Patenting of Animal Biotechnology: Ethical, Legal and Social Implications

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Abstract

Recent advancements in animal biotechnology have created enormous possibilities for increasing the livestock nutrition value of animal products and improving animal health. To encourage investment and promote innovation in this field, countries worldwide provide patent protection to animal biotechnology. Since animal biotechnology involves use of animals in whole or in part along with microorganisms, it raises serious ethical, legal and social issues touching upon the dignity of animal life. Countries vary in their approaches to patent law dealing with animal biotechnology based on their social, political and cultural setup. The debate pertaining to patenting of animal biotechnology is entangled between two continuums: first, innovation and economic growth and second implications of animal patenting on animal dignity, animal and human health, environment, biodiversity and agricultural structure. Against this backdrop, the present article undertakes an analysis of ethical, legal and social implications of the patenting of animal biotechnology in USA, EU, Canada and India.

Keywords: *Animal biotechnology, patent, Harvard oncomouse, microorganism, genes,*

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Introduction

Biotechnological advances relating to animals made colossal growth in the animal livestock by having better yields both in terms of quality and quantity. Animal biotechnology promises more productivity with less feed consumption and ensures healthy nutritional content through this productivity. Animal biotechnology creates an enormous potential to yield commercial results, attracting investors to invest heavily in this field. Investors see patent as an efficient tool to reap the benefits of their investments. Animal biotechnology does not focus only on enhancing and improving livestock but on enhancing animal health and using animals for experimental purposes to improve human health. The use of animals for experimental purposes raises ethical and moral issues to be dealt with within the IPR regime. Countries vary in their patent approaches to animal biotechnology despite the harmonisation provided by the TRIPS Agreement. Against this background, the present chapter analyses the ethical, legal and social implications of animal biotechnology patents, focussing on three jurisdictions, the USA, European Union, Canada and India.

Animal Biotechnology

Animal biotechnology has its roots in animal breeding, which is not new. It has been in practice for a long time; the only distinction between traditional animal breeding and animal biotechnology is that the former was restricted to selective breeding, while the latter involves recombinant technology, genetic engineering and gene-splicing techniques that can transform and tailor genetic traits.[1] It is defined as "a branch of biotechnology in which molecular biology techniques are used to genetically engineer (i.e. modify the genome of) animals to improve their suitability for pharmaceutical, agricultural or industrial applications."[2]Animal biotechnology yields significant results in increasing the livestock with products having good nutritional value with lower food input than that for the traditional breed of cattle. Transgenic cattle produce more milk as compared to traditional ones.Animals are also used as experimental models for human diseases such as hypertension and AIDS, for which no natural

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[1] Shobita Parthasarathy, *Patent Politics-Life Forms, Markets & Public Interest in the United States & Europe*" 81 (The University of Chicago Press, Chicago 2017).

[2] Animal biotechnology, nature portfolio, accessed from https://www.nature.com/subjects/animal-biotechnology.

animal model exists.[3]Given the high demand and consumption of animal products in the diet in many countries, the improvement of livestock is always preferred. Animal biotechnology promises to enhance and improve livestock.[4]In the biomedical research context, it has a twofold purpose: "to produce animals that can be employed in basic biological research into biological development and function, and to produce disease models that mimic human diseases and can therefore be utilised both in the study of disease (such as Parkinson's, cancer, cystic fibrosis, etc.) and to test new drugs."[5]It has been used to produce genetically modified animals that synthesise therapeutic proteins, have improved growth rates or are resistant to disease.[6]

Countries value the potential of animal biotechnology and have provided legal, policy and regulatory framework. India also recognises the potential of animal and livestock biotechnology. The Department of Biotechnology, Ministry of Science and Technology, Govt. of India has started an animal biotechnology programme, focusing on "improving animal health by developing newer vaccines and diagnostics, development of newer reproductive technologies genomics and genetic characterisation, production of biopharmaceuticals through transgenesis and animal products."[7] (DOB) Given India's largest animal husbandry sector and livestock population, animal biotechnology impacts the lives of rural households and small farmers. Animal health directly impacts the health of the people and the environment; therefore, the application of animal biotechnology is of great significance. With this realisation, the programme aims at "the sustainable growth of livestock and

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[3] Reid G. Adler, "Controlling the Applications of Biotechnology: A Critical Analysis of the Proposed Moratorium on Animal Patenting" 1 (Spring Issue) *Harvard Journal of Law and Technology* 1-61 (1988) available at https://jolt.law.harvard.edu/assets/articlePDFs/v01/01HarvJLTech001.pdf. (last visited on May 10, 2021).

