent on transgenic animal, the fact is not about only the patentability issue but granting patent is almost a step ahead for monopoly, which is an issue India like country where local markets are more in dominant position. Patent on transgenic animal leads to a huge difference on economical frustration.

2. Encouragement on Transgenic animals' patentability and restriction on Piracy: India restricts patentability on subject matter like pharmaceuticals inventions. Transgenic animals' patentability is in question in Indian patent structure, due to this uncertainty aspect of patentability, scope of piracy increases in a specific way. The United States Trade Representative investigates priority countries which are not providing adequate patent protection due to unfair trade practices. Piracy is one of them, which needs to be treated under sanction imposed. Though India has failed to impose sanction.

3. Accordance with WTO and other treaties: The Biodiversity Treaty aims for protecting animals and plants which is endangered but US does not sign the treaty as it may not allow research on the sector in biotechnology, GATT is the quite best multilateral agreement. India does not take any stand for proposed dispute resolution mechanism, denying the patentability

on genetically modified organism the first step to not compliance of international standard.

2. CONCLUSIONS AND SUGGESTIONS

In essence, the debate over animal patenting is a fight over other matters of policy.

Animal patenting is opposed by those who view it as a sign of several undesirable societal developments. The anti-patenting coalition has taken advantage of the new PTO regulation to voice their concerns about these broader developments. However, proponents of patenting have sufficiently shown how new forms of animal life benefit civilization. However, this scientific skill may potentially have unfavorable repercussions on our culture and environment, just like most new technologies. The transgenic animal patenting gives a rise to patentability all over the world, which also generates the economy. Since, the patent regime encloses the field of biotechnology and pharmaceuticals industry in such way that it can propagate the entire economy and invention in same pedestal.

Therefore, minimizing the negative effects of technology while optimizing its good contributions represents the real challenge. A blanket ban on animal patenting would be an overreaction on the part of the government, discouraging industry and inventors from working together to develop the technology's potential uses. It would not stop the production of genetically altered animals in laboratories, and it is unlikely to stop the selling of such animals either, considering the other tactics that biotechnology companies could use to safeguard their financial stakes in the animals. Therefore, despite its conceptual shortcomings and unjustified criticism, the case against animal patenting may prove to be quite helpful in pressing policymakers to consider a number of important issues that the country is currently experiencing. Indian Patent system increases the patentability requirement in the arena of international standard followed by USA, Europe and developed countries. Transgenic animal patentability protection is not only helpful for inventors but also it shows a dynamic evolution on Biotechnology industries and other industries.

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COMPETING INTERESTS

Authors have declared that no competing interests exist.

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