

## **RECENT CONTROVERSIAL ISSUES RELATED TO PATENTS**

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### **ABSTRACT**

In the following research paper, the author has dealt with recent controversial issues related to the patents. Focusing on the several aspects of issues the author has mainly focused on following topics such as genetic resources and benefit sharing, the issues involved with biotechnology, R&D and innovations as well as innovations made in outer space. Focusing individually the author has also cited examples on several issues.

### **INTRODUCTION**

In the recent years, the patent system has been used at much higher levels beyond what could have been imagined only a decade back. Numbers of patent applications have never been higher and there are a number of examples that patents have helped support the development of an ever-increasing range of technology. Yet this success has not given rise to universal satisfaction, either within the immediate circle of administrators and users of the patent system, or among the intended beneficiaries of the system more widely in society. The system today faces two main challenges: an internal challenge, concerning the actual operation of the system; and an external challenge, concerning the policy role, and the economic and social impact of the patent system.

Secondly, broader level of public debate, general apprehensions of patents are marked is marked with unease. Recently this enormous issue has come into the spotlight. This increased prominence has not been resulted from the various usage of technology but from the perceived negative effects of the system, including the controversy over the possibility that patents may be hampering governments' ability to deal with policy issues, concerns about the granting of patent protection to some forms of new technology, such as biotechnology, and about the granting of invalid patents, which may unfairly limit both the public domain and competition.<sup>1</sup>

The history of Patent law in India starts from 1911 when the Indian Patents and Designs Act, 1911 was enacted. The present Patents Act, 1970 came into force in the year 1972, amending

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<sup>1</sup> <http://www.wipo.int/tk/en/>

and consolidating the existing law relating to Patents in India. The Patents Act, 1970 was again amended by the Patents (Amendment) Act, 2005, wherein product patent was extended to all fields of technology including food, drugs, chemicals and microorganisms. After the amendment, the provisions relating to Exclusive Marketing Rights (EMRs) have been repealed, and a provision for enabling grant of compulsory license has been introduced. The provisions relating to pre-grant and post-grant opposition have been also introduced.

An invention relating to a product or a process that is new, involving inventive step and capable of industrial application can be patented in India. However, it must not fall into the category of inventions that are non-patentable as provided under Section 3 and 4 of the (Indian) Patents Act, 1970. In India, a patent application can be filed, either alone or jointly, by true and first inventor or his assignee

### **ACCESS TO GENETIC RESOURCES AND BENEFIT SHARING**

GR's as encountered in nature are not creations of human mind and thus they cannot be protected directly as intellectual property. Invention or plant varieties based on or developed using GR's may be patentable or protected by plant breeder's right.

Traditionally patents do not cover natural products. Overtime the scope of exception relating to nature has been greatly reduced but international intellectual property rights treaties have never yet gone so far as imposing patent protection for plant varieties. An alternative form has been developed progressively. Various factors have contributed to difficulties to protection to plant protection. One of these is that the notion of inventiveness, which characterized patents, will be diluted if plant varieties were brought on board, because a new plant variety was seen as more as an improvement of existing natural product rather than a scientific invention (Rangnekar, 2000). Further seeds have been always deemed to be a part of common heritage of human kind and were freely exchanged among farmers and farming communities (Shiva, 1994). Plant varieties can be only protected by such rights if they fulfill the four basic criteria's novelty, distinctiveness, stability and uniformity. Breeders have exclusive right to produce or reproduce protected varieties, to condition them for the purpose of propagation, to offer them for sale, to commercialize them, including exporting or

importing them, or to stock them in view of commercialization. It does not extend to acts done privately and for non-commercial use.<sup>2</sup>

The African model of legislation is promised on the rejection of patents on life or the exclusive appropriation of any life form, including derivatives. In this legislation the rights of author are slightly more defined. The protection extends to traditional knowledge that is relevant to plant and animal genetic resources. The turmeric patent is one of the noteworthy examples.

### **BIOTECHNOLOGY**

Biotechnology generally concerns the application of cellular and molecular biology to make or modify products or processes. It includes scientific and industrial disciplines focused on understanding and manipulating living or biologically-active material at the molecular level, often involving DNA techniques and the analysis of genetic information. Modern biotechnology is expected to lead to important breakthroughs in many fields, such as health, food, energy, and the environment.