[4] *Ibid*.

[5] M. Gjerris,A. Olsson*et.al.*(2006): Animal biotechnology and animal welfare. In: *Animal welfare*, Strasbourg: Council of Europe Publishing, 89-110 (2006) available https://forskning.ku.dk/soeg/result/?pure=files%2F99223308%2FAnimal_biotechnology.pdf(last visited on May 10, 2021).

[6] *Supra* note 2.

[7] Department of Biotechnology, Ministry of Science and Technology, "Animal and Livestock Biotechnology" available athttps://dbtindia.gov.in/schemesprogrammes/research-development/agriculture-animal-allied-sciences/animal-andlivestock (last visited on May 12, 2021).

poultry for nutritional security and economic prosperity as well as enhance production and productivity of livestock through biotechnological interventions."[8]

Animal Models

Animal model is a non-human animal used for research to better understand human disease. It avoids the added risk of causing harm to human being during the entire drug discovery and development process. Animal models are used to better understand a disease, its diagnosis and its treatment. An animal model exhibits the pathological condition or disease present in a particular animal or human. Based on different characteristics, animal models are of different kinds including spontaneous model, induced models and transgenic models:

Spontaneous models shape up as a result of naturally occurring mutations. Such disease models have been identified, characterised and preserved for investigative purposes. Induced models are produced by laboratory procedure like administration of a drug or chemicals, feeding of special diets or surgical procedure. The third category includes transgenic models. Transgenic animal models are created by the insertion of a particular human DNA into fertilised mouse oocytes, which are then allowed to develop to term by implantation into the oviducts of pseudopregnant females.[9]Animal models can be used as a research tool by the researchers along with cell lines, monoclonal antibodies, reagents, genes and gene fragments etc. In this regard, access to these tools is vital for biomedical research.[10]

Animal Patenting in the USA: Setting the Stage

The wide interpretation of Section 101 of the US Patent Act by the US Supreme Court in *Diamond v. Chakrabarty* [11] not only held genetically modified bacteria patentable but extended the scope of patentable subject matter to "anything under the sun that is made by man."[12]Microorganisms

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8 *Ibid.*

9 Amit D. Kandhare, Kiran S. Raygude *et.al.,* "Patentability of Animal Models: India and the Globe" 2(4) International Journal of Pharmaceutical & Biological Archives 1024-1032 (2011)available at fromwww.ijpba.info (last visited on May 12, 2021).

10 *Ibid.*

11 U.S. 303.

12 *Id.*, at 309, referring S Rep. No 1979, 82d Cong., 2d Sess., 5 (1952); H.R.Rep. No. 1979, 82d Cong., 2d Sess., 6 (1952).

expressing recombinant DNA were first produced in 1974 but the first genetically modified bacteria were granted patent in 1980 in *Diamond v. Chakrabarty*. After the Chakrabarty decision, genetically modified plants and animals were granted in 1985 and 1987. The traces of transgenic plants went back to 1982 when the FDA approved the first human recombinant DNA pharmaceutical (insulin). It was followed by the incident when A foreign gene was first expressed by a transgenic plant in 1982and a transgenic mouse expressing a rat growth hormone gene was also reported in that year.[13]

The USPTO issued the first animal patent in April 1988. It involved a transgenic non-human mammal, i.e. an oncomouse that has been genetically modified to increase susceptibility to carcinogens.[1415]*Ex parte Hibberd*[15], which gave way for patents on genetically modified plants, involved a patent application involving modified maize plants. Based on the wider interpretation given in *Diamond v. Chakrabarty*, the PTO Board rejected the Commissioner's narrow construction of Section 101 of US Patent Act and allowed patents on transgenic plants.[1617]It is noteworthy that despite granting patents on genetically engineered microorganism and plants, the Commissioner of Patents has been refusing the patents till the USPTO Board decided *Exparte Allen*[17], *which allowed patents on* polyploid (*i.e.*, containing multiple sets of chromosomes) oysters. Following this, the Commissioner announced that genetically modified animals are also patentable.[18] The USPTO issued this patent on Harvard Oncomouse in April 1988. The term oncomouse was given to the mouse since it was created for the study of breast cancer. The patent claim was directed to "the activated oncogene sequence in the animal's germ cells and somatic cells because the scope of the claim included the offspring of any mammal having the oncogene."[19] Following this patent, a significant number of patents were granted on animals, and majority of which were related to disease models.[20]

