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CHALLENGES IN BIOTECHNOLOGICAL PRODUCT INNOVATIONS PATENT: A REVIEW

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Manuscript Info

Abstract

This article evaluates patent protection as an incentive mechanism for biotechnology innovation in India, Since the 1970s much attention has been paid to the patentability of biotechnology. Most of the attention has focused on genetically modified organisms, whole and partial deoxyribonucleic acid (DNA) and other products derived from living systems using recombinant DNA and associated techniques ("modern biotechnology") The biotechnology revolution has just begun to touch lives in the developing world. India is one that has immense potential to utilize biotechnology amongst developing countries, to its advantage to solve some of its most intractable problems of productivity, health and environment. Recent amendments and enhancements to patent laws in India, a new acceptance of biotechnology patents in recent trends. Patents that have significant impact and it analyses the international patenting trends, and countries active in patenting their inventions. It also examines Indian patenting activity and its comparison with international trends to assess the Indian efforts. However, the Trade Related aspects of Intellectual Property Rights (TRIPS) Agreement, to which India is a party as a member of the World Trade Organization (WTO), requires some level of protection of in pertaining to biotechnological inventions, which include groups of plant varieties. India must implement most of its TRIPS obligations by end of 1999 and is currently in the process of drafting revised legislation. Data exclusivity allows protection of the innovative products for limited market exclusivity compensates biotech companies' investments in research and development.

Introduction:-

The biotech policy of India is continuously evolving but its basic concepts have been settled for creating a vibrant industry. The Indian biotechnology industry was slow to start but gained momentum and is now booming following

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the software sector. The current share in the global market in the global market is just 1.1%, but the Indian industry has the necessary ingredients to become a prominent player in the global biotech market.1 India's biotech sector is today among the top five in the Asia pacific region. India shows immense potential not only as a destination for new generation pharmaceuticals, biotech products and diagnostics but is also becoming an important hub for outsourcing of clinical traits and contract research. Over the past two decades, the Indian biotech sector has witnessed a number of scattered and sporadic initiatives on the academic and industrial front. Though India is yet to introduce a novel biotechnology product, it has strong science support and the potential to generate revenue of $5 billion and a million jobs by 2020. The ownership of IPRs in agri-biotech is now an issue in the development of products and the transfer of the technology to developing countries. Scientists now need to consider IPRs as an important factor in their research, especially where the aim is product development.[1]

One of the main features of modern agricultural biotechnology (agri-biotech) is its increasing proprietary nature. Unlike the agricultural sciences of the past, which came out of publicly funded labs, new biotechnologies are protected by patents and other intellectual property rights (IPRs).[2] Since the early 1990s, most major research organizations, whether public or private, are actively considering and/or implementing IPR policies.[3] Intellectual property represents products of the mind or intellect. They are ideas that, when converted to tangible forms, can be protected. Examples of intellectual properties include inventions, computer software, publications, videotapes, music, and plant varieties. The return on his effort by acquiring IPRs. They allow the inventor to restrict the use of the intellectual property, i.e., no one is allowed to use, manufacture, grow, sell or offer to sell the invention without permission. Several forms of this protection exist and they include copyright, trade secret, trademarks, plant breeder's rights, and patents.[4]

Role of Government in Biotechnology Sector

The national science and technology policy of the government and the Vision Statement on Biotechnology has been issued by the Department of Biotechnology (DBT) to provide a framework and give strategic direction to different sectors to accelerate the pace of development of biotechnology in India. This policy further aims to chalk out the path of progress in sectors such as agriculture and food biotechnology, industrial biotechnology, therapeutic and medical biotechnology, regenerative and genomic medicine, diagnostic biotechnology, bio-engineering, nanotechnology, bio-informatics and ITenabled biotechnology, clinical biotechnology, environment and intellectual property and patent law.[5]

Patenting Biotechnology Inventions in India

The Indian Patent Office considers biotechnological inventions to be related to living entities of natural origin, such as animals, human beings including parts thereof, living entities of artificial origin, such as micro-organisms, vaccines, transgenic animals and plants, biological materials such as DNA, plasmids, genes, vector, tissues, cells, replicons, processes relating to living entities, processes relating to biological material, methods of treatment of human or animal body, biological processes or essentially biological processes. The following biotechnological inventions are not considered as patentable under Section 3 of the Indian Patent (Amendment) Act 2005. [6]Living entities of natural origin such as animals, plants, in whole or any parts thereof, plant varieties, seeds, species, genes and micro-organisms.Any process of manufacture or production relating to such living entities. Any method of treatment such as medicinal, surgical, curative, prophylactic diagnostic and therapeutic, of human beings or animals

