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Juggling Aquaculture Intellectual property (IP): The Balance between Innovation and Access in Developing and Developed Countries, Anchored by US-India Case Studies

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

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ABSTRACT

Intellectual property rights are intangible rights which are attributed to the creator of a property which belongs to the mind, intellect and skills of the creator. Intellectual property (IP) rights are critical in the field of aquaculture, particularly when it comes to incentivizing the development and use of genetically modified (GM) species. These rights provide protection to innovators who have invested significant time, expertise, and resources into creating GM aquatic organisms. This study aims to addresses the challenges that developing countries face in protecting the IP rights in

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aquaculture field. The United States employs a comprehensive and inclusive strategy on biotech patents to promote innovation, but India enforces more stringent restrictions to balance scientific progress with ethical and societal considerations. This difference illustrates a wider chasm between wealthy and developing nations, as the latter frequently confront hazards of exploitation and insufficient acknowledgment of traditional knowledge and ecological contributions.

Keywords: Juggling aquaculture; intellectual property rights; genetically modified species; ecosystems and biodiversity.

1. INTRODUCTION

The five main seas make up almost two-thirds of Earth's surface and provide an environment that is favourable to the formation of many different kinds of life, many of which lack features seen in terrestrial ecosystems. Humanity has long reaped direct and indirect benefits in the form of industrial resources and economic opportunities from marine ecosystems and biodiversity. There are a lot of valuable resources under the water off the coast of India that might be used to make nutraceutical, pharmaceutical, and biological products that people can use for their health. However, although bioproducts derived from land are well-represented, marine-based patents are still in their infancy. There are a plethora of medical, ecological, and mariculture-related biotechnology applications for marine organisms. Due to the difficulties in reaching deep waters, marine ecosystems have received far less attention and study than terrestrial ecosystems. Fishing, processing, aquaculture/mariculture (with intervention), pharmaceuticals, nutraceuticals, cosmetics, feed and food, bioactive compounds, and other associated technologies and methods are the fields of patenting in the marine fisheries sector. Many technologies that have been developed and commercialized thanks to the Central Marine Fisheries Research Institute's efforts have benefited society and humanity in some way, shape, or form. In India's marine fisheries, scientists have developed new methods for growing pearls and other seafood on land, better ways to care for marine finfish and shellfish, ways to manage natural resources, tools for open-sea aquaculture, methods for making nutraceuticals and other products with added value, and many more related processes and products that are patented [1] (Trade Related Intellectual Property Rights in Fisheries: The Indian Context Kajal Chakraborty).

2. INTELLECTUAL PROPERTY RIGHTS AND GENETICALLY MODIFIED AQUATIC SPECIES

Intellectual Property Rights: Intellectual property rights are intangible rights which are attributed to the creator of a property which belongs to the mind, intellect and skills of the creator. A right is given to incentivise the creator to promote the development of intellectual property as well as for the increased wealth of a nation in an intangible form.

Intellectual property (IP) rights are critical in the field of aquaculture, particularly when it comes to incentivizing the development and use of genetically modified (GM) species. These rights provide protection to innovators who have invested significant time, expertise, and resources into creating GM aquatic organisms, such as transgenic fish, which have been engineered to possess advantageous traits like rapid growth, disease resistance, or environmental resilience. By granting IP protections, inventors can safeguard their work from being replicated or exploited without permission, thus ensuring a return on their investment and encouraging ongoing research and development (R&D). IP rights are a major driver of innovation in aquaculture, enabling companies and researchers to pursue advanced biotechnological methods that can improve both the productivity and sustainability of fish farming. For example, IP protections allow companies to secure exclusive rights to genetically modified fish that may grow faster, require less feed, or are resistant to specific diseases. Such traits can reduce production costs, lessen the environmental impact of aquaculture, and increase food security by producing higher yields.

By securing IP rights, companies can protect their inventions, making it easier to recoup the

[1] *Trade Related Intellectual Property Rights in Fisheries: The Indian Context Kajal Chakraborty*

substantial R&D costs associated with creating these organisms. This financial protection is crucial in industries with high upfront costs, as it provides an incentive for further investment and innovation. Additionally, IP protection can attract venture capital and partnership opportunities by ensuring potential investors that proprietary technologies are legally safeguarded.