Opponents to animal patents argued that it might enhance animal experiments, increasing animal suffering and posing risks to ecological balance

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13 *Supra* note 3.

14 *Ibid.*

15 U.S.P.Q. 443 (Bd. Pat. App. & Int. 1985).

16 *Supra* note 3.

17 U.S.P.Q.2d 1425 (Bd. Pat. App. & Int. 1987).

18 *Supra* note 3.

19 Kshitij Kumar Singh, *Biotechnology and Intellectual Property Rights-Legal and Social Implications* 33 (Springer, New Delhi 2015).

20 *Id.*, at 33-34.

and biodiversity. It may also disrupt the structure of agriculture. They asked for the moratorium till the full understanding of the effects of animal biotechnology.[21]Few critics maintained that due to the overproduction of products, there is no need for transgenic animals and plants that are even more productive.[22]They argued that sufficient economic incentives are available without animal patents for agricultural biotechnology to do business. Rather, transgenic animals would also be available to farmers with greater competition.[23]

On the other hand, the proponents of animal patenting asked for the same, given the potential value of patents for biotechnological research. Developed and developing countries started providing support to animal biotechnology through legislative and policy frameworks to secure human health and animal productivity.[24] Patent proponents further justified patents on animal biotechnology on the ground that it accelerates the innovation process by enabling potential inventors to invent around and encouraging investors to invest. They maintained that patent works as a technological information pool and advance the information system, induce an investor to invest and take commercial risk expenditure, encourage competition to "invent around" or improve upon a patented invention, and further advance the technology and stimulate innovation. The enablement requirement was challenging as it was difficult to set a more realistic standard.[25]They further contends that the combination of biotechnology and information technology creates more precision in the agriculture sector as a genetic engineer may predict more precisely than a traditional breeder. In the absence of scientific assessment of the technology, the emotional quotient may cloud significant developments and put on hold the pace of innovation.[26]The identification of disease-resistant genes into livestock species is very important. Transgenic mouse reflects as a powerful tool for research on the immune system, genetic disease mechanisms of embryonic development.[27]It is worth noting that except for the argument that

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21 *Supra* note 3.

22 *Ibid.*

23 *Ibid.*

24 *Ibid.*

25 *Ibid.*

26 *Ibid.*

27 *Ibid.*

the act of patenting living organisms was unethical, the rationales advanced by opponents of plant and animal patents were not patent law issues *per se*.[28]

As a policy US values the animal research and experimental use of animals for human and animal treatment, yet it disfavours the unnecessary use of animals in research. Rather it favours faster, less expensive, and more accurate non-animal testing methods.[29] In the United States, animal welfare committees were eastablished at all research facilities to promulgate guidelines for reducing pain and distress in these research animals. The Humane Society of the United States (the "Humane Society") believes that the patenting of animal conceptually "reflects human arrogance toward other living creatures that is contrary to the concept of the inherent sanctity of every unique being and the recognition of the ecological and spiritual interconnectedness of all life."[30] The Society assumes that patent protection for animal inventions will lead to a "dramatic increase in the suffering of animals resulting from agricultural, biomedical and other industrial research. However, it did not offer any scientific rationale to establish the general belief that genetic manipulation is necessarily harmful to an animal's welfare.[31]

Critics expressed their concerns regarding the implications of animal biotechnology on the environment and biological diversity. They contended that the introduction of genetically engineered organisms in the environment poses an unacceptable risk to the environment. However, in due course of time, scientists understood how these organisms could be safely introduced and handled in the environment. They further contended that patenting of animals may reduce genetic diversity, particularly in commercial animals. On the contrary, the House Committee on Agriculture found that "three times more wheat, three times more soybean, and six times more cotton varieties were developed during the 10-year period after enactment of the PVPA as compared to the same time period prior to its enactment."[32] Though such patents may affect breeders' access to plant and animal germplasm, with proper policies in

