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Animal Biotechnology and Intellectual Property Rights: A Comprehensive Analysis

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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

Animal biotechnology can be defined as the collection of methods employed for altering animals in order to serve different uses such as in the farming systems, laboratory and in the treatment of diseases among others. This field has come a long way and new accomplishments have been witnessed in such fields as genetic engineering, cloning and production of transgenic animals. Nevertheless, such enhancements also present related issues with regard to intellectual property rights as well. Taking the subjects of animal biotechnology with IPR, ethical, legal, and economical aspects into consideration. This paper gives a description of the developments made in the course of the animal biotechnology, analyses the existing legal regulation of IPR in this area and examines the main problems and barriers.

Keywords: IPR; biotech; patent law; transgenic animals; genetic engineering.

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1. INTRODUCTION

Animal biotechnology as a discipline has expanded fairly fast in the recent past; this has been brought by developments in genetic engineering and molecular biology. Current methods that are utilized by the scientists include CRISPR-Cas9, somatic cell nuclear transfer, recombinant DNA technology. They have implications in increasing yields in livestock farming, discovering new treatments for diseases, and boosting knowledge of biology [1]. But for the biotechnological innovations being commercial in nature, the need for the protection of intellectual property rights regarding these innovations in order to encourage innovation cannot be overemphasized while upholding the ethical and equitable use of the technologies cannot be overemphasized. In the initial stages it was a slow process and was not even considered popular enough. A new era of transition in the biomedical sciences was ushered in by the development of techniques such as gene editing, fusion of cells, culture and manipulation of cells, recombinant DNA or genetic engineering, and creation of monoclonal antibodies [2]. It was discovered in the meantime that the aforementioned advancements, when combined with reproduction technology, may alter cells, embryos, and animals, with remarkably positive results [3,4]. This sparked worries about the security of intellectual property in animal biotechnology. Currently, a significant domain of basic and applied biological research is focused on animal biotechnology, with the goal of creating transgenic or gene-edited animals for the finding of human diseases, veterinary vaccinations, and innately altered animals for organs and medicines [5]. All of this requires intellectual labour, and the results have significant economic implications. By immersing in IPR related to animal biotechnology, individuals can examine cutting-edge approaches, contribute to ground breaking research, and discourse real-world challenges [6,7].

Thus, in this article, the authors will try to analyse the foundational conceptions of animal biotechnology, underline significant improvements in the field, and examine the influence of IPR on advancing research and education in this vibrant area. Via an exhaustive summary, the authors also seek to nourish discernment into how animal biotechnology is recasting science and community, and how IPR conform as a necessary instrument for facilitating scientific query and improvement.

2. CONTEMPORARY ADVANCEMENTS IN ANIMAL BIOTECHNOLOGY

Many biotechnology-related procedures and techniques are currently protected by law, with the majority of these procedures having their origins in the United States. Subsequently, rival nations entered the emerging biotechnology markets. They realised how critical it was to change their national legislation to safeguard and encourage investment in biotechnology. Biotechnology inventors choose to patent their inventions even if there isn't a universal agreement on how biotechnology should be handled. Animal biotechnology encompasses a variety of techniques aimed at modifying animal genomes. Key advancements include:

2.1 Genetic Engineering

Techniques like CRISPR-Cas9 have enabled precise modifications in animal genomes, permitting for the creation of transgenic animals with required traits, such as disease resistance or enhanced productivity [8,9].

Genetically engineered animals are described using a variety of terminology, including the terms genetically changed, genetically manipulated, transgenic, and biotechnology-derived. In the early days of genetic engineering, the major technology used was transgenesis, that literally means the transfer of genetic material form one organism to another [10]. However, as research advanced, new techniques arose that did not call for transgenesis: modern uses allow for the generation of genetically altered animals through gene deletion or editing. To reflect this advancement and to encompass animals that are not precisely transgenic, the Canadian Council on Animal Care's (CCAC) recommendations now use the umbrella term "genetically engineered"[11].

Patents encompass a range of technologies that are used to edit the stem cells and genome of mice or rats [12]. The French institutes CERBM and IGBMC (Centre Européen de Recherche en Biologie et en Médecine–L'Institut de génétique et de biologie moléculaire et cellulaire) hold patents that describe the use of tamoxifen

medication to enhance Cre recombinase activity in transgenic mice [13].

2.2 Cloning

SCNT has been used to produce genetically identical animals, facilitating the study of genetic diseases and the conservation of endangered species [14]. Regulations pertaining to this technology have been set by the US Supreme Court. In Brenner v. Manson, the American Supreme Court clarified that "any invention not positively harmful to society" did not necessarily imply usefulness [15]. The Court voiced concerns about a monopoly on substances with unidentified activities and stated that the product's utility must go beyond demonstrating that it is the outcome of scientific study. Cultural adaptation has triumphed over biological adaptation in humans because it is a more effective mechanism of adaptation; it is faster and can be directed. A favourable genetic mutation that has just emerged in an individual can only be transferred to a sizable portion of the human population over a number of generations.

