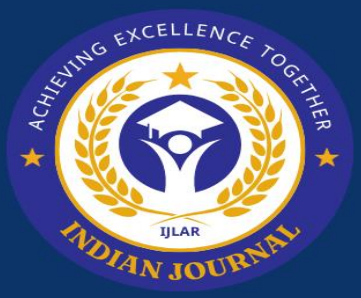

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Introduction

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Preface

The Indian Journal of Legal Affairs and Research is a testament to our unwavering commitment to excellence in legal scholarship. This volume presents a curated selection of articles that reflect the diverse and dynamic nature of legal studies today. Our contributors, ranging from esteemed legal scholars to emerging academics, bring forward a rich tapestry of insights that address critical legal issues and offer novel contributions to the field. We are grateful to our editorial board, reviewers, and authors for their dedication and hard work, which have made this publication possible. It is our hope that this journal will serve as a valuable resource for researchers, practitioners, and policymakers, and will inspire further inquiry and debate within the legal community.

Description

The Indian Journal of Legal Affairs and Research is an academic journal that publishes peer-reviewed articles on a wide range of legal topics. Each issue is designed to provide a platform for legal scholars, practitioners, and students to share their research findings, theoretical explorations, and practical insights. Our journal covers various branches of law, including but not limited to constitutional law, international law, criminal law, commercial law, human rights, and environmental law. We are dedicated to ensuring that the articles published in our journal adhere to the highest standards of academic rigor and contribute meaningfully to the understanding and development of legal theories and practices.

"GLOBALIZATION AND PATENT LAW: NAVIGATING CHALLENGES IN THE BIOTECHNOLOGY SECTOR"

AUTHORED BY - V V S S PRAVEENA
PhD. Scholar, KIIT UNIVERSITY

Abstract

Globalization has revolutionized the biotechnology sector by fostering international cooperation, innovation, trade, and R&D efforts. Innovation and the protection of intellectual property are essential to the development and commercialization of biotechnology, a key sector for healthcare, agriculture, environmental protection and pharmaceuticals. In this context, patents have become an important tool to safeguard biotechnological innovations, to draw investments, to enable technology transfer and to ensure economic growth. At the same time, as the world becomes global, the complexity of legal and regulatory aspects of patent protection and enforcement has grown. This paper explores the connection between globalization and biotechnology patents, by analyzing the development of global patent systems and the effects they have had on the biotechnology sector. It examines the history of patentability of genetic material and living things in biotechnology from key decisions of the courts like Association for Molecular Pathology v. Myriad Genetics and Diamond v. Chakrabarty, which defined the modern concepts of patentability of living things and genetic material.

The paper also examines the functions of international instruments like the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the World Intellectual Property Organization Patent Cooperation Treaty (PCT) in harmonizing international patent standards and in making patent filing easier. The study also discusses key issues that are likely to emerge in biotech patent enforcement in the context of globalization, such as jurisdictional conflicts, cross-border patent litigation, patent infringement via global supply chains, and compulsory licensing in developing countries. Particular attention is given to the Indian biotechnology industry and the peculiar provisions of the Indian Patents Act preventing patentability in certain instances, specifically Sections 3(b) and 3(d). To underscore the delicate

balance between patent protection, public health and affordable medicines, important cases in India, like Novartis AG v Union of India, are discussed and so are the cases of Bayer Corporation v Natco Pharma. The paper finds that globalization has fostered innovation and commercialization in biotechnology, but also has revealed problems with the international patent system. National patent laws, ethical issues with biotechnology, and disputes between private patent rights and public welfare still remain to be a source of legal uncertainty. Thus, there is a need for a balanced and harmonized international patent system that allows for the protection of innovation while also providing access, ethical responsibility and equitable technological progress in countries.

Keywords - Biotech Patent Enforcement, Compulsory Licensing, Cross-Border Patent Litigation, Genetic Patentability, TRIPS Compliance in Biotechnology.

