



# Legal Complications on Patenting Crossbreed Animals: A Comparative Discussion on India and Abroad

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**Author's contribution**

*The sole author designed, analysed, interpreted and prepared the manuscript.*

**Article Information**

DOI: <https://doi.org/10.56557/upjoz/2024/v45i194538>

**Open Peer Review History:**

This journal follows the Advanced Open Peer Review policy. Identity of the Reviewers, Editor(s) and additional Reviewers, peer review comments, different versions of the manuscript, comments of the editors, etc are available here:

<https://prh.mbimph.com/review-history/3820>

**Short Communication**

**Received: 02/06/2024**

**Accepted: 05/08/2024**

**Published: 14/10/2024**

## ABSTRACT

The patentability of cross-breed animals is a complex area facing constant evolution. The intellectual property law varies significantly in this domain between various jurisdictions. The study focuses mainly on a comparative analysis between IPR rights of India and abroad, where. This paper aims to provide a comparative discussion on the legal frameworks that govern rights of patentability of cross-bred animals in India and abroad, focusing on the lacunas that are highlighted to understand where the Indian legislation, despite being quite robust in plant cloning and breeding, falls short in animal cross breeding. The paper takes a dive into the international standards and practices and then tallies it in the Indian context. All the major and key jurisdictions such as the United States, European Union, and Australia are taken into consideration for the purpose of discussion, to understand what remedies could be generated on the basis of the comparative analysis. The Indian legislation, precedents and policies are considered to draw conclusions. It also

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tries to pass remarks on the implications on innovation, animal welfare, and efforts for global harmonization in IPR. To draft this paper, the authors have taken help from various primary and secondary resources.

*Keywords: Cross breeding; cross breed animals; patent; intellectual property rights; India.*

## 1. INTRODUCTION

The patentability of crossbreed animals is an intricate and constantly evolving area. In the field of biology, an invention that covers biological aspects is referred to as a biological patent. Obtaining patents for animals grants the right to use them [1,2,3]. Historically, patents were established to ensure that inventors would receive compensation and other benefits for their creations. However, in today's context, bioprospecting, also known as biopiracy, has become a highly profitable industry.

Interestingly, there is a lack of comprehensive legislative frameworks worldwide specifically addressing the crossbreeding of animals. While some countries have made significant progress in developing legislation for plants, they have not yet extended their focus to include animals in this regard. While India has significant legislative works on plant patents, it falls short on the same while dealing with crossbreed animal patents [4,5].

This paper aims to concentrate on the rights of patents, the procedures involved in obtaining them, their applications, and the legal consequences associated with the protection of such rights. It also explores violations of these rights, particularly in relation to crossbreeding various animals. The discussion will primarily focus on key jurisdictions across the world and subsequently provide a comparative analysis with the Indian legal system.

## 2. CONCEPTUAL FRAMEWORK

This part deals with the conceptual framework of the paper by giving a summary of the article so as to introduce the context in general. The second part focuses on the international standards and practices regarding cross breeding of animals and aims to provide for a broader idea of the popular methods and techniques observed in the prime areas. The third part, concentrates on finding out the legal frameworks and their similarity, if any, that has been adopted in many parts of the world and also looking into the historical background to

some extent, if any, that influenced such framework. The fourth part looks into the Indian laws, rules and regulations, if any, that safeguards the patenting rights of animal cross breeding. The fifth part marks a comparative discussion on the lacunas and drawbacks, if any, in the Indian legislative framework on the subject matter as compared to the international standards and practices. Finally, the sixth part sheds light on the key areas that needs focus to build a robust legal infrastructure for the betterment of the framework.

### 2.1 International Standards and Practices

In discussion of the international standards and practices, let us first focus on what the United Nations has to say on the matter. While the plant varieties had received recognition for a proper regulatory framework in safeguarding its IP rights since 1930, the same cannot be said for animal cross breeding. The Animal Breeder's Rights are considered to be the closest in consideration on the subject matter, which merely identifies and analyses the elements that could fit the criteria for implementation [6].