2.3 Transgenic Animals

The production of transgenic animals involves inserting foreign genes into an animal's genome. These animals are used for various purposes, including pharmaceutical production (biopharming), research models, and agricultural improvements. In order to carry out the transgenesis procedure, foreign DNA sequences must be inserted into the transfected cells' genomes and ensured to be integrated and passed on to the progeny. Practical uses of transgenesis in animal production include higher disease resistance, better growth rate and feed utilisation, improved prolificacy and reproductive performance, improved carcass composition, and improved milk output and/or compositions. One of the most crucial candidate genes for creating transgenic farm animals that will accelerate their growth and produce more milk is growth hormone.

3. INTELLECTUAL PROPERTY RIGHTS IN ANIMAL BIOTECHNOLOGY

Intellectual property rights has a crucial role in the development and commercialization of biotechnological innovations. Antibiotics, monoclonal antibodies, and vaccines all offer defence against infectious illnesses. Numerous IP protections apply to vaccinations due to the wide range of vaccine forms, vaccine components, delivery technologies, and distribution networks [16,17]. As our knowledge of the molecular biology of viruses has grown, so too has the use of viral gene expression techniques and virus sequences in the diagnosis and treatment of disease. This broadens the potential for patenting several vaccine ingredients. Also, patents reflecting multiple antigenic peptide (MAP) assays for the occurrence of viral infectious diseases in cattle, several forms of synthetic and recombinant antigen for fast sero-diagnosis of viral infectious diseases also exist [18]. Key forms of IPR relevant to animal biotechnology include:

3.1 Patents

Patents provide exclusive rights to inventors for their inventions, including biotechnological processes and products. In the context of animal biotechnology, patents can cover genetically modified animals, cloning techniques, and specific genetic modifications. About 600 animal patents had been issued globally by 2004, with the majority (80%) pertaining to the use of "animal models" in biomedical research [18]. Only three nations, including the United States and the European Union, permitted patents on research animals.

3.2 Trademarks

Trademarks protect brand names and logos associated with biotechnological products, helping companies differentiate their products in the market. Trademarks serve as a valuable tool for companies to differentiate their products and services, build brand loyalty, and prevent market confusion. In the context of animal biotechnology, trademarks can protect unique genetic modifications, biopharmaceutical products, and biotechnological processes.

3.3 Trade Secrets

Trade secrets keep confidential data that offers a competitive edge, such as proprietary techniques or genetic data. Unlike patents, trade secrets do not require disclosure of the protected information, providing an indefinite duration of

protection as long as the secrecy is maintained. Examples of trade secrets in animal biotechnology include proprietary genetic sequences, breeding techniques, and biotechnological processes [18]. A prominent example of trade secret protection in genetic engineering is the proprietary methods used by companies to develop disease-resistant livestock. These methods often involve complex genetic modifications that are kept confidential to maintain a competitive edge in the market [19].

4. CHALLENGES

The animal sciences have expanded the uses of biotechnology and molecular biological instruments. In the current environment, transgenic animals play a significant part in the growth of the pharmaceutical industry and medical research. Prospective development of industries related to biotechnologies and the importance of the patenting of genetically modified animals has been already realized by the countries of the developed world. Surprisingly, the poorest countries in the world have the highest biodiversity because they lack the means and know-how to turn their bioresources into goods that can provide income. Furthermore, the impoverished or developing nations lack the resources to fund research and adequately safeguard genetically modified animal patents. Strategic planning and diligence can help reduce the legal costs associated with intellectual property.

The legal protection of animal biotechnology is a contentious process, and as such, short-term growths are most expected to occur at the national and regional levels. We stress that in order to safeguard the results of innovative research processes or the final product, individuals working in biotech start-ups, academic institutions, or commercial pharmaceutical companies must possess a solid understanding of the patent system. Virtually every invention made by a scientist is impacted by IP [20].

However, in order to cope with the complicated issues of intellectual property and their rights and obligations, investigators and scholars functioning in the disciplines of animal biotechnology and genetic engineering need to receive training. The major challenges in this sector are provided below in the Fig. 1.