Introduction

Globalization refers to the continuous integration of central and peripheral nations' economy and culture which is a result of various factors like communication, transport and technology. This has ensured that there is ease in crossing the national borders in terms of capital, information, products and services hence the need to have economic integration and cultural interchange. In one way, authors argue that globalization has enhanced economic development in a number of ways such as opening new trade channels, new trading prospects, and ease of foreign investment. It has also encouraged innovation such as the global research partnerships and the sharing of new technical advancements. But then again so too are the negative consequences of globalization, economic differentiation, the Westernization of culture, and complexity of the regulations. Drawing the general conclusion on the impact of globalization it is possible to state that despite the seeming increase in the overall well-being of the society and the world, the negative processes are more than evident. So, it is important to regulate the impact of globalization because of its positive and negative effects caused by it in the further development.

Biotechnology in the context of globalization refers to the processes through which biotechnological research, development and marketing has gone international. Biotechnology includes using of biological systems or living organisms in the creation of technology apps and products to serve a specific or a range of industries, varying from medical to pharmaceutical, agricultural and environmental. It is the determinant of almost all issues affecting the world

including lack of diseases cure, world hunger and lack of environmental conservation. This includes biotechnology and biotechnology genetic engineering and molecular biology and bioinformatics.

Biotechnology is such an important field because it has the power to alter Industries and enhance the quality of the human life and health. It has specially benefited the field of medicine through the emergence of new drugs vaccines and diagnostic techniques that have been realized through biotechnology which has therefore boosted on individualized treatment procedures.[1] It has led to the introduction of Genetically Modified produce in agriculture, possible benefits being, they are nutritious and resistant to insects attack. Application: Biotechnology assists in environmental research in environmental friendly processes and bioremediation.

Biotechnology is so much a victim of globalization because it involves all this international cooperation, sharing of resources and knows how. Globalization also encourages the development of international regulatory structures that allow for the standardization of biotechnology product approval and release, making it much easier to bring new products to the world market. Globalization in biotechnology does, however, provide difficulties. That might stifle innovation and raise prices via complicated patent landscapes filled with competing intellectual property rights.

Historical Context: Patent Protection in biotech industry

While patent protection is not a new concept, dating back to early modern times, it has changed considerably over time. Originally, kings would issue patents to people or business as monopolies over certain inventions, encouraging ingenuity and inventiveness. With the passage of time, government granted advantages gave way to uniform legal framework known as patent laws, which gave inventors exclusive rights in an effort to promote innovation.

Because the biotechnology business depends so heavily on ground-breaking research and innovation, patent protection is especially important in this context. The biotech field really branched off as its own area during the 70's because of much advancement such as gene sequencing and recombinant DNA technologies. As biotechnology developed, research and development

[1] Angad Singh, Sharanabasava Hallihosur, and Latha Rangan, 'Changing landscape in biotechnology patenting' (2009) 31(3) *World Patent Information* 219.

(R&D) expenditure grew increasingly dependent on patent protection as a means of securing exclusive rights to ideas and recovering substantial R&D expenditures. The roots of modern patent law in the biotechnology field can be traced back to landmark decisions in the 1980s and 1990s that set legal precedents for the patenting of genetic material and life forms. The 1980 decision of diamond vs. chakrabarty,[2] decided by the US Supreme Court, was one of the most important turning points. This decision made it possible to patent genetically engineered microorganisms, which allowed the biotechnology sector to benefit from more extensive patent protection.

The world agreements such as the world trade organization's agreement on trade related aspects of intellectual property rights (TRIPS) helped to push the global movement towards intellectual property protection in the late 20th century. TRIPS forces all member countries including India to enact more rigid intellectual property laws, namely those concerning product patents in such fields as biotechnology. The patents (amendment) act, 2005, which brought India's patent laws into agreement with international norms as a result of its TRIPS compliance, marked a significant change in the legal environment surrounding patent in biotechnology. The law met the requirement of Article 27.3(b) of the TRIPS Agreement by specifically providing for the patentability of microorganisms.