For GM aquatic species, the most relevant form of IP is patents. The patent system necessitates the equilibrium of conflicting interests. Patent holders pursue exclusive rights to manufacture, market, and license their inventions to optimize earnings; nevertheless, many view this as harmful to societal interests, as patentees can set their own product prices. Although these concerns may hold some validity, the patent system, in fact, safeguards societal interests rather than undermines them. Inventions that receive patents include an enabling disclosure, which competitors frequently utilize to develop enhanced products and secure their own patents. Their enhanced items, accompanied by facilitating disclosure, establish the requisite foundation for subsequent advancements. Consequently, customers gain from the patent system, which inherently enhances market choice, while patent holders benefit by concentrating their efforts on delivering innovative and superior products aligned with consumer desires [2] (Trade Related Intellectual Property Rights in Fisheries: The Indian Context Kajal Chakraborty). Patents can apply to the unique genetic modifications made to a species, the protocols developed for breeding these organisms, and even the gene-editing technologies utilized in their creation. This can include specific gene sequences, methodologies for introducing genes into fish, and other proprietary innovations that make the GM species distinct. In some regions, additional forms of IP protection may be used, such as copyright for genetic databases or datasets used in breeding processes and trademarks for branding GM products in the marketplace. Each of these IP types offers different forms of protection, catering to various aspects of transgenic aquaculture.

Prevalent issues in IP and aquaculture: Although there are vast benefits in securing intellectual property in the domain of aquaculture. However, a significant challenge arises due to the territorial nature of IP rights. Patents, trademarks, and copyrights are generally restricted to the country in which they are granted. This means a patent awarded in one country does not necessarily confer protection in another, complicating the legal landscape for GM species that may be farmed or sold internationally. When a GM species developed in one country is intended for commercial use or breeding in a different country, the original IP protections may not be enforceable. This territorial limitation often necessitates separate patent filings in each target market, increasing costs and administrative burdens. The lack of universal IP standards for transgenic organisms thus creates legal and commercial challenges, limiting the scope of IP protection and adding complexity to international trade and commercialization.

Moreover, the inconsistencies in IP laws across countries is one of the other issues which create barriers to growth. As the intellectual property laws are territorial in nature, every jurisdiction varies in terms of standards of the patentability of GM organisms, and in some regions, biotechnological innovations may face restrictive patent criteria or ethical limitations. For instance, while certain countries may grant broad protections for genetically modified fish, others may impose restrictions or bans due to concerns over genetic modification's ecological or ethical implications. These differences complicate IP strategies for aquaculture businesses operating globally, as patents awarded in one jurisdiction might not hold in others. In jurisdictions where IP protections are weak or unenforceable, innovators face the risk of losing control over their inventions, which may reduce the incentive to introduce cutting-edge technologies.

As a result, companies are cautious about investing in markets with limited IP enforcement, potentially stifling the growth of transgenic aquaculture in regions where GM fish could benefit local industries and food supplies. Without reliable IP protection, companies may restrict their R&D efforts to regions with stronger legal frameworks, which limits the overall potential for global advancements in aquaculture innovation.

The difference can be well understood by a comparative study of granting of patent in India and the United State of America.

On the other hand, there is always a divergence in the developing country and developed country

[2] *ibid*

in the number of patents in any field including aqua-world. The developed countries are capable enough and economically independent to have advanced technologies, where the developing countries are having the similar facilities. Moreover, in the era of globalisation, the traditional knowledge and skills, bio-diversity by the local farmers in the developing country like India, are at stake. There is a huge scope of being exploited by the big MNCs. As a result of which, developing countries are continuously denied the benefits, which legitimately belong to them.

Patentability criteria in different jurisdiction for genetically modified organism:

3. UNITED STATES OF AMERICA

Legislations: The Constitution of the U.S. has given the power to Congress to make the laws of intellectual property laws under Article 1, section 8. (further reference in Annexure 1.A)

Accordingly, United States Code Title 35 is dealing with the federal Patent Laws of the Country and the USPTO has established. Apart from that the USPTO has the power to create regulations by virtue of Chapter 37 of the Code of Federal Regulations.

It is pertinent to mention here that for bio-tech inventions it has no other specific legislation and governed by this patent law only.