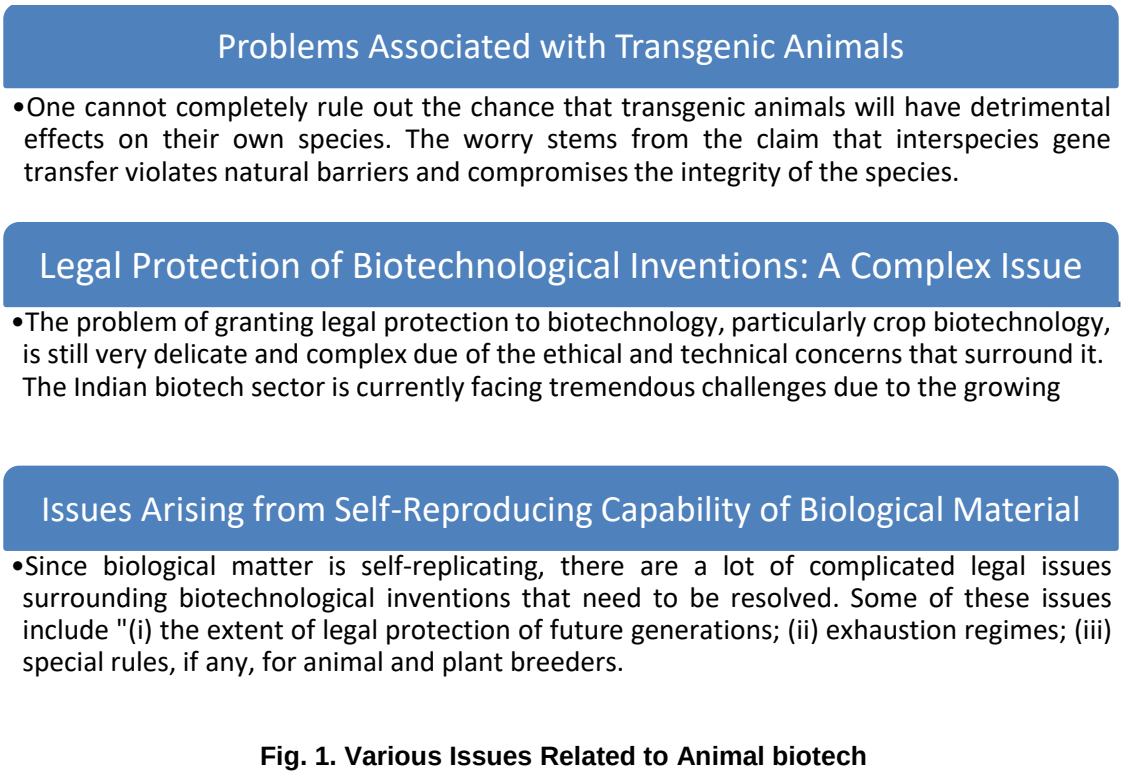

Fig. 1. Various Issues Related to Animal biotech

5. CONCLUSION

Animal biotechnology holds tremendous potential for advancing science, medicine, and agriculture. However, the commercialization of these innovations necessitates a careful balance between incentivizing research through intellectual property protection and addressing ethical, legal, and social implications. A robust and equitable regulatory framework is essential to harness the benefits of animal biotechnology while ensuring its responsible use. A contemporary branch of life science is biotechnology. The basis of biotechnology is the molecular (DNA/GENE) level [21].

The genetic composition of living things can be altered with the use of contemporary biotechnology instruments and methods. Modern biotechnology is the most beneficial technology for the environment, agriculture, and human health. defence, etc. GMOs like Bt cotton, insulin, and human growth hormone are a few instances of contemporary biotechnology. The patent offices of emerging nations face numerous complicated challenges and issues due to the recent and rapid advancements in biotechnology.

The pre-colonial patent rules of the developing countries are the primary source of these issues and hurdles, and the patent offices of these countries lack expertise in biotechnology technologies. Efficacious IPR frameworks can propel innovation by safeguarding inventors' rights and stimulating acquisition in research and development. However, they must be balanced with public welfare, assuring that biotechnological advancements stay unrestricted and valuable to society as an entirety. The intricacies of patenting living organisms, the ethical implications of genetic transformation, and the requirement for equitable access to biotechnological inventions are key points that must be preached through cooperative efforts between policymakers, scientists, industry stakeholders, and the public.

To conclude it can be stated that, it is crucial to foster an environment where innovation in animal biotechnology can flourish while preserving concentrated ethical paragons and equitable access. Continued dialogue, research, and transformation of IPR policies will be fundamental to navigating the challenges and prospects submitted by this rapidly developing field. Via such endeavours, we can harness the full prospect of animal biotechnology to discourse global challenges and enhance the well-being of both creatures and humans.

DISCLAIMER (ARTIFICIAL INTELLIGENCE)

Author(s) hereby declare that NO generative AI technologies such as Large Language Models (ChatGPT, COPILOT, etc) and text-to-image generators have been used during writing or editing of manuscripts.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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