The patenting of genetic material became a hot topic of discussion in the early 21st century, both legally and ethically. A significant turning point was the association for molecular pathology vs. Myriad genetics[3] case heard by the U.S Supreme Court in 2013.two genes, BRCA1 and BRCA 2, associated with a higher risk of breast and ovarian cancer were patented by myriad genetics. There were question over access to genetic testing and research because the company's patents granted it only authority to perform tests on certain genes. The S.C decided that because naturally occurring DNA sequences are natural phenomena, they cannot be protected by patents. Nonetheless, the court permitted the patenting of cDNA, which is produced artificially in a laboratory.

Patent systems are quickly evolving to accommodate fears over who will own and will have control of the fundamental biological technology as synthetic biology and gene-editing technologies continue to advance. The boundary between patenting natural phenomena and inventions created by humans is still a hot topic of debate, particularly as biotechnology research continues to explore new avenues for manipulating living things.

[2] 447 U.S. 303 (1980)
[3] 569 U.S. 576 (2013)

Importance of patenting in biotech sector

Patenting gives scope for innovation because they give exclusive rights to inventors, yet they also stimulate the sharing of information by requiring inventors to disclose their inventions in order to receive protection. In the realm of biotechnology, where strides in one area often rest on the shoulders of previous discoveries, the need to protect innovation, while at the same time, furthering the public's understanding, becomes all the more imperative. Nonetheless, patenting innovations in biotechnology presents particular difficulties. Specifically, the patenting of genetic sequences and other naturally occurring biological components has come under fire. Those against it argue that to patent these things is to allow monopolies over the building blocks of life itself, denying access to vital research tools and stifling future innovation.

One of the major reasons that patents are so important in biotechnology is because they attract investment. Biotechnology is a capital intensive industry, requiring millions of dollars for regulatory approval, clinical trials, research. Investors are more likely to invest in biotech companies that have been successful in getting patents on their inventions because patents provide some security and promise future profits.[4]

Patents allow for exclusivity, yet encourage collaboration in the biotechnology field. Patents provide the basis for partnerships and licensing between companies, universities, and research institutions, as they exactly define who owns rights to what ideas.

The patent system helps a lot in the transition of technology from academia to industry. Many of the great biotechnological breakthroughs are produced in government funded research labs. This association can then in turn sells or lease their technology to private business that can then commercialize it once it is patented. This process ensures that the research makes the leap from the lab into real world applications that benefit society as a whole.

Economic expansion is heavily driven by biotechnology (at least in such areas as environmental management, agriculture, and healthcare) in the sense that patents allow for the sale of new products and processes that increase output and efficiency. Patented genetically modified crops have the potential to boost agriculture output and decrease the need for pesticides, which is

[4] John Butcher, 'The Importance of Patents in Biotechnology' (UK Human Rights Blog, 21 February 2020) https://ukhumanrightsblog.com/2020/02/21/the-importance-of-patents-in-biotechnology-john-butcher accessed 8 September 2024.

advantageous for both framers and the economy.[5] In a similar vein, patented biopharmaceuticals provide fresh approaches to treating illnesses and generate major business growth in the medical field.

Global patent systems and biotech industry

As the biotechnology industry has expanded on a global scale, it has become imperative to develop powerful international patent regimes to protect biotechnological innovations worldwide. With the growth of biotechnology, genetically modified organisms (GMOs), drugs and bioengineering processes being sold on a global market, companies must also cope with a complicated and diverse patent terrain. The global biotech patent system has been significantly shaped by international agreements such as the TRIPS agreement, the patent cooperation treaty (PCT) of the world intellectual property organization (WIPO) and attempts to harmonize patent laws.

- The role of TRIPS agreement

  One of the biggest strides in the harmonization of international intellectual property laws was made in 1994 with the creation of the TRIPS agreement through the world trade organization. TRIPS sets up a minimum level of protection and enforcement of intellectual property rights, including patents, for all WTO member countries. This was particularly significant in the area of biotechnology because it created a more solid and consistent foundation for the intellectual property protection of biotechnological inventions worldwide. The TRIPS requires all member countries to provide patent protection on "inventions, whether products or processes, in all fields of technology"(article 27)[6] which includes biotechnology. The agreement also stipulates that patents must be available and patent rights enjoyed without discrimination as to the field of technology, so as to ensure that biotechnological discoveries are protected to the same degree as other inventions.