While the patentability criteria prescribed in patent laws apply to inventions in all fields of technology in the same manner, the application of patent law to biotechnological inventions has to deal with a number of particularities that may not exist in the same way in other areas of technology. One set of issues relates to the scope and legal standards of patent protection. While in principle, in accordance with the Agreement on the Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), patents are available for any invention in any and all fields of technology, the issue of the patentability of biological materials, isolated or derived from naturally occurring living organisms, has triggered widespread discussions. Some argue that such biological materials are mere “discoveries”, and therefore not patentable, while others argue that they are manmade “inventions”. With respect to industrial applicability (usefulness) and sufficiency of disclosure, the exclusive patent rights may be granted only where an appropriate level of concrete and practical use of the biotechnological invention is disclosed in the patent application. The debate addresses the importance of ensuring that claims are not broader than is justified by the invention disclosed in the patent application, in particular, where it is an early and fundamental stage of innovation or a new gene with its future application still not determined. The application of the patentability

<sup>2</sup> S. Biber klemm & T cottier eds. , Rights to genetic resources and and Traditional Knowledge : Basic Issues and Perspectives ( Wallingford: CABI, 2006) p.112-154

criteria has further implications on licensing and other issues related to the exploitation of patents. In this context, exceptions and limitations to patent rights, in particular, research and experimental use exception has been considered important for down-stream innovation.

In addition, a number of typical issues relating to biotechnological inventions result from the fact that biological material is capable of reproducing itself. This specific characteristic requires determination of law as to, for example: (i) the scope of legal protection of future generations; (ii) exhaustion regimes; (iii) special rules, if any, for plant and animal breeders or farmers. Further, the development of genetic engineering resulted in the possibility of overlap between plant variety and patent protection even in countries where patent protection for plant varieties is excluded. While each of these systems provides a scope of protection and rights as well as limitations that are distinct from each other, the interplay between the two systems is under scrutiny. Other relevant issues, such as the conservation of biodiversity and ethical dimensions of the protection and commercialization of biotechnological inventions, have been discussed in many for a, for example, the World Trade Organization (WTO), the Convention on Biological Diversity (CBD), and the Food and Agriculture Organization (FAO). As to biodiversity, reference is made to the issue of genetic resources, including “disclosure requirements” and prior art databases.

One of the prime issues is of the ethical issues that relates to rights conferred by the sovereign states to owners. In the context of biological inventions, the situation has become more complex especially for the developing countries after Chakrabarty was allowed a patent on his invention of modified pseudomonas that had an additional plasmid incorporated by , by which organism has the ability to produce huge amount to hydrocarbons.<sup>3</sup>

### **INVENTIONS MADE IN OUTER SPACE:**

Despite the fact that space technology has long been one of the most advanced technical areas in the world, and outer space activities are, in fact, the fruit of intellectual creations, it is only in recent years that intellectual property issues have begun to be raised in connection with extraterrestrial activities. Some of the reasons for this are that space activities are increasingly shifting from being state-owned activities to becoming private and commercial activities. Further, an increasing number of space activities are operated under international cooperation schemes, which depend on a simple, uniform and reliable international legal framework.

<sup>3</sup> US Pat 4,259,444( to Chakrabarty AM) 31<sup>st</sup> March 1981

As regards inventions made and/or used in outer space, one of the issues frequently raised is the applicability of national/regional patent law in outer space. While patent protection is subject to the applicable territorial legal framework, according to international space law, the state in which the space object is registered retains jurisdiction and control over that space object. The question arises as to whether the territorial jurisdiction under intellectual property law permits the extension of each national (or regional) law to the objects which the respective country has registered and launched into outer space. In the absence of explicit international rules, under a number of international agreements concluded with respect to international space projects, registered space objects are treated as quasi-territory for the purposes of intellectual property.

As prescribed in Articles I and II of the Treaty on Principles Governing the Activities of States in the Exploration and Use of Outer Space, including the Moon and Other Celestial Bodies (Outer Space Treaty), the exploration and use of outer space for the benefit of mankind and the non-appropriation of outer space by any nation are fundamental principles under international space law. While recognizing the importance of intellectual property for the exploration of outer space and the further development of science and technology, questions have been raised as to whether the protection and enforcement of intellectual property rights may conflict with the said fundamental principles in terms of access to knowledge and information derived from space activities and in terms of the freedom of exploration and use of outer space.

