

# **ILE INTELLECTUAL PROPERTY AND CORPORATE LAW REVIEW**



VOLUME 2 AND ISSUE 1 OF 2023

**INSTITUTE OF LEGAL EDUCATION**



## ILE INTELLECTUAL PROPERTY AND CORPORATE LAW REVIEW

(Free Publication and Open Access Journal)

Journal's Home Page – <https://ipclr.iledu.in/>

Journal's Editorial Page – <https://ipclr.iledu.in/editorial-board/>

Volume 2 and Issue 1 (Access Full Issue on – <https://ipclr.iledu.in/category/volume-2-and-issue-1-of-2023/>)

### Publisher

Prasanna S,

Chairman of Institute of Legal Education (Established by I.L.E. Educational Trust)

No. 08, Arul Nagar, Seera Thoppu,

Maudhanda Kurichi, Srirangam,

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### **Protection of Bio-Technical Inventions: First Step to Sustainable Development**

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**Best Citation** – Debapriya Biswas, Protection of Bio-Technical Inventions: First Step to Sustainable Development, *ILE INTELLECTUAL PROPERTY AND CORPORATE LAW REVIEW*, 2 (1) of 2023, Pg. 19–24, ISSN – 2583–6153.

#### **Abstract**

From times immemorial, nature has been a source of life for everyone on Earth, including humans. But, with the advancement of humans, the way of living has been changing rapidly. With such rapid change, even the usage of the natural and biological resources has been redefined through the advanced technology that can now even deconstruct it to its genetic sequence while modifying it the same to a desired result.

This paper explores the concept behind these biological or 'bio-technical' inventions, discussing the concept and working behind it while also highlighting the legal protections given to them. Since even the concept these inventions are quite new, the paper also discusses the need of further protection to the developing innovation in the said field.

The effects and aftereffects of the lack of acknowledgment of such inventions as manmade due to the ideology that every living organism can only originate or be created by nature is also explored while highlighting the contrast with using the exact man-made modified biological inventions in our daily lives in the form of cosmetics, medications, vaccines and even food products.

Lastly, the paper concludes with some suggestions on how to possibly address the issue on the dire need of such addressing since the lack of it results in slack in innovation, which

results in the halt in the advancement of technology.

**Keywords:** Biotechnology, Intellectual Property, Patent, Bio-technical Inventions and Genetic Resources.

#### **Introduction**

With the role of nature abundant in every aspect of human society, biological resources such as flora, fauna and microbes have become commercially exploitable materials due to their wide range of usage. And while many people may already be aware of it, seldom does anyone understand how integrated and complex it can be as an economic potential material. In simpler terms, biological resources have infinite potential as economical assets to the development of the future of human society, let it be through the production of direct agricultural products or through the manufacturing of technologies we use in our day-to-day lives.

This highlights how biological resources can be a vital source of income and development for any country, due to which many nations have their own public laws relating to the protection of these biological resources and their diversity. Most of these statutory laws give protection to biodiversity as a natural resource; preserving it as a Public Trust, with the duty of its protection often falling in the hands of the governmental authorities.

In recent times, beyond the obvious usage of biodiversity as natural resources, the concept of treating certain biological resources as intellectual property has also been explored. However, intellectual property law in biological resources has been a relatively new and unexplored idea in many nations, which has often met with ethical restrictions and arguments due to the prevailing ideology that living organisms cannot be monopolised since life is gifted by the nature and cannot be created artificially.

While the ethical concerns are quite valid, one cannot overlook the exceptions of organisms 'made' or 'cultured' through human intervention as well as the process of such intervention to produce variations in the biological resources which would not have existed otherwise without any such intervention. Thus, unlike what many people may presume, there is a scope for biodiversity as an intellectual property that is still being explored.