35 U.S.C. 101 particularly of the specify the requirements of the granting a patent. in this section the patent is granted to the inventions or any discovery or modification which has the novelty and the inventive step [3] United States Code Title 35, 1987). (further reference in Annexure 1.B)

Apart from this provision, there is no provisions which laid down the non-patentable subject-matter. Eventually, U.S. got a widest scope of patent protection. In order to secure the patent, all that is needed to fall under the categories of 'new and useful', be it discovery, inventions or any improvement over the existing art. Moreover, no limitation is provided for the clause 'new and useful'. And the judiciary has acted accordingly upon it.

The legislative left the section very wide but the judiciary has tried to frame the scope of ambit of section 101 in a little extent. The present scenario with respect to patentability of the biotech process or product specially referred to genetic engineering is analyzed below with the help of judicial approach.

Product of nature is not patentable but man-made are patentable.

Judicial Approach: This case is a landmark and the most significant one in the field of biotech specifically in genetic engineering patent. Prior to this case, the U.S. Supreme Court has expressly laid down that the product of the nature is not eligible for patent protection as there was no creation[4] (Funk Bros, 2019).

The brief facts of the case: The plaintiff, Chakrabarty, here manufactured a genetically modified bacteria through recombinant DNA technology which is not available in the nature [5] (Diamond, 1980). The bacteria have the capability of breaking the crude oils and hence will be helpful in treating the oil spill in the water bodies. The plaintiff applied for the patent before the patent office and office had denied the patent by stating that the microorganism is freely available in the nature [6] (Diamond, 1980). The board of Appeals also went in the similar line with the patent office and denied the patent. However, the Court of Customs and Patent Appeals had granted the patent. But the commissioner of Patent & Trade-mark appealed before the Supreme Court [7] (Diamond, 1980). The Supreme reaffirmed the patentability of the bacteria [8] (Diamond, 1980).

Issue: The issue of the case is so obviously that whether it is a natural product or man-made? And this GMOs are eligible for patent or not?

The court held that: According to the U.S. Supreme Court, it was not a natural product and man-made manufactured bacteria thus entitle to patent protection. The court interpreted the term 'manufacture' as 'for use from raw or prepared materials by giving these materials new forms,

[3] *United States Code Title 35 – Patents S 101*

[4] *Funk Bros. Steel Co. v. Kalo Inoculant Co, 1948, 333 U.S. 127 68 S. Ct. 440; Justin Burum, Sue Burum, Minnesota State University, Mankato, 'CRISPR and Patent Law: Molecular Biology Is Not the Only Thing That Is Confusing!' (2019) 52(1) NATIONAL SOCIAL SCIENCE JOURNAL<https://www.nssa.us/journals/pdf/NSS_Journal_52_1.pdf> accessed 5 May 2020*

[5] *Chakrabarty (n 246)*

[6] *ibid*

[7] *Diamond v Chakrabarty 447 U.S. 303, 100 S. Ct. 2204 (1980)*

[8] *ibid*

qualities, properties, or combinations, whether by hand-labor or by machinery'[9](Margo, 2003). The Court defined 'composition of matter' to include 'all compositions of two or more substances and ... all composite articles, whether they be the results of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders or solids' [10] (Margo, 2003). The manufactured genetically modified bacteria have fulfilled the requirement of 'new and useful' as there was a human intervention produced unknown micro-organism. It was a 5-4 judgement. The dissenter has disagreed with the majority because of conflicts in genetic research [11] (Margo, 2003). However, the majority also acknowledged that the recombinant DNA technology becomes controversial in the field of patent nonetheless there are no laws which could restrict its patentability[12](Margo, 2003). The Court also added that it is the duty of the Congress to enact clear laws to determine a balance between its efficiency and the values of the society [13](Margo, 2003).

This judgement has concluded with the incredible note that 'Anything under the Sun is patentable'. From then to now the U.S. court has continued to enlarge the scope of section 101 as much as possible with this precedent.

Harvard Onco-mouse Patent: Few years later, in 1987, after the judgement of Diamond v Chakrabarty, the UPSTO has taken an unbelievable step in patenting the genetically modified live forms by declaring that genetically modified animals will be under the purview of patentable subject-matter. The statement was- 'non-naturally occurring, non-human multicellular living organisms, including animals, to be patentable subject matter' [14] (Non-naturally Occurring Non-Human Animals Are Patentable Under § 101, 33 Pat, 1987; LjDeftos, 2000; Bioethics and Patent Law, 2006).

This ignites the public debate both on favouring the step and on against of this patent subject. The oppositions wanted to ban even the research on the animals in this field considering the animal rights.