  However, trips does allow member countries to include exemptions in their patentability provisions, such as those related to inventions contrary to morality or public order, or those related to surgical, therapeutic, and diagnostic methods. And the national courts have

[5] Elisa Mutia Buctuanon, 'Globalization of biotechnology: The agglomeration of dispersed knowledge and information and its implications for the political economy of technology in developing countries' (2001) *New Genetics and Society*.
[6] Agreement on Trade-Related Aspects of Intellectual Property Rights (adopted 15 April 1994, entered into force 1 January 1995), art 27.

interpreted these regulations, especially in light of recent biotechnological breakthroughs. Such as the Indian Supreme Court denying a patent in the Novartis A. G. vs. Union of India case.[7] The court used India's patent law section 3(d)[8] which says that no patent shall be granted for pharmaceutical substances unless the new form shows increased efficiency. This choice also illustrated the amount of flexibility that TRIPS allows countries in implementing their own safeguards for public health.

TRIPS ensure that biotech corporations have multijurisdictional protection of patented biotechnological inventions, be they genetically modified plants or biopharmaceuticals. This has lead to the expansion of R&D facilities abroad, as well as the marketing of biotech products in numerous foreign markets, and the rise in research collaborations across borders. However, TRIPS has also been condemned for impeding accessibility in developing countries, particularly with regard to essential drugs. Things like compulsory licensing which allows governments to authorize the production of patented drugs without the consent of the patent owner in times of national emergency. The landmark case Bayer Corporation v. Union of India[9] where India granted a compulsory license for Bayer's cancer drug Nexavar, illustrates the delicate balance between patent rights and access to life-saving biotechnological products under the TRIPS framework.

- WIPO's Patent Cooperation Treaty (PCT) and Global Biotech Patents

  Patent Cooperation Treaty (PCT)[10] is another important international tool that facilitate biotech patents easy to be protected internationally under the management of the World Intellectual Property Organization (WIPO). By the aid of the PCT, inventors can file one international application and it will be transmitted to several countries of their choice not on the list of review. This has provided convenience to the biotech business entities that wish to seek protection of their ideas in several jurisdictions through patents. Through the use of PCT, biotech firms avoid the nuisance, time, money and managerial fatigue of having to make individual application for patents in every country across the globe. Thus, for a world connected field like biotechnology, the PCT or Patent Co- operation Treaty

[7] Civil Appeal No. 2706-2716, Supreme Court of India
[8] The Patents Act 1970, s 3(d) (India).
[9] *Special Leave to Appeal (C) NO(S). 30145/2014*
[10] Patent Cooperation Treaty (adopted 19 June 1970, entered into force 24 January 1978)

procedure offers a system for the filing of an application for a patent and attaining patent protection in numerous countries simultaneously. More than 150 countries have joined PCT by 2023 and thus, it remains an important part of international applications for patents. Because the PCT reduces time for filing patents internationally, saves on duplicated efforts, and enables businesses to assess the likely market return on their inventions before they go through the expensive process of registering their ideas in numerous international locations, the PCT has been very influential towards promotion of innovations in the biotech field. Its application can also be evidenced in case law like Canada Commissioner of Patents v. Harvard College (2002)[11] where the body discussed importance of international patents in the field of biotechnology. This case will explain how different national laws applicable to patents work. The Canadian Supreme Court turned down patent for Harvard Oncomouse which is a genetically modified mouse conventionally used in cancer research. These variances are however dealt with by the PCT that offer a procedural format that is standard in helping in dealing with the different issues.