### **Biodiversity as Intellectual property**

Before diving into the concept of biodiversity as an intellectual property, let us first understand what is meant by biological resources as well as biodiversity. Biological resources, in a nutshell, include all the products and processes of nature that makes part of the living, such as flora, fauna, microorganisms, proteins, molecules, tissues, and cells as well as genetic resources like RNA and DNA.<sup>73</sup> On the other hand, biodiversity is the diversity or variety in the biological resources which may be introduced naturally or artificially by bringing changes in the ecology or environment of the biological resource.<sup>74</sup>

Most of the biological resources and their variations one is acquainted with are created naturally from the effects of different ecological interferences, which leads to the evolution of the organisms to adapt to their environment; thus, changing their very genetic structure to pass onto their next generations for better chances of survival.<sup>75</sup> However, with advanced technological resources, humans can now artificially create the desired ecological changes as well; thus, helping in the evolution of biological resources in the direction desired which may have never existed without human interference.

These artificially cultured biological products are what one can identify as intellectual properties since their very existence is the result of tests and experiments conducted by the human intellect. And while this may sound quite bizarre and unbelievable, we humans have been using such methods for the past century to create bio-technical inventions like artificial DNA sequences, growing stem cells by cell culturing<sup>76</sup> and even in vaccine development.<sup>77</sup>

Bio-technical inventions, in simpler terms, are referred to the products that are made by modifying the versions of biological resources either completely or partially for specific usages. The process and techniques to produce such inventions are usually explored in the field of biotechnology.<sup>78</sup>

Biotechnology and its inventions are used in a variety of fields including the agricultural industry, food industry, and pharmaceutical industry as well as for research purposes in relation to space and marine life. In fact, certain Biotechnological inventions are also used as a sustainable alternative to the mechanisms currently used by humans – specifically in the field of agriculture and animal husbandry, where the usage of chemicals is leading to adverse effects on the products being produced.

### **Innovation and sustainability**

While the concept of bio-technical inventions is not new per se, its role in sustainable development is something still being explored as environmental concerns were not being taken much sincerely until the last few decades. Thus, it led to the development of bio-technical products much more in the pharmaceutical industry than any other since most of the biological resources were used to develop

<sup>73</sup> S.K. Chaudhuri, 2003, *The impact of IPR on biodiversity*, available at: [https://www.researchgate.net/publication/28805051\\_The\\_impact\\_of\\_IPR\\_on\\_biodiversity](https://www.researchgate.net/publication/28805051_The_impact_of_IPR_on_biodiversity).

<sup>74</sup> *Ibid*.

<sup>75</sup> P. Hunter, 2007, *The human impact on biological diversity. How species adapt to urban challenges sheds light on evolution and provides clues about conservation*, EMBO Reports, 8(4), 316-318, available at: <https://doi.org/10.1038/sj.embor.7400951>.

<sup>76</sup> J. Gardner, & A. Webster, 2017, *Accelerating Innovation in the Creation of Biovalue: The Cell and Gene Therapy Catalyst*, Science, Technology & Human Values, 42(5), 925-946, available at: <https://doi.org/10.1177/0162243917702720>.

<sup>77</sup> J. Castiblanco, & M. Anaya, 2015, *Genetics and Vaccines in the Era of Personalized Medicine*, Current Genomics, 16(1), 47-59, available at: <https://doi.org/10.2174/1389202916666141223220551>.

<sup>78</sup> 2002, *Genetic Inventions, Intellectual Property « Rights and Licensing Practices*, Organisation For Economic Co-Operation And Development (OECD).

drugs, antibiotics, antidotes and vaccines for the ever-increasing diseases in both humans as well as animals.<sup>79</sup>

This gradual development also led to such inventions being used to produce cosmetic as well as agricultural products; with the cosmetic industry usually dealing with the production of certain acids and drugs used in serums and cosmetic procedures while the agricultural industry dealing with the production of fertilizers, zootechnics as well as technology for diagnostics for the domesticated animals.