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28 *Ibid.*

29 *Ibid.*

30 *Ibid.*

31 *Ibid.*

32 H.R. REP. NO. 1115, 96th Cong., 2nd Sess. 4 (1980) (House Committee on Agriculture Report to Accompany H.R. 999).

place, it could stimulate the quality of germplasms.[33] On the religious front, the National Council of Churches, while not opposed to genetic engineering *per se*, believed that the "[r]everence for all life created by God may be eroded by subtle economic pressures to view animal life as if it were an industrial product invented and manufactured by humans." Moreover, the Council feared that the "rapid pace of this technology is outstripping society's capacity for considered moral judgment."[34]

However, those who oppose the patenting of animals on ethical grounds have not demonstrated that applying the patent system is harmful to society or animals. It is also noteworthy that public opinion is not opposed to the genetic engineering of plants and animals.[35]There is no evidence that Congress intended the patent system to exclude categories of inventions such as transgenic animals.[36] Concerns about the applications of transgenic research will continue to exist regardless of patents. Such concerns are much more reasonably addressed by existing agencies having appropriate experience and sufficient regulatory jurisdiction *(e.g.,* the EPA and the USDA for environmental risks, and the USDA and the NIH for animal research).[37]

The United States granted 45 animal patents from 1995 to 2001. It includes patents on genetic markers for genetic improvement, statistical methods for genetic improvement, transgenic and cloned animals, expressed sequence tags.[38] The US makes a reservation regarding human cloning while allowing cloning of animals is acceptable (at least for research purposes).[39] Animal rights activists oppose patenting any invention derived from animal research; however, individuals who believe that "animal rights are subordinate to those of humans, but that they deserve proper care and welfare then the issue of patenting is much less of a concern."[40] As regards to xenotransplantation, it

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33 *Supra* note 3. 34 *Ibid.*

34 *Ibid.*

35 *Ibid.*

36 *Ibid.*

37 *Ibid.*

38 Max F. Rothschild, "Patenting of Genetic Innovations in Animal Breeding and Genetics" available athttps://www.semanticscholar.org/paper/Patenting-of-geneticinnovations-in-animal- Rothschild/ 8add8e0007136ac6311cf4fe173452621052b510 (last visited on May 14, 2021).

39 *Ibid.*

40 *Ibid.*

was slowed down due to the fears of retroviruses and diseases like mad cow disease and AIDS, nevertheless, it is likely that "will be development of transgenic lines of animals for biomedical research (not food production) and applications that do encompass genes from other species."[41] Many believed that patent favours quality of research and securing funding from investors, it can also promote technology transfer and predicted that "in the 21stcentury sequenced genomes, transgenic livestock and cloned animals will become the norm."[42]Commenting on the US patent approach to animal biotechnology, Shobita Parthasarathy maintains that the USA endorsed a very technical meaning of patents by restricting its meaning to include stimulating innovation and market and excluding any further implications in itself. This interpretation allowed only decisionmakers and traditional market players in the discussion by precluding civil society groups. Furthermore, they justified their stand that patents are in social benefit in line with the argument that the government's role was to facilitate the creation of the market by identifying the inventions through objective patent decisions. Only market players and their representatives were deemed relevant and legitimate to the discussion.[43] Moreover, the USA does not pay much attention to categorising an invention based on life forms and considers genetically modified organisms as technologies.[44]

Animal Patenting in European Union: The Weighing Up Test

Patentability of a subject matter is governed by the European Patent Convention 1973 (EPC), along with the Legal Directive 98/44/EC of the European Parliament and the Council of European Union on the Legal Protection of Biotechnological Inventions (hereinafter Biotech Directive) and the national laws of the European states. The Biotech Directive explains the actual scope of the EPC. To bring more clarity, the Administrative Council of the European Patent Organization amended the Rule 23 of the Implementing Regulations of the EPC on 16 June 1999.[45]In the European Union (EU), the legal framework does not allow patents on plants and animal varieties. Article

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41 *Ibid.*

42 *Ibid.*

43 *Supra* note 1 at 113.