Within one year of such declaration, in the year of 1988, it has approved the patent genetically modified mouse [15] (Bioethics and Patent Law, 2006). The patent application was filed by the Harvard researchers Philip Leder and Timothy Stewart, the inventor of the mouse. Patent was granted on 'a transgenic non-human mammal whose germ cells and somatic cells contain a recombinant activated oncogene sequence introduced into said mammal…'[16] (Bioethics and Patent Law, 2006).

It is a remarkable move because this patent is actually the very first patent on the upper form of life (mammal). The objective behind the genetic modification of the mouse was to intensify the growth of cancer. Consequently, it will be of great significance in the research of developing the therapeutics for human.

The previous controversy was got more heated and the public were exposed to a situation where in one side the potential benefits of human and the other side the morality issues of patenting the animals. Although the Animal Legal Defense Fund had moved to the federal court, the court dismissed due to lack of locus standi [17](LjDeftos, 2000).

Re Roslin Inst: The next development in the domain of genetic engineering is the genetically modified sheep. The sheep has been cloned

[9]ibid; Margo A. Bagley, 'Patent First, Ask Questions Later: Morality And Biotechnology In Patent Law', (2003) 45(2) Wm. & Mary L. Rev., <https://scholarship.law.wm.edu/wmlr/vol45/iss2/3 > accessed 6 May 2020

[10] ibid

[11] ibid

[12] A. Bagley, 'Patent First, Ask Questions Later: Morality And Biotechnology In Patent Law', (2003) 45(2) Wm. & Mary L. Rev., <https://scholarship.law.wm.edu/wmlr/vol45/iss2/3 > accessed 6 May 2020

[13] ibid

[14] Non-naturally Occurring Non-Human Animals Are Patentable Under § 101, 33 Pat. Trademark & Copyright J. (BNA) No. 827, at 664 (Apr. 23, 1987); LjDeftos, 'Patenting Life: The Harvard Mouse that Has Not Roared', (TheScientist 26 Nov 2000)<https://www.the-scientist.com/commentary/patenting-life-the-harvard-mouse-that-has-not-roared-55323#:~:text=The%20U.S.%20oncomouse%20patent%20was,tortuous%20as%20the%20Canadian%20mouse's.> accessed 8 May 2020 ; 'Bioethics and Patent Law: The Case of the Oncomouse', (WIPO 2006) <https://www.wipo.int/wipo_magazine/en/2006/03/article_0006.html> accessed 8 May 2020; Margo A. Bagley, 'Patent First, Ask Questions Later: Morality And Biotechnology In Patent Law', (2003) 45(2) Wm. & Mary L. Rev., <https://scholarship.law.wm.edu/wmlr/vol45/iss2/3 > accessed 8 May 2020

[15] ibid

[16] ibid

[17]LjDeftos, 'Patenting Life: The Harvard Mouse that Has Not Roared', (TheScientist 26 Nov 2000) <https://www.the-scientist.com/commentary/patenting-life-the-harvard-mouse-that-has-not-roared-55323> accessed 10 May 2020

from an adult somatic cell. In the case of Re Roslin Inst., [18] (750 F.3d 1333, 1337 2014; Hunton, 2008; Justin, 2019) before the US Fed. Cir. Court, patent was granted for the process of making such but the sheep was not patented [19](Justin, 2019).

However, the patent was not granted because there was no new creation which satisfy the patenting norm, not because of public order or ethics or morality [20] (Justin, 2019). Hence the case went in the same line with that of Myriad.

Patent regiment in India and biotech inventions: Indian Patent Ac 1970 governs the present patent policy in the country. The Act has specified that for the patent protection every invention should be novel, having an inventive step and utility[21] Indian Patent Act 1970 s 2(j)). Moreover, the Act very clearly and specifically talks about the inventions which are not patentable unlike US.

The Indian Patent Act 1970 did not promote the biotechnological inventions from its starting date as there was no such demand in this field in India. It was after the ratifying the TRIPS, India for bring the national law in conformity with the TRIPS had amended its provisions. The amendments actually paved way the protection of patent to the biotechnological inventions.

The first amendment to the Act, after the TRIPS was done to grant the patent protection to inventions relating to the chemical substances which will particularly be used for drug and food substances[22] (The Patent Act 1970 (as amended in 1999) s 2). By enabling the patent protection to chemical substances, India has stepped into the first stair of the development of biotech industry.