Another issue relates to the interpretation of Article 5ter of the Paris Convention for the Protection of Industrial Property, which provides for certain limitations of the exclusive rights conferred by a patent in the public interest in order to guarantee the freedom of transport (doctrine of temporary presence). The question is then whether the doctrine of temporary presence also applies to space objects, for example, in the case of the transport of patented articles to or from a Space Station through a launching site in a foreign country.

It is expected that technical and financial input from the private sector will become more and more important in the future development of space activities. Although a number of public policy tools can be envisaged to attract the participation of the private sector, intellectual property protection will play an important role in developing successful space business models involving public/private collaborations.

If we look into the context of India commercialization of space activities is in the process of establishing a vast space activities and a vast market where India plans to and has already begun to sell, its space products. Thus the process of Antrix corporation industry relationship, private participation in space activities both in India and in international ventures, transfer of technology and product marketing needs to be clarified. So it's the need of the hour that the India should adopt a domestic space legislation keeping in view of the dramatic changes that are taking place in domestic as well as international spheres'.<sup>4</sup>

### **PUBLIC HEALTH AND PATENTS:**

Although scientific and technological innovation has contributed to significant improvements in health conditions, health crises, relating, in particular, to HIV/AIDS, malaria, tuberculosis, and, most recently, avian influenza, continue to create major problems in many parts of the world. In various national and international forums, solutions are sought in respect of the role of patents in pharmaceutical innovation and fair and affordable access to health care.

The patent system is designed to promote innovation and, at the same time, offer a mechanism ensuring that the fruits of that innovation are accessible to society. In the contexts of public health, the challenge for policy makers is to find an optimal balance between the rights of patent owners, who provide technological innovations to improve health conditions, and the needs of the general public.

In general, the development of new drugs requires heavy investment and long-term research, coupled with expensive clinical trials and regulatory approval procedures. The exclusive right conferred by a patent is one of the incentives for developers of new drugs to make the necessary investments into that research. Clearing issues, such as ownership and licensing policies for innovation derived from public research, would contribute to the promotion of a more effective deployment of public funds and public R&D programs. At the same time, the patent system also contributes to society by making available patent information, which is freely available to other researchers to further improve existing technologies. With a view to facilitating commercialization and ensuring access to patented technologies, the patent system is primarily based on conferring an exclusive right, in conjunction with a voluntary licensing mechanism. However, taking into account the public interest and policy objectives beyond the patent system, there are a number of flexible mechanisms built in the patent

<sup>4</sup> YADAV, AYUSH, IPR and its Protection in Outer Space Activities (February 8, 2012). Available at SSRN: <https://ssrn.com/abstract=2001551> or <http://dx.doi.org/10.2139/ssrn.2001551>

system, such as the possibility of issuing compulsory licenses, research exceptions and parallel imports.

On the other hand, some consider that the current patent system does not adequately address public health crises. It is argued that the commercial incentives provided by the patent system are not sufficient to ensure the development of new products in certain areas, for example, in respect of neglected diseases, and those patent rights, which are enforced on the basis of commercial and market-based considerations, prevent access to, or increase prices of, essential medicines. Some criticize that the safeguard mechanisms built in the patent system, such as compulsory licenses or research exceptions, are not sufficiently broad to cover existing needs. Further, the number and, at times, the broad scope of patents granted in the field of early fundamental research have raised concerns about patent thickets and royalty stacking. In particular, reach-through claims in respect of research tools are considered a potential obstacle to further research and development.

Till 2005 drugs for medical purposes were not patentable in India. Therefore, it was apprehended that the switchover from the non-patent regime to the patent regime would not be a smooth one. India has high technical expertise and infrastructure to manufacture medicines. Even then, almost 60% of Indian population is not under the reach of modern medicines and depend on local treatments or herbal formulations. The low coverage of the modern medicine is mainly due to low earnings, poor accessibility of medical facilities and low awareness or education among the masses. In the last few years, the price of many of the medicines including essential antibiotics have skyrocketed due to organized efforts of the manufacturing firms and monopolistic conditions existing in the drug industry. Low profit margin on the low cost medicine for the poor has desisted many of the pharmaceutical companies from venturing into that sector. Moreover, many of the new medical researches are targeting the developed countries with promising profits for medicines for lifestyle diseases, whereas developing countries are still in need of basic health care. In these circumstances, it will not be improper to expect a price rise for many of the medicines in India. Comparing the price for same medicine among countries with and without patent regime for medicines, it was found that in some countries with patent right, the drug price was higher up to 41 times than in India prior to 2005 (with no drug patents). The policy option in this sector mainly lies in the development of low cost medicines in the country itself with an eye on bringing more and more rural poor under modern medical facilities. Similarly,

there is option for controlling the price by even provisions available in the TRIPs itself like compulsory licensing and parallel import (which requires political will).<sup>5</sup>