44 *Id,* at 114.

45 *Supra* note 19 at 66-67.

53 (b) of the EPC provides: "European patents shall not be granted in respect of (b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision shall not apply to microbiological processes or the products thereof." Discoveries are not patentable unless produced by a technical process. Article 3 (2) of the Biotech Directive provides: "Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature." Therefore, both the Biotech Directive and EPC prohibit pants on plants and animal varieties and essentially biological processes for the production of plants and animals; however, neither make it explicit if the products derived from those processes are excluded from patenting. Given this situation, the Enlarged Board of Appeal of the EPO has, in practice, allowed patents on products derived from using essentially biological processes (product-by-process claims).[46]The situation has been changed in 2017, when the European Patent Office has changed its regulations, clarifying that "plant and animal varieties obtained through essentially biological process (such as genetically modified plants) will not be considered patentable."[47]To this effect, the Administrative Council of the EPO has added a second paragraph to Rule 28 of the Implementing Regulation of the EPC explicitly stating that European patents will not be granted in respect of plants or animals exclusively obtained through an essentially biological process.[48]It has put to the rest the previous practice of the EPO of granting patents on the products derived from essentially biological processes.

Regarding the Harvard Oncomouse case, the European Patent Office (EPO) issued patent on this invention in the year 1985. Still, this decision was challenged in 2005 on ethical and moral grounds as well as on the ground of being violative of *ordre* public clause.[49]EPO developed a utilitarian balancing

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46 Tobias Cohen, Jan-Jap Kuiperset. al., "European Patent Office Amends Rules for Plants and Animal Patents *Mondaq* 15 August 2017 available athttps://www.mondaq.com/patent/619876/european-patent-office-amends-rulesfor-plant-and-animal-patents(last visited on May 14, 2021).

47 *Ibid.*

48 *Ibid.*

49 Tetyana V. Komarova, 'The Patentability of Biotechnological Inventions in the EU: An Impact on Therapeutic Practice' 73:8 *Wiadomości Lekarskie* 1747-1751 (2020)

test, aimed at making a risk-benefit analysis, "weighing the suffering of the oncomice against the expected medical benefits to humanity."[50]In addition to this, a few other factors could also be considered in conducting this balancing test, including "environmental risks (neutral in this case), or public unease (there was no evidence in European culture for moral disapproval of the use of mice in cancer research, i.e. no moral disapproval of the proposed exploitation of the invention in this case)."[51] Based on these considerations, EPO concluded that the use of oncomouse could provide a substantial medical benefit and outweigh 'moral concerns about the suffering caused to the animal.'[52]Notably, the EPO came up with a different conclusion in Upjohn Pharmaceutical Company Case, where the company filed a patent on a transgenic mouse, 'into which a gene had been introduced such that mouse would lose its hair.'[53] The patent involved techniques aimed at curing human baldness. After weighing the claimed benefits, i.e., usefulness in research to cure hair loss against the harm suffered by the mice, the EPO concluded that the harm outweighs the benefits in the present case, and 'the exploitations of the invention was contrary to morality and therefore, not patentable.'[54]It was also due to the fact that the European Patent Convention excludes the patentability of animal species but not the patentability of animals. The patent, however, was revoked on other grounds i.e., non-payment of registration fee.[55]

The common concern between the USA and the European Union about the patenting of animals was that first, it leads to the commodification of life forms and second, that it may lead to an area of research, which is usually considered by others as unethical.[56] Both in Europe and USA, civil societies organised their efforts on the same line to raise an objection against the patenting of

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available at https://www.researchgate.net/publication/344811265 (last visited on May 14, 2021).

50 "Bioethics and Patent Law: The Case of the Oncomouse" Issue 3 WIPO Magazine (June, 2006) available athttps://www.wipo.int/wipo_magazine/en/2006/03/article_0006.html (last visited on May 14, 2021).

51 *Ibid.*

52 *Ibid.*

53 *Ibid.*

54 *Ibid.*

55 *Supra* note 49.