The second significant amendment was in the year of 2002 in the section 5 of the original Act. Section 5 of the original Act permitted the patent for chemical processes. But this amendment extended the protection to the biochemical, biotechnological and microbiological processes [23] (The Patent Act 1970 (as amended in 2002) s 5).

This put forth another mile stone for the development of biotechnology. However, the subsequent amendment in 2005 deleted the provision of section 5.

Another noteworthy amendment to give a wide road in bio patent is the insertion of sub clause (j) to section 3 of the Act; which says, 'plants and animals in whole or any part thereof other than micro- organisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals' [24](The Patent Act 1970 (as amended in 2002) s 4).

Therefore, the patent protection for the micro-organism has been granted only and only it fulfil the criteria of the patent eligible triple test that is novelty, inventive step and utility.

In the year of 2005, another set if amendment was passed in order to comply with TRIPS. The application of Budapest Treaty and extending the patent to all the product and process instead of only process patent subject to conditions lay down in the Act [25](The Patent Act 1970 (as amended in 2005) s 2(aba)).

Plant and animal are excluded from the patentability: The another section 3 (j) of the Act clearly precludes the animal and plant from patent but includes the micro-organism, however it should be man-made, otherwise it will not be protected because under 3 (c) naturally occurring product is not a patent-subject. The provision says that, 'plants and animals in whole or any part thereof other than micro-organisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals are not patentable' [26](The Patent Act 1970 s 3(j)).

This clause was added by the amendment of 2002.

4. JUDICIAL APPROACH

Dimminaco AG v. Controller of Patents and Designs: In India, there is no such significant

[18] *750 F.3d 1333, 1337 (2014); Hunton Andrews Kurth LLP, 'In re Roslin Institute (Edinburgh)' (LEXOLOGY 8 May 2008) <https://www.law.ox.ac.uk/sites/files/oxlaw/oscola_4th_edn_hart_2012.pdf> accessed 12 May 2020; Justin Burum, Sue Burum, Minnesota State University, Mankato, 'CRISPR and Patent Law: Molecular Biology Is Not the Only Thing That Is Confusing!' (2019) 52(1) NATIONAL SOCIAL SCIENCE JOURNAL<https://www.nssa.us/journals/pdf/NSS_Journal_52_1.pdf>*

[19] *ibid*

[20] *ibid*

[21] *Indian Patent Act 1970 s 2(j)*

[22] *The Patent Act 1970 (as amended in 1999) s 2*

[23] *The Patent Act 1970 (as amended in 2002) s 5*

[24] *The Patent Act 1970 (as amended in 2002) s 4*

[25] *The Patent Act 1970 (as amended in 2005) s 2(aba)*

[26] *The Patent Act 1970 s 3(j)*

cases on gene patenting. However, in 2002, the Hon'ble Calcutta High Court, had took a remarkable step in order to set up the whole biotechnological industries. The case is relevant to discuss in the connection of section 3(j).

The context of the case was that the patent application was for a live vaccine for protecting poultry against Bursitis infection [27] (Dimminaco, 2002). The application was not succeeded in obtaining the patent from the Controller of the Patent. The applicant moved further before the Calcutta High Court and the honorable Court has granted the patent [28](Dimminaco, 2002).

The court has given the meaning of manufacture according to dictionary meaning as there is no definition in the Act.

According to the Court, there is nothing in the Statute which bars from patenting. The ultimate test would be vendible test [29] (Dimminaco, 2002). The said test would be satisfied if the invention resulted in the production of some vendible item or it improved or restored the former conditions of the vendible item or its effect was the preservation and prevention from deterioration of some vendible product.[30] The court further stated that the vendible product meant something which could be passed on from one man to another upon transaction of purchase and sale. In other words, the product should be a commercial entity [31](Dimminaco, 2002).

Moreover, the product has gained the novelty, inventive step and utility so it's a patent eligible invention [32](Dimminaco, 2002).

After this landmark judgement the amendment of 2002 was passed and Indian Patent Act open its access to the biotech inventions.