[1] T. Ramakrishna, Innovation, Invention in Biotechnology and IntellectualPropertyRights Law: Can India Catch The Bus (3rd Edition, 2008)

[2] Sachin Chaturvedi, Dynaimcs of BiotechnologyResearch and Industry in India: Statistics, perspectives and Key Policy Issues, 35-62 (Organisation for EconomicCooperation and Development, 2006)

[3] Ashok K.Chauhan, A Textbook of Molecular Biotechnology (I.K. International Pvt. Ltd. 2009) .

[4] Janice M. Mueller, Biotechnology Patenting in India: Will Bio-Generics Lead a 'Sunrise Industry' to BioInnovation (No. 2, 2008 ed. University of Missouri-Kansas City Law Review 2008)

[5] HS Chawla, Patenting of BiologicalMaterial and Biotechnology, 44-51 (Journal of IntellectualPropertyRights 2005)

[6] Biotechnological Innovations Patent: A Review 131-135 (2nd Edition, ISSN 0976-044X RishabhaMalviya 2010)

7.Jayshree Watal, Indian patent Law on Biotechnological Inventions, 79-83 (4th ed. Asia Pacific Biotech 200

or other treatments of similar nature . Any living entity of artificial origin such as transgenic animals and plants, or any part thereof.Biological materials such as organs, tissues, cells, viruses and all the process of preparing them.Essentially biological processes for the production of plants and animals such as method of crossing or breeding.

Medical Biotechnology

In India, the pharma industry is one of the first to reap the benefits of biotechnology. Human health biotechnology products account for about 60% of the domestic market, while biodrugs, vaccines and diagnostics have significant market shares as well. Consequently, Indian pharma is beginning to harvest the benefits from enhanced IP protection of their products. An example is Ranbaxy's NDDS for Ciprofloxacin licensed to Bayer for $65 million plus royalties. Other Indian research based companies have earned about $70 million from R&D milestone payments Promoting Transfer of Agri-Biotech to Developing Countries. Developing countries frequently lack the required IP management capacity and resources to perform product clearance analyses and evaluations that facilitate the legitimate import, use and/or export of technologically advanced products. Thus, to help transfer of appropriate agri-biotech to developing countries, capacity building in IPR management is of vital importance from both the donor and the recipient side.8 This can involve the following: A patent is an exclusive right given to an inventor to exclude all others from making, using, selling or offering to sell the invention in the country that granted the patent right, and importing it into that country. In agricultural biotechnology, patents may cover, for example, plant transformation methods, vectors, genes, etc. and in countries that allow patenting of higher life forms, transgenic plants or animals.

Biotechnology Companies in India

India is home to over 300 biotech companies with a total bioscience investment of more than $500 million. Though this is a small share of the global biotech market, the promise of the growth of the industry in India is significant. It is estimated that the domestic market for biotech products will grow tremendously and India may claim 8% of the world's biotechnology companies by 2010. The major players in the Indian Industry include: Biocon, Serum Institute of India, Panacea Biotech, Nicholas Piramal, GlaxoSmithKline, Abbott, Ranbaxy etc. The active role of Indian biotech companies has become visible through various efforts and final revenue generated by them. ABLE, the association of Biotechnology Led Enterprises, for example, is a forum of leading Indian biotechnology companies to generate a symbiotic interface between the industry, the government, academic and research bodies, and domestic and international investors. India has sailed through the journey from a state of a total lack of IP awareness to the present state of proactive pursuit of IP in frontier areas of technology. Having unleashed India's IT potential in the recent past, the time has now come to harness the tremendous strengths and energies of the countries in the Biotechnology Sector. According to a broad concept of case law which includes the decisions of patent offices, in that – especially in the biotechnology field – they are the creators of law.Concerning the relevance of the analysis of the different "formants" of legal rules.[7]

In particular, the UNESCO "Universal Declaration on the Human Genome and Human Rights" of 1997 prohibited profiting from the human genome in its natural state, the "European Patent Convention" of 1973 stated that biological materials and processes may be patented if they are the result of an inventive step, and directive no. 98/44/EC provided that natural plant varieties, animals and processes may not be patented, while biological material which has been isolated from nature and purified may be .