The concept of applying for patents on living organisms originated roughly in the 1980s. Most of the countries of the world do not have proper mechanisms or infrastructure to even start the process, let alone excel in it or generating significant outputs. A famous case that is frequently referred in this regard is that of the *Diamond v. Chakrabarty* [7] that made the Supreme Court of the United States respond in a wide ambit when the five pro judges reflected their opinion that "anything under the sun that is made by man" is patentable, against the four other dissenting judges. This judgment laid down the foundation for alteration of the previously followed idea that protection through patent is unavailable in food production [8].

Another important international legislative framework is the Nagoya Protocol, adopted in 2010 and enforced in October 2014, which includes traditional knowledge but focuses on fair access to genetic resources and sharing benefits from their use. The Protocol mainly

targets the commercial use of wild species, especially plants and has little applications on livestock and therefore as a result, the Protocol's impact is considered limited [9].

## 2.2 Legal Framework across the World

There are little legislative works found across the world on cross breeding of animals. There is no direct legislative drafting regarding the subject matter, however, some of them are mentionable. The United States for instance, has the Animal Welfare Act (AWA), which is considered as the primary federal legislation but it is disputed to have completely eradicated inhuman treatment towards non-human animals. While puppies, felines, apes and monkeys, rodents, hares, or other mammals are used for scientific investigation, examination, and experiment purposes are included, yet fowls, pests such as mouse, rats, etc. bred for use in research, and other farming animals, such as, but not restrained to, cattle or poultry birds, are not taken into account in the purview of the Act's coverage. The amendment of 1985 has decreased the level of possible suffering of primates for research purposes by promoting physical environments suitable for adequate psychological well-being, but the Act has been overall criticized for being weak to defend its objectives. On the other hand, the Patent Act, 1952 [10]. This law states that for something to be eligible for a patent, it must be new, useful, and not obvious. Section 101 of the act explains that patents can be provided for fresh and resourceful activities, hardware, constructor, structure of matter, or transformations on these. Biotechnology patents typically fall under the "composition of matter" category. Before transgenic organisms were developed, animals and other natural products were not eligible for patent protection. However, that scenario changed drastically after the *Diamond v. Chakrabarty* case. Soon after, the head of the PTO stated that artificially occurring creatures with multiple cells can now be patented. Researchers from Harvard obtained the animal patent for the first time for their onco-mouse within two years. In terms of the absence of laws governing biotechnology research and animal cloning, the EU and the US are comparable. By virtue of Article 100 of the Treaty of Rome, the EU is able to demand that member states impose civil penalties on individuals who violate its directives, limit the use of animal cloning and biotechnology research, and reject patent applications pertaining to biotechnology or

biotechnology-related products, such as medications and food [11]. The evolution of European patent law is comparable to that of American patent law. The European Patent Office (EPO) granted the first transgenic animal patent in 1990, and it was for the same Harvard mouse that was patented in the US. Animals with different genes from different animals are equally patentable in Europe and the US, notwithstanding minor differences in the EPO's standards. According to article 52(1) of the Convention on the Grant of European Patents (EPC), "European patents shall be granted for any inventions which are susceptible of industrial application, which are new, and which involve an inventive step." The European Patent Office (EPO) grants patents for transgenic animals and the specific gene sequences inserted into these animals, in contrast to the United States. In Europe, it is possible to patent the animal and its genetically modified genes separately [12].