Such inventions were only possible after the impressive growth seen in the medical field in relation to biotechnology and the extraction of genetic materials from biological resources. And with the start of such innovations, the range of usage of biological resources started becoming even wider as companies started to realize the economical potential of genetic resources.

While humans have been using the biodiversity around them as raw materials for as long as we have existed, using the very genetics of the biological resources has opened a completely new area of innovation alongside the usage of its physical carcass. It resulted in the development of technology that could help humans to artificially synthesise chemicals and hormones while also recreating materials like meats, muscles and organs that could be used for transplant during medical procedures.

And when environmental concerns started arising, different alternatives than the ones used currently were explored to avoid further damage to the Earth while also making a profit in a cleaner manner. This mentality resulted in many bio-technical inventions being focused on the areas of agriculture, afforestation, protection and maintenance of marine ecology and even substitution of the current sources of energy.

Problems arose when bio-technical inventions started becoming mainstream, with the main issue being the lack of legal protection for such inventions. Since the ideology that any living organism cannot be recognised as intellectual property was very prevalent, it wasn't until the 1980s that the notion somehow shifted to consider it as a possibility. It was the landmark judgment of *Diamond vs. Chakrabarty*<sup>80</sup> that addressed the question of whether a living organism can be patented – opening a long-awaited scope of intellectual property law in the arena of biodiversity.

In the aforementioned case, the defendant Anand M. Chakrabarty was a marine biologist who genetically engineered a bacterium called the *pseudomonas putida*, from the genus of *Pseudomonas* which was known for its capability to degrade hydrocarbon.<sup>81</sup> However, unlike its parent genus, the bacterium engineered by Chakrabarty was much faster at consuming hydrocarbons, making it capable of breaking down oils at a much faster pace.

Since the bacterium was efficient at breaking down oil at such a magnificent pace, Chakrabarty proposed to use it to break down the crude oil in oil spills that occur in the oceans due to any failure at the extraction process – a reoccurring accident that can be seen in the American coastlines. With such a bio-technical invention, treating oil spills becomes much more cost-friendly as well as environment-friendly since it cleans the affected areas of the ocean much faster and with much more precision than other types of machinery.

However, the issue arose when the patent application for the aforementioned bacterium was rejected by the (then) US Commissioner of Patents and Trademark, Sidney A. Diamond on the ground that living organisms cannot come under patentable subject matter. This matter was brought before the Board of Patent Appeals

<sup>80</sup> *Diamond vs. Chakrabarty*, 447 U.S. 303 (1980).

<sup>81</sup> Frank P. Darr, *Policy Implications of Diamond v. Chakrabarty*, Patent Coverage, Ohio State Law Journal, Vol. 42:1061, available at: <https://core.ac.uk/download/pdf/159590614.pdf>.

<sup>79</sup> *Ibid.*

and Interferences where the judgment was held against Chakrabarty, stating that living organisms can only originate from nature and humans do not have any hand in the creation of life. But the said judgment was reversed by the United States Court of Customs and Patent Appeals, where the Court held that the living status of the microorganism is not of legal relevance when concerning its patentability.

When the case appeared before the Supreme Court, the Court reinstated the previous judgment held by the US Court of Customs and Patent Appeals, concluding that Chakrabarty had not merely discovered the existence of the bacterium but genetically adapted and engineered it in a manner that could not have existed naturally if not modified with human intervention.

This judgment brought on a wave of change in intellectual property law worldwide as the concept of biodiversity as an intellectual property finally started to be recognised. It resulted in many genetic engineers finally being able to gain legal protection for their bio-technical inventions, leading to the flourishing of the biotechnology industry.