- Harmonization of Patent Laws across Jurisdictions

  Globalization has boosted efforts to synch the regulations of patents across nations hence narrowing the gap on the award and enforcement of patents across the world. This harmonization was improved with the use of the TRIPS Agreement since it was laid down the universal standards of patent protection. Regional conventions such as ARIPO[12] and EPC[13] have however helped to increase more standardized patent laws as well.

  Since harmonization decreases legal concern, it is very central for the biotech segment. Some of the real medicines which are often sold cross-border are gene treatments and genetically modified crops respectively; therefore it is important for companies to seek patent rights in various countries. The harmonization initiatives that have aligned the patent rules may now be making it easier for the biotech businesses to operate in the foreign markets due to ease in the cross-border filing ad enforcing of patents.

[11] 4 SCR 45, 2002 SCC 76 (Supreme Court of Canada).
[12] African Regional Intellectual Property Organization
[13] European Patent Convention

However, there are still significant variations between country patent systems, especially when it comes to the patentability of biotechnological materials. For example, the European Patent Office (EPO) permits the patenting of genetically modified plants and animals in Europe, however various European nations have put particular ethical limitations on these patents. The European Court of Justice's 2011 decision in the case of Brüstle v. Greenpeace[14], which concerned the patentability of human embryonic stem cells, serves as an example of the continuous moral and legal discussions that influence biotech patents worldwide.

- Patent Prosecution and Filing Strategies for Biotech Companies

  The process of getting a patent, from the time the application is first filed until it is eventually granted, is known as patent prosecution. To expedite their submissions and optimize protection, biotech businesses frequently combine regional and worldwide patent regimes, such as the PCT and EPC. For instance, a business creating novel gene treatment may first submit a patent application through the PCT, reserving the option to submit applications in other nations while determining the invention's prospective market. The business can seek national phase entrance in important markets including the US, Europe, Japan, and China following the PCT application.

  Another important factor for biotech companies to think about is cross-border patent enforcement. Legal battles over patent infringement may be expensive and time-consuming, especially when taking place in nations with different legal systems. Biotech firms need to be ready to fight for their patents in several courts, sometimes in concurrent cases. A noteworthy example of the global character of patent enforcement in the biotech sector is the 2019 case of Amgen Inc. v. Sanofi,[15] which featured a patent dispute over cholesterol-lowering medications and was contested in numerous jurisdictions, including the U.S. and Europe.

[14] (Case C-34/10) [2011] ECR I-9821 (CJEU).
[15] (2019) 872 F.3d 1367 (Fed. Cir.), cert. granted, 139 S. Ct. 787 (2019).

Globalization and Patent Enforcement Challenges in Biotech

The biotechnology industry's globalization has resulted in notable obstacles as well as possibilities for the protection of intellectual rights. As a knowledge-intensive sector that frequently produces expensive, ground breaking breakthroughs, biotechnology mostly depends on intellectual property (IP) protection to sustain investment and innovation. However, there are significant obstacles to patent enforcement because to the international nature of biotech supply chains and disparities in country patent laws.

- Jurisdictional Issues in Enforcing Biotech Patents

  One of the issues surrounding patent enforcement in the biotech sector therefore arises from the fact that patents are territorial in nature a classification that requires the patent to be enforced under the laws of the country in which it was granted. Hence, in globalization, biotech discoveries may incorporate several nations in issues to production and distribution, research, among others. Therefore, there are several challenges in enforcing the biotech patents in the several region of the world.

  For example, there could be a vast disparity in the legal provisions concerning the patentability standards and the protection of biotechnology innovations in the United States, the European countries, and the developing world; this is a problem that hampers the attempts of biotechnology firms at protecting their innovations' benefits online. Biotechnology product which includes genetically modified organisms (GMOs) and processes are covered by U. S. patent statutes. Nevertheless, the stringent regulation on the patent of the pharmaceutical and living things has the potential to create patent issues in countries such as Brazil and India. Various challenges that arise when implementing jurisdictional patent laws were revealed by the 1984 court case between Roche Products where Bolar Pharma used the patented medicinal material in research before the patent's expiration. Although the Bolar exception for research was perhaps settled by the U. S law in the end, other nations are possibly without equivalent protection which is likely to lead to complicated legal procedures.