### **R&D INNOVATION AND PATENTS:**

One of the rationales for patents is that they stimulate economic and technological development and promote competition by creating a financial motivation for invention in return for the disclosure of the invention to the public. Although the potential of the patent system has been widely recognized in the context of dynamic innovation activities, some critics have claimed that the current patent system stymies R&D and technological advances.

In view of the rapid technological innovation and the social and economic challenges, the function, value and impact of the patent system need to be constantly adjusted and implemented so that the optimal balance between the right holder, new entrants to the market and the public at large is achieved. In order to foster R&D in new technologies, such as information and communication technologies and biotechnology, the patent system needs to be shaped so as to swiftly and strategically respond to the challenges arising from those new technologies. Further, in order to support a comprehensive and complex technological development, it is essential to strengthen public R&D activities, including those in universities, and promote better collaboration between the private and the public sectors. It is important to set up policies which provide a balance by offering both incentives to stimulate R&D and ensure a competitive environment for pioneers, for down-stream researchers and for producers at the end of the value-added chain.

One of the major functions of the patent system is the dissemination of technical information. Patent information is a valuable and comprehensive source of technical, commercial and legal information that can be used directly for scientific and experimental purposes and as a basis for stimulating the adaptation and improvement of the technology described in patent documents immediately after their publication. Recognizing the importance of the dissemination of technical information, a growing number of IP offices and organizations are using the Internet to offer access to their patent documents' databases.

If we take an example of Cameroon that is located on Africa's west coast, on the Gulf of Guinea. Its population, estimated at 15 million, comprises some 250 ethnic groups, and its mainly agricultural economy (42% of GDP), with a GDP of about USD 10.1 billion, is the

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<sup>5</sup> Pradeep Kumar and Deoaki Nandan, HPPI, Vol 32(1),2009



largest in the six nation Central African Economic and Monetary Community (CEMAC). Cash crops, such as cocoa, coffee, timber, cotton, bananas, and oil exports are the foundation of Cameroon's economy. Cameroon is a founding member of AIPO (its negotiation power could be questioned as many believe that poor countries cannot challenge the views of those providing financial support to their ill economies) and in this context, all the conventions, treaties, agreements (TRIPS) and regulations adopted by the board of directors of AIPO will enter into force in Cameroon as national laws. In order to follow up AIPO treaties and agreements, It has been created within, the Ministry in Charge of Commerce and Industrial Development an office of Intellectual property in charge of relaying the missions of AIPO on the national territory. The government, through the law of April 2002, instituting the Investment Charter of Cameroon, has reaffirmed its determination to build a competitive and prosperous economy by boosting investments and savings, and attain its economic and social objectives. The Government of Cameroon therefore opted for: The reassertion of the market economy as the ideal economic system; The commitment to safeguard the free macro-economic market. The clarification and consolidation of the role of the university and the national scientific and technical research system as a crucial factor in the transformation and mastery of the economic and social structures; The quest for an appropriate institutional and regulatory framework to guarantee the security of investments, provide support to investors, and ensure fair and prompt settlement of investment-related as well as commercial and industrial disputes; The acquisition and mastery of appropriate technologies and facilitate their dissemination. In order for this last point to be fully implemented, the Government of Cameroon will set up the following bodies: An Industrial Partnership Council; An Entrepreneurship Institute; A Trade and Industry Observatory; A Standardization and Quality Board; and An Intellectual Property Centre. This centre is aimed at resolving the shortcomings of the national office of Intellectual Property based at the Ministry in Charge of Mines, Industry and Technological Development.

### **CONCLUSION:**

Thus the patents and their usages have been dramatically increased in the recent years due to several factors in different fields whether it be genetic resources, outer space, nanotechnology or outer space etc. Various international organizations and treaties have been signed up together to create a better world for innovations and development.

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