56 *Supra* note 1 at 113.

biotechnology. However, both the jurisdictions are convinced with the potential economic contribution of patents permitted animal patents.[57]Unlike the USA, EU doesn't take the help of techno-legal justification; however, it recognised maintaining moral standards of society in the patent discourse and therefore gave space for civil society groups and individual citizens as official observers and opponents. To establish a balance, the EPO inculcated the weighing up test in the patent system, giving bioethicists, philosophers, and social scientists to have their say. Though EPO has rarely involved these considerations and mainly relied upon the abstract interpretation of ordre public clause to conduct ethics assessment.[58]EU recognises that animals have dignity, and they should be treated fairly against the process of patenting and commodification. It recognises the principle of weighing up to preserve the dignity of animals. However, it is not clear how many times EPO utilises this exception to reject the patents on animals. This test can be seen as a justification for applying narrow patents, as was clear in the Harvard oncomouse case. At least one example has been cited by high-ranking EPO officials where a patent application on a mouse genetically engineered to suffer from baldness.[59]

Animal Patenting in Canada: Higher and Lower Life Forms

Despite having a similar patent law to the USA, the Supreme Court of Canada, in a 5-4 decision[60], overturned the decision of the Federal Court of Appeal and held that a genetically modified non-human mammal (i.e., Harvard Oncomouse) was not patentable under the current Canadian Patent Act. In this case, the majority expressed legal and ethical concerns regarding patenting higher life forms in the absence of any explicit legislative direction from the Canadian Parliament. On the contrary, the minority believed that the patenting of biological inventions was necessary to encourage research and development in new technologies.[61] Referring to the direction from the Parliament regarding the patentability of higher life forms, the majority observed that "the patenting of higher life forms under the current Canadian Patent regime would be a 'radical departure' from the traditional patent regime and would, therefore,

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57 *Ibid.*

58 *Id.,* at 114.

59 *Ibid.*

60 *Harvard College v. Canada (Commissioner of Patents),* 2002 SCC 76, [2002] 4 S.C.R. 45.

61 *Supra* note 19 at 88.

require 'an un- equivocal direction from Parliament'."[62]Though the majority agreed that the Patent Act does not explicitly differentiate between lower and higher life forms, it explained that making such a distinction "is nonetheless defensible based on common sense differences between the two."[63]Though various social groups, including civil society groups and animal rights groups, welcomed this decision, the biotechnology industry expressed great disappointment. In the absence of a clear line of distinction between higher and lower life forms provided by the Supreme Court, "this distinction thus far has been presumably left to the Canadian Patent Office, which currently equates patentable 'lower life forms' with matter that is essentially unicellular."[64]

Patenting animal biotechnology under the TRIPS Agreement

Article 27.3 (b) of the TRIPS Agreement throws light upon the patentability of animals and maintains:

Members may exclude from patentability:

(b) plants and animals other than microorganisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

TRIPS Agreement allows Members to exclude patents on plants and animals and biological processes for the production of plants and animals as an option while mandating patents on microorganisms, microbiological and non-biological processes. It also mandates that the Members shall provide protection to plant varieties either through patents or by an effective sui generis system or by any combination thereof. Though it does not mandate the same protection to animal varieties.

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62 *Id.,* at 89.

63 *Supra* note 60 at para. 188.

64 *Supra* note 19 at 88.

Patenting of Animal Biotechnology in India

The provisions of the Patents Act 1970 directly relating to the patenting of animals are Sections 3(b) and 3(j). Section 3 (b) provides what is not an invention: an invention the primary or intended use or commercial exploitation of which could be contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment;[65]

In the light of section 3 (b) of the Patents Act 1970, the most probable implications of animal patents would be on animal life, animal and human health and the environment. Public order and morality could be strong grounds for rejecting patents on animal-related inventions. Section 3(c) prohibits patents on "discovery of any living thing or nonliving substances occurring in nature."[66] By implication, naturally occurring living things including animals, animal parts or genes are not patentable. IPO Guidelines on the Examination of Biotechnology Applications for Patents, 2013[67] expressly state that sequences isolated directly from nature are not patentable. Section 3(i) excludes from patenting "any process for the *medicinal*, *surgical*, *curative*, *prophylactic*, *diagnostic*, *therapeutic* or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products."[68] Though the IPO has granted patents for **"**in vitro diagnostic methods" performed on tissues or fluids, which had been permanently removed from the body, however, the Biotechnology Guidelines brought in vitro diagnostic methods under the remit of Section 3(i). Hence, the IPO is unlikely to grant such patents in the future. Much depends on how the courts interpret this provision.[69] Section 3(j) of the Patents Act, 1970 is directly related to the animal patents. It provides that "plants and animals in whole or any part thereof other than microorganisms but including *seeds*,

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65 Section 3(b) of the Patents Act 1970.