However, while the patentability of microorganisms was addressed, other biological resources such as flora and fauna were still not accepted as intellectual property in many nations. This led to a halt in the innovations relating to hybrid plants and any modified animals. And while that in itself may not be considered an issue, it does come into question whether this would slow the advancement of current technology.<sup>82</sup>

As mentioned earlier, attempts at sustainable development are still being made as much as possible but most of the sustainable alternatives suggested to the current outlets are not only costly but also hard to maintain and

find.<sup>83</sup> To counter this, more funds are required to be put into this field – which can only be done so if there is a guarantee for the return of such a high investment. For this kind of guarantee, legal protection is also required, which unfortunately most bio-technical inventions do not yet have around the globe.

With the usage of bio-technical inventions being as wide as it is, there is a dire need for legal protection to facilitate innovation in this field. However, the current protection available to such inventions is only through granting of patency under Intellectual Property law, which in itself is a lengthy process with a narrow field of interpretation. Since only genetic resources and microorganisms are currently accepted subject matter in Patent Law in many nations, innovation in relation to biotechnology concerning plants and animals has been halted.<sup>84</sup>

### Issues in Protection

The major issue in the protection of bio-technical inventions is that most of the world does not consider biological resources as intellectual property. While it is true that there is a high scope of exploitation if biological resources are considered individual (intellectual) property, not giving certain protection under private law gives leeway to the unauthorised usage of genetic knowledge and resources gathered by scientists or indigenous communities over a period of time.

This issue intensifies when concerning hybrid and genetically modified plants since while many nations do consider genetic resources and microorganisms as subject matters to Patents, plants are still strictly considered as a product of nature only.

This devolves the innovation in relation to floral bio-technical inventions, which could have helped the agricultural sector the most,

<sup>82</sup> K.S. Kardam, 1996, *Patentable Inventions in Biotechnology*, Journal of Intellectual Property Rights, Vol 1, pp 133-138, available at: <https://old.amu.ac.in/emp/studym/100020073.pdf>.

<sup>83</sup> 2002, *Genetic Inventions, Intellectual Property « Rights and Licensing Practices*, Organisation For Economic Co-Operation And Development (OECD).

<sup>84</sup> K.S. Kardam, 1996, *Patentable Inventions in Biotechnology*, Journal of Intellectual Property Rights, Vol 1, pp 133-138, available at: <https://old.amu.ac.in/emp/studym/100020073.pdf>.

specifically in the development of high-yielding crops for the consumption of both humans and animals. In fact, many such plants are currently also invented that are genetically modified to have additional nutrients than their parent genus.<sup>85</sup>

Such bio-technical inventions can help prevent disorders caused due to deficiency of nutrients while also developing crops that can be widely available at a cheaper price. Many bio-technical inventions concerning plants have also explored the scope of faster growth to facilitate afforestation in the areas needed. However, the development of such inventions has become increasingly slow due to little to less legal protection given against the unauthorized use of third parties.

Currently, only the US allows the patentability of all biological resources including the modified varieties of plants and animals. And while that, in itself, arises the question of where the line should be drawn for bio-technical inventions from natural biological processes and products, it also gives scope of protection to these inventions while facilitating innovation in this field.

This, in turn, resulted in many bio-technical inventions being innovated in the US but not being popularised around the globe due to the lack of legal protection being given to such inventions. Such disconnection also leads to obstruction in development as well as irregular development in the areas where Intellectual Property law is not much prevalent. Enforcement of protection of such bio-technical inventions also becomes difficult since each nation has different legal provisions concerning these inventions.

### Aftereffects

As previously mentioned, the lack of protection given to genetically modified biological resources has resulted in a slump in innovation

in the field of biotechnology, especially since this field needs a huge amount of funding as well as time for any development of new inventions. Since no concrete standardized protection is given for fauna and floral biological inventions, it discourages people from stepping into this field in fear of getting their hardwork being exploited by some third party.

This is especially true for bio-technical inventions relating to agricultural products; specifically, hybrid seeds and crops which can be cross-bred and used in an unauthorised manner by the local farmers. Similar is the case for sustainable farming methods and machinery that are not protected in many nations like India<sup>86</sup> which can result in generic versions of such machinery being mass-produced without any authorisation from the actual inventor.