- Patent Infringement and Global Supply Chains

  Globalization has impacted upon the supply chains of biotechnology because nowadays the firms buy the materials, conduct experiments, and fabricate products in various countries. Since goods or components produced in one country are bought in another, there is the likelihood that intellectual rights have been infringed hence increasing the hazard of patent infringement due to the fragmented manufacturing processes.

  One of the leading challenges is having to determine in which nation a lawsuit is to be filed whenever patent violation occurs in one country but the final product is being used or commercialized in another. For instance, in Life Technologies Corp. v. Promega Corp. (2017)[16] the U. S. Supreme Court determined that a single component of a patented invention manufactured in one country and then imported into another is not unlawful under the laws of the United States. This decision also showed that because supply chains cross international borders enforcing patents on biotechnology products becomes almost impossible because components manufactured in one country may not be protected by patents in other countries.

  Furthermore, as demonstrated by the 2013 case Bowman v. Monsanto Co[17]., the international character of biotech production can give rise to complicated problems with parallel imports and exhaustion of rights, in which goods that are lawfully sold in one nation are imported into another without the patent holder's permission. This case illustrated the difficulties in enforcing laws resulting from the international trade in biotech products. The lawsuit concerned the worldwide usage of genetically modified seeds that Monsanto had patented.

  Enforcement efforts may also be hampered by different national standards for patent infringement and damages judgments. Pfizer had major obstacles while trying to enforce its Viagra patent in China, as the case Pfizer v. China Patent Review Board (2011)[18] illustrates. Pfizer had successfully patented the medication in a number of nations, but the Chinese Patent Review Board invalidated the company's patent, underscoring the challenges associated with enforcing biotech patents in nations with underdeveloped

[16] 580 US 140 (2017).
[17] 569 US 278 (2013)
[18] (2011), Beijing Higher People's Court, China.

intellectual property laws. This instance emphasizes how important it is to standardize patent requirements between legal systems to guarantee uniform enforcement.

- Compulsory Licensing in Developing Countries

  As such, compulsory licensing is the process whereby a government allows the manufacture of a copyrighted product-usually some sort of drug-without first attaining permission from the patent holder, generally for use that benefits the greater good when it comes to public health. Globalization has had an effect on this in terms of how compulsory licensing is used in the biotechnology industry, mainly in those developing countries around the world where access to cheaper yet life-saving drugs is important.

  Under the WTO, the TRIPS Agreement allows its member countries, under specific conditions such as a national emergency or any other circumstances that could pose urgency, including public health emergencies, to grant compulsory licenses (Article 31)[19]. This provision has been highly applicable within the context of patents related to medicines in the biotech and pharmaceutical industries, where the costs of those medicines upon being patented are exorbitantly high for those countries. One such decision that Bayer Corporation v Natco Pharma[20] has elicited deep interest is that the Indian government has issued a compulsory license for Bayer's patent of Nexavar cancer drug and thereby allowed generic manufacturer Natco to produce the drug inexpensively. The case clearly explains the divergence of interest between holders of patent rights and public health, especially in countries that are less developed.

  Whereas compulsory licensing can be used to tackle public health crises, there are obstacles for biotech organizations because this can obscure their opportunities to get an adequate return on the high costs from developing new medications. Further, compulsory licensing tends to create reluctance in investing in some markets since there may be high probability of losing the patents.

[19] Agreement on Trade-Related Aspects of Intellectual Property Rights (adopted 15 April 1994, entered into force 1 January 1995) art 31.
[20] *Special Leave to Appeal (C) NO(S). 30145/2014*

- Cross-Border Biotech Patent Litigation

  Because the biotech business is cross-border, it often leads to cross-border litigation where issues of the same or similar biotech patent rights are concurrently litigated in many jurisdictions. Such situations are highly complex, considering that different countries have different patent laws, methods of enforcement, and judiciary systems. Biotech businesses have to invest significant resources and practice scrupulous strategic planning if they will successfully navigate these disputes on a global level.

