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EDITORIAL NOTE

Intellectual Property is the key driver to propel the economic growth of a nation. Hence, understanding IP gains utmost significance not only from a business point of view but also from a socio-economic perspective. We as nationals of any country should be vigilant in protecting and defending our IP rights. However, there are multiple issues and challenges that need discussions, and reforms. The IP Press Law Review (IPPLR) is an initiative of The IP Press to extend our objectives of spreading awareness on the issues concerning intellectual property rights and related laws. It aims to promote study and research in the field of intellectual property laws in the form of academic literature. This issue reflects some of the key concerns of the Intellectual property regime both under national and international parlance. It is envisioned to embody some of the most brainstorming insights that help readers to grasp the discourse around contemporary developments in the field of Intellectual Property Law. Throughout the year, the editorial board has reviewed the papers with multiple rounds of editing to ensure quality and standard.

This issue presents intriguing issues and challenges pertaining to intellectual property law in the national as well as the international regime. The first paper encapsulates the protection of personality rights under Intellectual property laws and briefly presents the status of multiple jurisdictions. The second paper discusses a pertinent issue of protection of fictional characters that have been a cause of concern in many disputes. The author discusses the theoretical framework and analyses various tests laid down by the judiciary.

The third paper explores religion as a subject and object of the trademark. The author determines the legality of the trademark of religious symbols for private companies and religious organisations. The fourth paper presents a policy discussion on the overlap between trademark and functionality doctrine. The fifth submission deals with the congruence of intellectual property assets in combination and corporate restructuring wherein the author states that IP has immense power to help businesses to grow and hence its valuation becomes an important aspect of commercialization of IP. The sixth paper demonstrates how open-ended section 57 of the Copyright Act, 1957 is which leads to ambiguity. The author asserts reforms in the current provision of moral rights. The seventh paper discusses the recent dissolution of the intellectual property appellate board in the backdrop of the Tribunal Reform Bill, 2021. The eighth paper discusses the relevance of IP Due diligence and suggests quarterly checks and steps carry out the due diligence process to combat the closing down of businesses and lifelong losses. The ninth paper presents analyses of the patent denials in the biotechnology sector and their impact on the industry. The tenth paper presents an interesting analysis of trademarkability of non-conventional trademarks due to hindrances of graphical representation and discusses multiple judgements of the European courts. The last two items present an analysis of two landmark cases, one Monsanto case and two, Phonpe v. Bharatpe trademark tussle.

Happy reading!

IN THIS ISSUE

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DENIAL OF PATENTS IN THE BIO-TECHNOLOGY SECTOR AND ITS CONSEQUENCES ON INDUSTRY DEVELOPMENT

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ABSTRACT

Patents have been increasingly used globally as a form to financially protect the creators of original inventions. Any new product or process of doing something which constitutes an inventive step and is capable of industrial application is usually eligible for patent protection. In fact, the significance of patent protection is paramount in any industry to garner investor confidence. Without the financial protection accorded by patents, investors are likely to shy away from exposing their capital for the development of new inventions. Without investments for research, development and innovation across different industries are bound to fail. To ensure that intellectual property rights are globally respected, international treaties like the Trade Related Intellectual Property (TRIPs) Agreement have been put in place to govern the grant and enforcement of patents. With the goal of promoting technological innovations, the TRIPS Agreement provides for the protection and enforcement of intellectual property rights. Discussing the nature of patent protection, this paper aims to analyse the provisions of the TRIPS Agreement with respect to patents as well as how they have been given effect by international jurisprudence. As we will see, courts around the world have often used the provisions of international treaties to deny patent protection, especially in the bio-technology sector. Consequently, the repercussions of patent denial will be discussed with its broader implications on the development of the industry. Finally, a suggestive discussion will shed light on issues of the current patent enforcement regime which may need to be reconsidered to streamline the long-term objectives of treaties like the TRIPS Agreement.

Keywords: Patents, Bio-technology, TRIPS, inventions, patent enforcement regime.