## 2.3 Indian Regulatory Framework

The Indian legislation too has worked significantly on plants but have turned their faces from animals regarding the subject matter. The Biodiversity Act, 2002 [13] and the Protection of Plant Varieties and Farmers Rights Act, 2001 [14] have been implemented after India became a member state of the International Union for the Protection of New Varieties of Plants (UPOV) [15] in 1961, and Convention on Biological Diversity (CBD) [16] in 1992. The Patents Act, 1970 [17] was amended in 2005 [18] after India adopted the TRIPS agreement [19] in 1995. But nonetheless, these legislative works are inadequate in addressing the issue that patenting cross breeds. Inventions involving living things and genetically modified creatures were not really protected by patents until the 1970 Patent Law Amendment of 2002. Following the decision in *Dimminaco A.G. v. Controller of Patent and Design* [20], this was altered. The Calcutta High Court ruled that a method for creating live viral vaccines is patentable since the word "manufacturing" encompasses and is not restricted to living things. The court found that the method involved in bringing the final product to light can be regarded as and characterised as an innovation for all intents and purposes, even if the finished result contains a live virus. The case for genetically modified organism and living organism patents was strengthened by the ruling in *Monsanto Technology LLC v. Nuziveedu Seeds Ltd.* [21]. The Honourable Supreme Court ruled in this

case that patents could be obtained for genetically modified cotton seeds, so enabling the American corporation Monsanto to submit their patent applications.

### 3. DISCUSSION

Patenting crossbred animals falls under biological patents. An invention covering biology is called a biological patent. In the past, patents were established to guarantee that inventors would earn compensation and other advantages for using their creations. Nowadays, bioprospecting, also known as biopiracy, is a lucrative industry [22]. First-world bio prospectors use legacy knowledge as a guide to mine the rich generic resources of the third world for medicinal chemicals and other products [23]. This is resource theft from the community, and it will increase the wealth of developing nations. Consequently, for goods derived from flora and knowledge that they have used for thousands of years, indigenous peoples might be required to pay royalties. Around the world, a wide range of organisations representing farmers, legislators, religious authorities, and environmental NGOs oppose biopiracy [24]. A "halt to the patenting of all life forms" and the denial of a patent application pertaining to human genetic material are demanded in a declaration signed by 118 indigenous organisations from 27 different countries. For organisms that are not present in nature, patents may be granted. This is not to say that a superior dairy cow, pig, or mixed-breed dog cannot be patented after years of meticulous breeding. A plant or animal that exists in the wild cannot be patentable. Animals that have undergone genetic modification and are therefore extinct in the wild are eligible for patent protection. These species are commonly called "transgenic" animals because their genomes have been modified by adding genes or DNA from humans or other animals. These organisms are altered by scientists to give them desired characteristics for study or experimentation [25].

### 4. CONCLUSION

A number of countries forbid the patenting of animals. In 2002, the Canadian Supreme Court heard arguments about the Harvard Onco-Mouse patent and ruled that higher organisms, including mammals, are not eligible for patent protection. Joining Canada in prohibiting animal patents are European countries like Brazil, China, Denmark, India, Ireland, Netherlands,

Norway, Belarus, etc and Asian countries like the Philippines, Russia, and Thailand. With US, there are some other authorities as well such as the European Patent Office, UK, Australia, and Japan who also provide patents on animals [26]. The US patent system has two significant limitations on the availability of animal patents: (1) a moral restriction that forbids patents on human/animal chimaeras, and (2) a utility requirement that requires the invention to be helpful or beneficial to society. Since transgenic animals are used for beneficial research, patents for them typically satisfy the utility criteria; nonetheless, patents do not cover concepts that are directly related to humans. Extra exclusions are included in the European Patent system for inventions that violate public policy or morality. Under this approach, non-technological considerations including environmental hazards, ethical ramifications, and animal welfare are taken into account during the patent process [27]. Furthermore, while deciding whether or not to provide patent for animals, the European Patent system considers the positive outcomes of the invention to humans against the suffering of the related animals. Numerous organisations think that the US should take up these non-technological challenges [28].

### DISCLAIMER (ARTIFICIAL INTELLIGENCE)

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### COMPETING INTERESTS

Author has declared that no competing interests exist.

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