66 Section 3(c) of the Patents Act 1970.

67 Guidelines on the Examination of Biotechnology Applications for Patents, 2013 available at https://ipindia.gov.in/writereaddata/Portal/IPOGuidelinesManuals/1_38_1_4biotech-guidelines.pdf (last visited on May 14, 2021).

68 Section 3(i) of the Patents Act 1970.

69 "Biotechnological inventions in India: law, practice and challenges" Remfry & Sagar, *Lexology* available at: at https://www.lexology.com/library/detail.aspx?g=8405b078-b301-4672-8850-84f74ea23aa7 (last visited on May 14, 2021)

varieties and *species* and *essentially biological processes* for production or propagation of plants and animals."[70] The scope of *'microorganism'*, *'microbiological process' 'essentially biological process'* and *'non-biological process'* are enormously contentious in India and depends on the court's interpretation of these terms. Section 3 (p) is a distinct addition to the Patents Act 1970, which excludes traditional knowledge from patentability. It precludes from patentability "an invention which in effect, is traditional knowledge or which is an aggregation or duplication of known properties of a traditionally known component or components."[71] To pass the traditional knowledge bar set by section 3(p), patent claims are examined against searches of traditional knowledge databases, including the Traditional Knowledge Digital Library. [72]

Based on the Patents Act 1970 and IPO Guidelines for Examination of Biotechnology Applications for Patent, recombinant nucleic acid sequences, gene sequences, amino acid sequences with delineated function or utility specified; method for expressing the sequences, plasmids; vector containing the sequences/ cDNA sequences; expression vectors containing the particular sequence; recombinant gene probes/ primers**;** recombinant microorganisms are patentable. While living entities of natural origin such as animals or its parts, plants or its parts, seeds, genes., any process of manufacture of production of living entities; any method of treatment of human beings and animals, any method of diagnosis of disease affecting human beings and animals; transgenic plants and animals per se or their parts; biological materials such as organs, tissues, cells per se; essentially biological process for production of plants and animals. Any biological material or process causing serious prejudice to human, plant, health, or the environment; cloning human beings or animals is not patentable. This description is not exhaustive but illustrative to reflect how India could promote animal biotechnology. Indian patent law gives due regard to animal life and dignity through numerous safeguards, yet India needs to strategise patent policies to trigger innovation in agriculture and medicine.

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70 Section 3(j) of the Patents Act 1970.

71 Section 3(p) of the Patents Act 1970.

72 *Supra* note 69.

Conclusion

Patenting animal biotechnology has been contentious and evolved in due course of time that witnessed changes through legislative and judicial approaches. Every jurisdiction has recognised animal biotechnology's economic potential and provides patent protection to animal biotechnology. Though the ethical and social aspects are broadly considered relevant to patenting, countries overlook the same practically. The dignity of animal life has been raised and pushed by animal rights groups, civil society groups, for example, in the EU and India, which contains several provisions safeguarding animal life and health. The issue of patenting animal biotechnology is contentious. The principal argument placed in favour of patenting is that it encourages investment, promotes innovation, quality of research and technology transfer in this field, and no country can afford to avoid it.Nevertheless, causing unnecessary suffering to animals must be avoided in the name of innovation. The ethical and social concerns are as important as the economic concerns and it should not be avoided as non-scientific concerns. Europe's utility criterion based on weighing the benefits of animal models for experiments seems appealing in tune with the dignity to animal life. However, it should be examined to what extent it is followed in practice while granting patents on animal biotechnology. Distinction should be made if the ethical and social objections to the patenting of animal biotechnology are routed to the patenting or to the technology itself. Patent law is based on policy levers set by the state, and it could not be devoid of ethical, social and cultural ethos. Patent practices must be guided by the ethical, social, cultural ethos and economic requirements. Efforts are required to be made through scientific advancements that animal sufferings are minimised.