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1. INTRODUCTION

Through this paper, we shall understand how international jurisprudence has interpreted international and domestic laws with regards to patent protection in the bio-technology sector. In doing so, this paper shall attempt to shed light on how modern innovation has thrown all the assumptions we had about the development of technology out the window. International laws on patent protection have greatly underestimated the rapid advance, especially in the bio-technology sector. In fact, this particular sector has advanced so much that one could argue that the laws governing its protection are lagging behind the times. Before justifying this stance, we first need to understand what patent protection is, the existing international and domestic laws in place, and judicial interpretation in cases.

Patent protection serves as an incentive given to individuals and companies, which gives them exclusive rights to commercially benefit from any invention, whether it is a product, a new process of doing something or a new technical solution to a problem, for a certain time.[1] The two types of patents are:

- Product patents, which are granted for apparatus which serve as the end product of an invention (example – mobile phones, cars, etc.).[2]
- Process patents, in which protection is provided for the method or process through which the end product is obtained (example – an innovative method of harvesting crops).[3]

Thus, we could surmise that the nature of a patent consists of three significant elements. Firstly, it provides the inventor with an exclusive right. Secondly, the protection accorded to the inventors to commercially benefit from their invention becomes contractual once a patent is granted. Finally, the rights accorded through the patent are time bound, i.e., they cease to exist after the period of protection granted by the patent.

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[1] Deborah E. Bouchoux, *Protecting Your Company's Intellectual Property: A Practical Guide to Trademarks, Copyrights, Patents & Trade Secrets* (AMACOM Division of American Management Association International 2001) 153-160.
[2] Michael Waterson, '*The Economics of Product Patents'* [1990] 80 AER 4, 863-869.
[3] George P. Carroll, '*Process Patents Involving Principles of Nature'* [1910] 19 YLJ 3, 172–179.

Internationally, the TRIPs Agreement is one of the leading conventions on patent law. Members to the TRIPs Agreement are obligated to give effect to its provisions through their domestic laws to promote global cooperation in the enforcement of patent protection. For example, India, being a signatory to TRIPS, has made three amendments to its Patents Act, 1970 to accommodate the provisions of the Agreement.[4] However, being an international treaty, the Agreement cannot afford to be too stringent with its provisions due to the possibility of members defaulting. Thus, it has to provide certain exceptions where member countries can use their discretion to deny patent applications. As we shall see, courts around the world have often used these exceptions to deny patent protection to inventions in the bio-technology sector, which could effectively stunt research and development in the industry due to the resulting drop in investors' confidence.

2. THE TRIPS AGREEMENT, 1994 (RELEVANT LAWS ON PATENT PROTECTION)

The TRIPS Agreement, which is one of the leading international conventions on intellectual property, serves as a model for its member countries while drafting their domestic patent laws. Negotiated in the Uruguay Round of the General Agreement on Tariffs and Trade (1989-1990)[5], and administered by the World Trade Organization, the TRIPS Agreement provides its member nations with the minimum standards of regulating different kinds of intellectual property. The Agreement also provides enforcement procedures, dispute resolution procedures and remedies.[6] Since signatories to this Agreement are required to uphold its principles through their domestic laws, it would follow that any such law which is counter-productive of the objective of the TRIPS Agreement would also stem from an interpretation of its own rules. Thus, it is important to first observe the relevant laws on patents in the TRIPS Agreement before analyzing how their interpretation in domestic laws has affected development in any sector.

Article 27(1) of the TRIPS Agreement requires its member nations to provide patent protection for any invention, whether it is a product or a process of doing something, in all fields of technology as long as they are new, involve an inventive step and are capable of industrial application.[7] Thus,

[4]Jerome H. Reichman, *The TRIPs Agreement Comes of Age: Conflict or Cooperation in the Post-Transitional Phase?, Intellectual Property: Trade, Competition, and Sustainable Development the World Trade Forum* (edited by Thomas Cottier, Vol. 3, University of Michigan Press 2003) 115-140.
[5] Daniel Gervais, *The TRIPS Agreement: Negotiating History* (Sweet & Maxwell 2012) Part I.
[6]The Agreement on Trade-Related Aspects of Intellectual Property Rights 1990, art 1(3).
[7]The Agreement on Trade-Related Aspects of Intellectual Property Rights 1990, art (1).

it would follow that any invention that is unique and achieved through human ingenuity should be eligible for patent protection.