It results in hesitation on the side of the inventor from going to nations where bio-technical inventions are not given proper protection – most of which are developing nations that may need these inventions for their development, especially when considering bio-technical inventions in the agricultural field.

Most of the development in the Biotechnological field has been in the area of genetic engineering, specifically in the cloning and deconstruction of DNA and RNA as well as the coding of genetic sequences of both flora and fauna.<sup>87</sup> Stem cell applications as well as the synthesization of artificial enzymes and hormones have also been advanced only because genetic resources are given the protection as intellectual property in most nations due to international conventions like the Convention on Biological Diversity (CBD) of 1992.

Such advancement in development can also be seen in other areas of biotechnology if the scope of intellectual property law in biodiversity

<sup>85</sup> M. Newell-McGloughlin, 2008, *Nutritionally Improved Agricultural Crops*, Plant Physiology, 147(3), 939-953, available at: <https://doi.org/10.1104/pp.108.121947>.

<sup>86</sup> Indian Patent Act, 1970, § 3, Acts of Parliament, 1970 (India).

<sup>87</sup> K.S. Kardam, 1996, *Patentable Inventions in Biotechnology*, Journal of Intellectual Property Rights, Vol 1, pp 133-138, available at: <https://old.amu.ac.in/emp/studym/100020073.pdf>.

is universalised beyond just the genetic resources and the microbes. In fact, the evidence of such was also reported by the World Bank in the 1990s, stating that appropriate legal protection encouraged productive research and development.<sup>88</sup> In addition to that, the United Nations Conference on Trade and Development (UNCTAD) of 1991 also highlighted the importance of intellectual property law in the negotiation of trade and without such legal provisions, even the market access of such inventions can become problematic.<sup>89</sup>

Thus, to facilitate and encourage innovation in the field of biotechnology concerning not only genetic resources and microbes but also plants and animals, there is a dire need for the development of intellectual property law as well as awareness about it and its importance in the variety of fields that it affects. Since intellectual property law and technology transfer plays a vital role in research in recent times, it becomes important to address their uniformity or lack thereof which can act as a large obstruction.

### Conclusion and Suggestions

In the end, there is a clear need for distinction between what consists of natural biological processes and what identifies as human inventions while also highlighting how much modification shall be enough to consider it an invention resulted due to human intervention. And while the concept itself may seem quite vague and abstract, even a basic addressal of this concept can set a codified provision for the Judiciary to interpret from.

The main issue for debate is whether such bio-technical inventions can be protected by any other aspect of the intellectual property law than the Patent. Since patentability in itself has a very narrow interpretation, the aspect of other

laws has been considered; however, no other intellectual property law has much scope for protecting the process and product of bio-technical inventions except Trade Secret and Technology Transfer, among which Trade Secret has no proper codification itself.

Thus, to protect biological resources as well as bio-technical inventions, there needs to be an international convention which addresses not only the protection of genetic resources and microbes, like the Convention on Biological Diversity, but other resources as well.

From the cosmetic sector to the medical sector and even the agricultural industry has a prominent use of biological resources and inventions derived from the modification of it. Thus, there is an immediate need for proper regulation and preservation with utmost care while also encouraging innovation and development through its usage. Only the balance of both can lead to the path of sustainable development while also protecting biodiversity, including the bio-technical inventions.

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<sup>88</sup> World Bank, 1990, *Strengthening Protection of Intellectual Property in Developing Countries: A Survey of Literature*, Discussion Paper, Washington, DC, USA, available at: <https://documents1.worldbank.org/curated/en/663011468739527882/pdf/multi-page.pdf>.

<sup>89</sup> UNCTAD, 1991, *Trade and Development Report*, United Nations Conference on Trade and Development (UNCTAD), New York, USA., available at: [https://unctad.org/system/files/official-document/tdr11\\_en.pdf](https://unctad.org/system/files/official-document/tdr11_en.pdf).