The above scenario of the biotech patent clearly possesses a message that the way of patenting biotechnology is not that smooth with that of the other countries which are discussed here. It is evident that US is much lenient in granting patent whereas in India is rigid in many part. India does not allow the patent to the plant and animal and if it consist essentially biological process. However, transgenic animal as a whole is patentable. But the process to make the transgenic animal should not be essentially biological process. The term 'essentially biological process' has not been defined in Indian Patent Act 1970 neither in any biotech guidelines. The Indian Patent Office released biotechnology rules in March 2013, although failed to define what is meant by "essentially biological process". The instructions include multiple illustrative examples pertaining to Section 3 (j) of the Patents Act. One assertion indicates that a purported method involving cross-breeding to generate pure hybrid seeds, plants, and crops is an essentially biological process and is therefore not permissible under Section 3(j). This example does not indicate if intermittent steps in the claimed method, which need significant human interaction, would affect the patentability of the technique.

In India, any cross-selection in fishes is not patentable. However, there is a sui-generis system which is in accordance with TRIPS, gives protection to the breeder and the farmer as far as plant is concerned. No such rights have been provided for the breeder of the fish in the same Act.

Apart from the protection of patent, Geographical indication and trade-mark protection is inevitable in the domain of aquaculture. As far as Indian Geographical Indication Act is concerned, there is a different classification for fish as well but there is no registry for the same under the Act.

Intellectual property rights and Benefit Access Sharing: The ABS legal framework, initially defined in the 1992 Convention on Biological Diversity (CBD), mandates that a recipient of genetic resources and/or traditional knowledge related to these resources must secure prior informed consent from the provider country, typically via a permit, prior to accessing the resource, often accompanied by specific conditions. The recipient must equitably divide the advantages derived from the resource with the supplier in accordance with mutually established terms, typically through a contract [33](Alsaleh et al., 2017).

Since the Convention on Biological Diversity (CBD) came into effect in 1993, there has been a growing number of investigations into the laws

[27] *(2002) I.P.L.R 255(CAL)*
[28] *(2002) I.P.L.R 255(CAL)*
[29] *ibid*
[30] *(2002) I.P.L.R 255(CAL)*
[31] *ibid*
[32] *ibid*

[33]*Alsaleh, Mohd & A.S., Abdul Rahim & qi, Long & Yuan, Yuan. (2024). Evolution through intellectual property rights in the aquaculture sector: reshaping aquaculture production networks. Environment, Development and Sustainability. 1-28. 10.1007/s10668-024-05242-9.*

that regulate access to genetic resources and the distribution of the benefits that result from their utilization for the purposes of conservation, world food security, and health security, particularly in relation to the agricultural and pharmaceutical industries. However, the collection, utilization, and dissemination of genetic resources and associated knowledge for aquaculture has only lately been a focal point of the regulatory debate. This is in reaction to the growing significance of aquaculture in the provision of food on a global scale.

Other international agreements that shape national laws concerning the use and exchange of aquaculture genetic resources are:

Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits: Arising from Their Utilization to the Convention on Biological Diversity 'Nagoya Protocol', which operationalises the CBD's ABS framework and establishes significant innovations including rules for traditional knowledge associated with genetic resources and measures for cross border monitoring and compliance);

Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS): which sets minimum standards of protection for a range of intellectual property including patents and copyright that are increasingly becoming relevant to aquaculture

United Nations Convention on the Law of the Sea (UNCLOS): which applies to living resources within and beyond national jurisdictions and is currently the subject of negotiations for a legally binding instrument on the conservation and sustainable use of marine biodiversity in areas beyond national jurisdiction (United Nations, n.d.).

When adopting and implementing ABS measures, Parties are required to "consider the importance of genetic resources for food and agriculture and their special role of food security," as stated in article 9(c) of the Nagoya Protocol. This provision is significant because it stipulates that Parties must do so. Despite the fact that this does not go so far as to impose an obligation for special measures (such as simplified access procedures), it does require the Parties to consider special treatment for access to and sharing of the benefits that result from the utilization of genetic resources and traditional knowledge for food and agriculture, including aquaculture.

In India**,** The Central Parliament of India enacted the Biological Diversity Act in 2002 (ABS Act) and established implementation regulations through the Biological Diversity Rules 2004. In reaction to the enactment of the Nagoya Protocol, the Central Parliament published its Guidelines on Access to Biological Resources and Associated Knowledge and Benefits Sharing Regulations 2014, which contains specific provisions regarding procedures and benefit-sharing formulas for particular categories of access. India enforces the ABS Act via a three-tier institutional framework, comprising the National Biodiversity Authority (NBA) at the national level, State Biodiversity Boards (SBBs) at the state level, and Biodiversity Management Committees (BMCs) at the local level [34](Indian Biodiversity Act, 2002. (2002)).