However, it must also be noted that the TRIPS Agreement also provides certain conditions when member nations can exercise their discretion to exclude certain subject-matter from patent protection. For example, Article 27(2) allows members to exclude any inventions from patentability which are deemed necessary for the protection of public order, morality, health, human, plant or animal life, or to avoid prejudice to the environment.[8] Similarly, Article 27(3) allows members to exclude from patentability any medical methods for the treatment of humans or animals and the production of plants and animals through essentially biological processes.[9]

A. Compliance of Domestic Laws with TRIPS Agreement

As discussed above, members to the TRIPS Agreement are obligated to structure their respective domestic intellectual property laws in compliance with the Agreement. For example, the United States law 35 USC § 101, which provides for the conditions and exceptions to patent protection, is obligated to do so within the confines of the TRIPS Agreement. Similarly, even the exceptions to patentability in India[10][11]mentioned in Section 3 and 4 of the Patents Act, 1970 adhere to the Agreement. If member nations are obligated to model their laws in such a manner, it would also follow that they may make provisions for denial of patents provided they do so within the confines of Article 27(2) and 27(3) of TRIPS.

While both the above-mentioned Articles can only be used by members to deny patents in good faith, a study of international jurisprudence around them is required before commenting on the effectiveness of these Articles in promoting the broader goals of technological innovation around which the Agreement was drafted.

[8] The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), 1990, art 27(2).
[9] TRIPS, art 27 (3).
[10] The Patents Act 1970, s 3.
[11] The Patents Act 1970, s 4.

3. HOW DOMESTIC INTERPRETATION OF THE TRIPS AGREEMENT HAS AFFECTED THE BIO-TECHNOLOGY SECTOR

Now that we have cleared the statutory aspect of patent protection, we can begin developing our argument on how statutory interpretation has fared in real world cases. As discussed above, Article 27(3) of TRIPS allows members to exclude from patentability, production of plants and animals through essentially biological processes. It was under the ambit of this Article, that the United States excludes patentability for products, which constituted natural phenomenon.[12] Eventually, this interpretation was evolved by a US Appeals Court to exclude any products, which did not possess "markedly different characteristics than those found in nature".[13]The courts' decision would not come as a surprise to experts on patent law as most countries would usually classify products which do not have markedly different characteristics than those found in nature as 'products of nature'. Such products which do not convincingly have any characteristics, which are not freely found in nature, are then excluded from patentability as exceptions under the TRIPS Agreement.[14]

The reasoning behind excluding such biological processes from patentability was explained in *Funk Bros Seed Co. v. Kalo Inoculant Co.*, where the court stated that manifestations of laws of nature are "part of the storehouse of knowledge and free to all men".[15] This interpretation was also used in *Diamond v. Chakrabarty* where the court held that a new mineral discovered, a new plant found in the wild or even genetically engineered microorganisms are not patentable as they would be considered 'natural phenomenon'. It further explained that under US law 35 USC S 101, living things were not patentable.[16] The scope for interpreting natural phenomenon became even more clear in subsequent cases where courts established that even novel and beneficial mathematical formulas[17], discovery of new ways to harness qualities of unique metals[18] or concepts of electromagnetism and steam power[19] would not be patentable as these were 'naturally occurring concepts' which do not have any distinct qualities from those found in nature. Even isolated human

[12] United States Code, Title 3, Section 101.
[13] *Diamond v. Chakrabarty* [1980] 447 U.S. 303(1980).
[14] Rochelle C Dreyfuss, '*Patenting nature-a comparative perspective'* (2018) JLB 5.3, 550-589.
[15] *Funk Brothers Seed Co. v. Kalo Inoculant Co.* [1948] 333 U.S. 127 (1948).
[16] *Diamond* (n 13).
[17] *Parker v. Flook* [1978] 437 U.S. 584 (1978).
[18] *Funk Brothers Seed Co.* (n 15).
[19] *O' Reilly v. Morse* [1853] 56 U.S. 62 (1853).