Contrarily, in Europe "it has generally been the case that if the methods used to isolate a DNA sequence are routine and the starting materials are available, there will be no inventive step"[8] Patent protection for biotechnological inventions, as known, is justified in order to guarantee adequate incentive and return on the huge investments which are necessary to do research in the field. For an overview of the economic studies in this regard, and the related acknowledgment of the patent's incentive function, at least in the biotechnological, pharmaceutical and chemical sectors (as characterized by high risk research projects).[9] In fact, the subject matter protected by patents is basically

[7] R. Sacco, "Legal Formants: A DynamicApproach to Comparative Law (I-II)", 39 American Journal of Comparative Law 1 et seq. and 343 et seq. (1991)

[8] S.A. Jameson, "A Comparison of the Patentability and Patent Scope of Biotechnological Inventions in the United States and European Union", 35 AIPLA Quarterly Journal 193 et seq.,at 222 et seq. (2007).

[9] B. Hall & D. Harhoff, "RecentResearch on the Economics of Patents", 4 AnnualReview of Economics 541 et seq. (2012).

information, as such not rivaled or easy to copy: so, without a system of protection which enables innovators to charge a price for innovative products above the marginal cost, they would not be effectively motivated to either bear the research and development expenses and to innovate or disclose innovation, to the detriment of the public welfare. However, as known, patent protection also gives rise to relevant social costs, which are due basically to:

1. The static welfare losses due to the above mentioned mark up on the marginal cost of producing the result of the invention;
2. The possible waste of resources originating from the patent race and related litigation;
3. The increased cost of secondary innovation, that is especially relevant in the biotechnology framework, where innovative activity is to a large extent a cumulative process, with present innovations which are mostly incremental, depending on past innovations. [10]

In re Kubin[11], must be held to be excluded wherever there is a wide knowledge about the protein a target gene encodes plus general knowledge of the techniques for isolating and sequencing the same gene. The requirement of industriality needs the identification of specific methods of use for the finding, and so allows the limitation of the patent exclusive only for a specific application of the invention24. Moreover, as far as the extension of patent protection for biotechnological inventions is concerned, according to the traditional approach of the American model, the distinction between patents for inventions of products and processes is still fundamental. In principle, as is well known, the patent for a product is held to provide protection for the product regardless of how it is obtained and for all its possible uses.

The concept indicates, as known, "'an overlapping set of patent rights' which require innovators to reach licensing deals for multiple patents from multiple sources", with the possible result of obstructing entry to some markets and so impeding innovation, with effects which damage not only the producers of innovation but also the licensees of inventions and the consumers of the final product, With regard to biotechnological inventions, however, under the first profile, considering their peculiarity of being living and self replicating matter, the opinion of those who state that the patent grants exclusive production rights for the finding only when it is produced through the process described in the patent application seems convincing.

Restrictive Patentability Criteria

Section 3(d) of the Indian Patents Act explicitly excludes from patentability new forms of a known substance that does not result in "enhancement of the known efficacy of that substance." This requirement, interpreted by India's Supreme Court to mean "therapeutic efficacy," excludes from patentability many significant inventions in the biopharmaceuticals area, such as new forms of known substances with improved heat stability for tropical climates, or having safety or other benefits to patients that may not result in "enhanced clinical efficacy" per se. This provision appears to be inconsistent with India's obligations pursuant to Article 27 of the TRIPS Agreement, which requires that patents be made available to "any inventions … in all fields of technology, provided that they are new, involve an inventive step, and are capable of industrial application." Further, Section 3(d) effectively creates an additional hurdle to patentability that is applied only to certain chemical products, and therefore appears to violate the non-discrimination clause with respect to field of technology set forth in TRIPS Article 27.

India is an important market to biotechnology companies and patents on key products result in sales of hundreds of millions of dollars. However, difficulty in obtaining and enforcing intellectual property rights in India remains a barrier to biotechnology companies. BIO is encouraged by the new willingness to engage all stakeholders by the new government but uncertainty remains.

Since the start of the new Indian government led by Prime Minister NarendraModi, the United States and India have re-started discussions on a variety of trade and IP fronts. Most notably, the two countries have agreed to establish a new High-Level IP Working Group that will meet at least annually. In addition, the two countries met last November 2014 under the auspices of the Trade Policy Forum and the High-Technology Cooperation Group for the first time in two years. These are important milestones and the innovative biotechnology industry will be watching closely developments in these various forums.