The ABS Act broadly encompasses wild and domesticated biological resources and associated knowledge, both in situ and ex situ, that are 'occurring in India' (Sections 2 & 3), including traditional knowledge. However, its applicability to digital sequence information and resources situated in private conditions or collections remains ambiguous. Foreign entities (non-citizens, non-residents, and organizations not registered or incorporated in India) must undergo a comprehensive process for prior informed consent through a benefit-sharing agreement with the NBA to utilize resources and knowledge for commercial, research, bio-survey, and bio-utilization purposes (section 3), unless they are collaborating with sanctioned Indian institutions (section 5). A streamlined notification mechanism exists for Indian nationals to inform the SBBs for the aforementioned purposes, except 'commercial utilization', the transfer of research results, or the application for intellectual property protection (sections 6, 7) [35] (Indian Biodiversity Act, 2002. (2002)). 'Commercial utilisation' excludes conventional breeding and traditional procedures employed in agriculture, horticulture, poultry, dairy farming, animal husbandry, or apiculture (section 2(f)). A straightforward interpretation of animal husbandry encompasses aquaculture; nevertheless, it remains ambiguous whether the cultivation of aquatic flora is included. Benefit-sharing agreements are mandated solely for

[34] *Indian Biodiversity Act, 2002. (2002)*
[35] *Indian Biodiversity Act, 2002. (2002)*

foreign users, with advantages directed to the NBA, the BMCs, and/or benefit claimants, defined as 'the conservers of biological resources, their by-products, creators and holders of knowledge and information pertaining to the utilization of such biological resources, innovations, and practices associated with such use and application. [section 2(a)] [36] (Indian Biodiversity Act, 2002. (2002)).

The sustained expansion of the aquaculture sector to achieve governmental production and economic objectives will necessitate, among other measures, enhanced seed quantity and quality for various animal, plant, and microorganism genetic resources. Despite the existence of literature on breeding and biotechnology advancements, there is an absence of references to any permission, reporting, tracking, or monitoring obligations for aquaculture organizations or genetic resource users within the country. The significance of traditional knowledge related to plant genetic resources is thoroughly documented in India. Nonetheless, there is a lack of published information regarding the specific traditional knowledge related to aquaculture species and techniques, as well as the Access and Benefit-Sharing (ABS) of such traditional knowledge [37] (Indian Biodiversity Act, 2002. (2002)).

5. CONCLUSION

The relationship between intellectual property rights and aquaculture highlights considerable opportunities and distinct obstacles. Although breakthroughs in genetic engineering and biotechnology could transform aquaculture techniques, the territorial structure of intellectual property rights complicates the legal and commercial environment. Divergences in patentability standards among jurisdictions result in a fragmented system that restricts the enforcement of protections for genetically modified organisms, hence increasing costs and administrative challenges for innovators.

The United States employs a comprehensive and inclusive strategy on biotech patents to promote innovation, but India enforces more stringent restrictions to balance scientific progress with ethical and societal considerations. This difference illustrates a wider chasm between wealthy and developing nations, as the latter frequently confront hazards of exploitation and insufficient acknowledgment of traditional knowledge and ecological contributions. These disparities highlight the necessity for unified global standards that consider both innovation and fair benefit-sharing.

Additionally, international frameworks such as the Nagoya Protocol and the TRIPS Agreement provide mechanisms to tackle access and benefit-sharing concerns regarding genetic resources (Smith et al., 2017; WTO, 2017). These procedures necessitate rigorous application and conformity with national legislation to guarantee equitable and sustainable utilization of aquatic biodiversity.

As aquaculture increasingly contributes to global food security, it is essential to promote international cooperation that addresses regulatory discrepancies, strengthens intellectual property rights, and protects the interests of all stakeholders, particularly those from biodiversity-rich poor countries. Such steps are essential to fully harness the potential of intellectual property for fostering sustainable growth and innovation in the aquaculture sector.

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 this manuscript.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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ANNEXURE

1.A. Art 1 sec 8 clause 8 of the U.S. Constitution-

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;

1.B. 35 U.S.C. S 101

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful imprsovement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

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