genes were held to be not patentable in the high-profile case of *Association for Molecular Pathology v. Myriad Genetics* on account of the genes existing naturally and the only discovery in the case being their location.[20] Such court decisions made it clear that the discovery of scientific principles, concepts and living or non-living natural occurrences were not eligible for patent protection.

A. The Roslin Institute Case

While most of the above-mentioned cases would seem reasonable to any expert on patent law, the case of *In Re: Roslin Institute* may raise some concerns. In 1996, Ian Wilmut and Kieth Campbell, along with their colleagues at the Roslin Institute, Scotland successfully cloned the first mammal ever, Dolly the sheep. The method they used to achieve this was called Somatic Cell Nuclear Transfer (SCNT) which was a novel and unique process. While the Institute received a process patent on the SCNT method in 2009, they had also claimed a patent on another product: Dolly herself as well as any animal cloned using their SCNT method.[21]

Dolly enjoyed a short life as the first mammal to be cloned from an adult cell, succumbing to a lung disease in 2003. Although Dolly died in 2003, Roslin Institutes attempt to patent her and lay commercial claim to all animals cloned using their method spanned over a decade. The US Patent and Trademark Office (PTO) cited 35 USC S 101 which excludes "laws of nature, abstract ideas and natural phenomena" from the subject matter of a patent to deny a product patent for the cloned sheep. Consequently, Roslin Institute attempted to appeal against the PTO's decision in the Patent Trial and Appeal Board in 2013. However, the decade-long saga ended in 2014 when the U.S Federal Appeals Court gave a final verdict against granting a product patent to Dolly's creators.[22]

Now, with reference to earlier discussed jurisprudence, we know that the 'product of nature' exception to patentability has been used to include both, naturally occurring products (e.g.- the discovery of a new metal) and non-naturally occurring products that do not have any distinct characteristics than that found in nature (e.g.- genetically engineered microorganisms that classify

[20] *Association for Molecular Pathology v. Myriad Genetics, Inc.* [2013] 569 U.S. 576 (2013).
[21] Lauren Matlock-Colangelo, '*Broadly Unpatentable: How Broad Method Claims Have Limited Patentability Of Diagnostic Inventions'* [2019] 119 CLR 3, 797-836.
[22] ibid.

as natural phenomenon).[23] We also know that the cloned sheep, which was technically a living organism, would justifiably not be patentable under 35 USC S 101 as explained in *Diamond v. Chakrabaty*.[24] The problem lies when the requirement to possess "markedly different characteristics than found in nature" starts being used to refuse patent protection to products created more through human ingenuity and intervention than 'laws of nature'. The court in the Roslin Institute case used the earlier Supreme Court decisions to determine the scope for patentability. Here, the court held that although the cloned sheep was produced through biotechnological methods, it was still an exact genetic replica of the "naturally occurring" sheep from which it was cloned. Since it did not possess any markedly different characteristics than the sheep found in nature, it could not be patented as well.[25] While the Institute claimed that the cloned sheep could be distinguished from the natural sheep through its mitochondrial DNA, the judge in this case did not give it much consideration since it was not mentioned in the patent application.[26] The judgment may seem more problematic when one considers that once the sheep was cloned, factors such as age and weather conditions would give them a unique appearance which would be distinct from the original animal. Even if one ignores all technical aspects and intricate legal interpretations from earlier case law, the conclusion of the Roslin Institute case would be a denial of patent protection to a product which was widely considered a scientific breakthrough in the bio-technology sector with far-reaching possibilities.