[10] V. Denicolò, "Do patents over-compensateinnovators?", 22 Economic Policy 679 et seq. (2007); S. Scotchmer, "Innovation and Incentives" passim (MIT Press, Cambridge - USA 2004); for an heterodox point of view, seealso M. Boldrin& D. Levine, "The case againstintellectualproperty", 92 American EconomicReview, 209 et seq. (2002)

[11] 561 F.3d 1351 (Fed. Cir. 2009).

Separately, the industry has noted some other developments in the environment for IPintensive industry. For example, the announcement that the Department of Industrial Policy & Promotion (DIPP) would not issue a compulsory license as requested by the Ministry of Health and Family Welfare, effectively raising the standards required by the Indian government before issuance of a compulsory license. In addition, DIPP commissioned a National IPR Think Tank tasked with developing a new National IPR Policy, a draft of which was released in late December 2014. In reviewing this draft, BIO has found that while the authors express the need for respecting IPR, they do not necessarily give a strong rationale for doing so, thereby missing an opportunity to impress upon the government and the public how strong and effective enforcement of IPR is beneficial to India's economic development. Finally, in regards to this draft IPR policy, the authors do not address some of the more controversial issues being debated, such as compulsory licenses. Again this is a missed opportunity to articulate the government's position on this and other critical issues. BIO looks forward to further opportunities to share our views with the Indian Government on this draft policy.

In recognition of both the improvement in the IP environment and the willingness to engage in dialogue, therefore, BIO requests that USTR designate India to the Priority Watch List with an Out of Cycle Review to monitor IP rights in India. The Indian generic industry routinely uses this opposition process to delay the grant of U.S. biotechnology patents in order to produce their own legal copies of products that otherwise should be enjoying meaningful patent protection in India as they do in other countries. Patent term extensions to compensate for such losses do not exist in India, further exacerbating the problem. Due to the broad nature of post-grant challenges, unlimited pre-grant opposition should be abolished or severely curtailed to better reflect international practice. The ability of third parties to submit references pre patent grant provides sufficient opportunity to weed out applications that do not meet novelty and inventive step requirements; and should be the preferred method of challenge pre-grant.

In May 2016, India announced a new National Intellectual Property Rights (IPR).[12] That policy document recognizes the economic and socio-cultural benefits that a strong IP regime could bring to India through economic growth, employment, and a vibrant R&D environment. BIO will welcome India's plans to implement the National IPR Policy that would improve the incentives for innovators and innovation in India through improved intellectual property protections. BIO also appreciates the opportunities it has been afforded to engage with the Government of India as it considers its innovation policy environment. BIO supports the Modi Administration's efforts to create a world-class IP environment for innovation in India, and urges India to use the new IPR Policy as a basis for taking steps that address attributes of its IPR regime that continue to hinder the IPR environment for BIO members. BIO also notes the strong and independent court system for enforcement of IP in India and the improvements that are being made in this area. While it is a valiant effort, however, the text does not address the fundamental weaknesses in India's IP framework, notably for biopharmaceuticals.

Conclusion:-

The study examined the field of biotechnology and identified some of the important areas in the context of patentability in this field. The article underscores the fact that patenting in biotechnology gives rise to complex issues as it involves patenting of living organisms, and how Indian patent provisions address the issue of patentability in this subject domain without violating the TRIPS Agreement. Finally, when and if a modern bioeconomy emerges, intellectual property will, in our view, be crucial to any strategy intended to address distributive justice concerns. Maintaining flexibilities in implementing intellectual property regimes is unlikely to prove enough, however, as developing countries often do not exercise them. We touched on some of these reasons earlier, such as the effect of the trilaterals influencing developing world patent office practice. But developing countries have also largely failed in formulating internal intellectual property policies that take into account their local needs. They do this, paradoxically, at the same time that they call for greater flexibilities and recognition of their needs at the international level. Just as OECD countries and the pharmaceutical industry are beginning to entertain discussions about how to better align intellectual property with development, developing countries must also ensure to reconcile local practice and policy with calls for reform on the international stage.

[12]Department of Industrial Policy and Promotion, "National IntellectualPropertyRights Policy," May 12, 2016, availableat http://dipp.gov.in/English/Schemes/Intellectual_Property_Rights/National_IPR_Policy_08.08.2016.pdf (last visited Sep. 26, 2019).