  The contradiction in the decisions given by a number of jurisdictions is what creates problems when it comes to cross-border biotech patent litigation that companies may face. For instance, a certain patent can be invalidated in one country yet declared valid in another. This would mean inconsistent legal consequences. This has explicitly been stated in the landmark judgment on the theory of equivalence given by the UK Supreme Court in the 2017 case of Eli Lilly and Company v. Actavis UK Limited.[21] The court ruled that because Actavis had developed a product different from Eli Lilly's patented chemical, it infringed Lilly's patent on a cancer therapy. The decision extended the UK's patent protection regime but left unanswered how such cases would be treated elsewhere, such as in the US or the EU.

  Another issue with cross-border litigation involves forum shopping, a process in which parties try to file lawsuits in jurisdictions that prove to be more favorable to their case. Within the biotech industry, this is extremely prevalent, as defendants will often seek to litigate within countries with fewer protections in place, where patent holders will try to file for motions of infringement in countries that have much stronger IP enforcement mechanisms, such as the United States or Germany. This complexity was perhaps best dramatized in the case of Genentech Inc. v. Hoechst GmbH[22] in 1998, which saw simultaneous litigation over a patent issue related to recombinant DNA technology in both U.S. and European courts.

[21] UKSC 48, [2017] RPC 21.
[22] [1998] EWHC 241 (Pat), [1999] RPC 147 (UK High Court)

Challenges of Globalization in Indian Biotech Patent Filings: Legal Hurdles and Case Law"

India's biotechnology patent applications face a number of particular obstacles as a result of globalization, mostly because of the nation's own legal system and socioeconomic factors. The definition of what, under Indian law, qualifies as patentable subject matter is one of the main points of contention. The Indian Patents Act, 1970, specifically bans discoveries pertaining to plants, animals, and biological processes that are deemed to be against public order or morals, as stated in Section 3(b). The patenting of biotech items is made unclear by this clause, especially when it comes to genetically modified organisms (GMOs) and medications.

This problem was brought to light in the Novartis AG v. Union of India (2013)[23] case, in which the Indian Supreme Court denied Novartis's request for a patent on the cancer medication Glivec on the grounds that the invention did not satisfy the requirements for innovation under Section 3(d) of the Act. In contrast to more permissive international norms, biotech companies now find it more challenging to get patent protection in India as a result of this verdict, which aims to prevent the "evergreening" of patents.

Another major issue that globalization brings the Indian biotech industry is India's policy on compulsory licensing. Although, this is partly corresponding to global trends set by the TRIPS Agreement, where emphasis has been made on public health, India's more focused use of compulsory licenses in biotech related patents have been particularly visible especially within the pharmaceutical sector. The Bayer v. Natco (2013)[24] was the first compulsory licence granted in India for the cancer chemotherapy drug Nexavar in order to make available affordable generics. These are measures that have erected a peg to the wheel of any multinational biotech company that wants to seek patent protection in India for their new products since they stand high risks of forfeiting patent exclusivity in the name of putting public interest first. In particular, compulsory licensing poses a problem for international biotechnology companies when the formulated strategic management plans take into account the tremendous market opportunities in the country, as well as the dilemmas of preserving and safeguarding accession agreements on the one hand and public health rights on the other.

[23] Civil Appeal No. 2706-2716, Supreme Court of India
[24] *Special Leave to Appeal (C) NO(S). 30145/2014*

Conclusion

The emergence of the globalization factor has had profound impact on the current biotechnology industry enabling international relations, competitions, and the expansion of the biotechnological products and services market all over the globe. But it has also created a new set of issues especially in the area of patents, and more specifically patents protection. One of the main challenges that biotech companies experience when operating on an international level has to do with jurisdiction, second, the issue of consistency of patent laws, and, third, the problem of enforcing patents and other protections of intellectual property internationally. These challenges are keener in the biotechnology industry because of the nature of the products that emanate from biotechnological inventions; most of which are border line between patentable and unpatented inventions.