4. CONSEQUENCES OF STRICT JURISPRUDENCE ON INDUSTRIAL DEVELOPMENT

While the SC decisions discussed to shed light on the scope of "products of nature" have always had their critiques for including non-naturally occurring products within their ambit, the Roslin Institute case serves as a perfect example of how the current regime could potentially be counter-productive to the overall goal of the TRIPS Agreement, i.e., the promotion and encouragement of development in technology and industry.[27] While the denial of patent protection to Dolly could be

[23]Tup Ingram, '*Association for Molecular Pathology v. Myriad Genetics, Inc.: The Product of Nature Doctrine Revisited'* [2014] BTLJ 29, 385–417.
[24]*Diamond* (n 13).
[25]*In Re: Roslin Institute (Edinburgh)* [2014] 750 F.3d 1333 (Fed. Cir. 2014).
[26]ibid.
[27] Peter K Yu, '*The objectives and principles of the TRIPS agreement'* [2009] *Hous. L. Rev.* 46, 979.

justified by legal experts using previous case law, industries such as personalized medicine and biotechnology would be greatly impacted by the courts' rationale.

The general hostility towards granting patents to human made products which are identical to nature could cause investors to shy away from promising areas of biomedical and technological research.[28] The Roslin Institute case provides the perfect example to highlight this issue due to the sheer potential of the product which was denied patent protection. The success of cloning animals has opened the path to evolutionary concepts such as cloning human cells as possibly even creating lab grown organs. However, no matter the potential, no development can happen on this front without proper investments for research and development. The denial of patent protection to cloned animals would definitely weigh on an investor's mind, whose primary goal is to financially protect his interests. If investors are convinced that they would not be able to commercially benefit from the products created, investments in the particular area of research would irrefutably be stunted.[29] Supporters of the current regime may argue that in the Roslin case, a process patent on the SCNT method should be sufficient to tackle this issue. However, such claims do not account for the fact that the average investor does not understand the subtle differences in the types of patents and are still much more comfortable with a product patent. Even those who understand the differences are sure to reconsider their investments if a product patent is blatantly denied, even if the researchers still hold a process patent.

A. The Potential 'Domino Effect'

Even before the Roslin Institute case, one could argue that the Supreme Court decision in the Myriad Genetics case set the stage for a disastrous blow on the biotechnology sector. Judge Thomas' view on this case led many to expect a complete cessation of the personalized medicine industry.[30] Here, the creation of cDNA (composite DNA) was held to be patent eligible only if it could be distinguished from actual DNA.[31] While a layman may not realize the significance of this distinction, it essentially only allowed longer strands of cDNA which were distinguishable from actual DNA to be patented. The shorter strands which could not be distinguished were excluded

[28] Ted Sichelman, '*Commercializing Patents*." [2010] 62 SLR 2, 399-411.
[29] ibid.
[30] Clark D Asay, '*The Informational Value of Patents*.' [2016] 31 BTLJ 1, 259–264.
[31] Association for Molecular Pathology v. Myriad Genetics, Inc. [2013] 569 U.S. 576 (2013).

from patentability.[32] One could argue that it was this requirement to be 'distinguished from nature' that was amplified into a decision where the cloned sheep was denied patentability on the same grounds on account of being identical to the sheep from which it was cloned.

One of the biggest issues with the courts' interpretation in cases related to biotechnology is that they seem to penalize 'perfect' inventions while making allowances for imperfect ones. Justice Thomas' comments on the Myriad decision leads us to believe that short strands of cDNA could not be patented on account of being indistinguishable from actual DNA.[33] This pill seems hard to swallow because the exact recreation of organic material should be considered the epitome of success in cloning technology. The pinnacle of personalized medicine, at least with regards to cloning, would be to eventually create lab grown organs which would be completely indistinguishable from naturally occurring organs as only such organs can be safely transplanted to prolong human life. Such indistinguishable organs would undoubtedly be considered a bigger technological breakthrough than cloned organs, which are distinct from naturally occurring organs. If Judge Thomas' explanation is considered, such 'perfect' lab grown organs could be excluded from patentability. In such a scenario, no commercial company would risk spending billions of dollars on research necessary to make this goal a reality. Without the possibility of exclusive rights, development in such promising fields is bound to dry up.[34]

B. Challenges and Suggestions

An objective analysis of the reasons given by courts to deny patents will reveal that the logic used to do so had some degree of legal backing. In a system where precedent is given paramount importance, it is only natural for courts to structure their verdict keeping previous jurisprudence in mind. However, when accepted legal interpretations visibly pose obstacles to the broader goals behind which the statute was drafted in the first place, a need for review arises. The primary goal of the TRIPS Agreement is to promote technological development and innovation.[35] However, when exceptions in the TRIPS Agreement are used by courts to justify denying patent protection

[32]Sebastien Bradley, '*Cross-Country Evidence On The Preliminary Effects Of Patent Box Regimes On Patent Activity And Ownership.*' (Vol. 108, Proceedings. Annual Conference on Taxation and Minutes of the Annual Meeting of the National Tax Association 2015), 1–15.
[33]ibid.
[34] Clark D Asay, '*The Informational Value of Patents*.' [2016] 31 BTLJ 1, 259–264.
[35]Peter K Yu, '*The objectives and principles of the TRIPS agreement'* [2009] *Hous. L. Rev*. 46, 979.

to genuine innovations like cloned animals and genetically engineered microorganisms, it has the opposite effect which is counter-productive to this goal.

The major obstacles faced with any international treaty, is the issue of enforceability. Various failed treaties in the past have proven that no matter how admirable the intentions, they are bound to implode if their member nations do not follow them. Thus, to ensure success, international treaties usually tend to be more relaxed in their restrictions to encourage member nations to follow their provisions. However, vague statutes which are open to broad interpretation is not an effective solution to reduce restrictions. As discussed above, if statutes leave a broad scope for interpretation, there exists a strong possibility that judicial interpretations may lead to their provisions having a diverse impact on their overall objectives.

To overcome the issues caused by a lack of proper guidance, the TRIPS Agreement may need to be reviewed. Although the current statute makes an admirable attempt to balance the rights of the inventor and the rights of domestic governments to restrict patentability for the common good[36], the provisions in place are vague and could be interpreted in numerous ways. A clarification on how the exceptions to patentability can be used along with exact conditions could go a long way in ensuring that patents are only denied for situations envisaged by the drafting body.

Furthermore, if the goals envisaged by the TRIPS Agreement are to be realized, the judiciary needs to remain cautious of the real-world impact of their decisions. Rather than trying to interpret the scope of the exceptions within the international treaties, the judiciary should structure their verdicts in light of the broader goals of the statute they are interpreting. Finally, a proper balance must be struck while determining whether a product is a natural phenomenon or a creation through genuine human intervention. The precedent of requiring inventions to possess 'markedly different characteristics than those found in nature' should be reassessed considering modern technological breakthroughs which seek to duplicate natural phenomena. Industries like the biotechnology sector, often hailed as the 'the future of science' will only be able to thrive if their rights are protected by intellectual property laws in a structured manner.

[36]ibid.

5. CONCLUSION

The purpose of this paper was to highlight the importance of statutory provisions and the ways in which they are interpreted. As we have seen, even domestic laws which are consistent with the TRIPS Agreement can be used to deny patent protection to products in a manner which can threaten the fundamental objectives of the Agreement. One of the major reasons for patents being denied in the *Myriad Genetics* and *Roslin Institute cases* could be that science has evolved beyond the expectations of the drafters of the Agreement. While making provisions to exclude 'products of nature' from patentability, it is possible the drafters did not take into account the fact that the latest breakthroughs in the biotechnology sector would be identical to natural products. However, just like biotechnology, and every other industry in the world, law is an evolving concept as well. It needs to constantly adapt to the dynamic developments in the world it seeks to regulate. Keeping this in mind, certain provisions of the TRIPS Agreement as well as domestic laws modelled around it may need to be reviewed or restructured. It is crucial that developments in different industries are kept in mind while doing so to ensure that all new, unique and innovative inventions are given sufficient protection to facilitate their development.