

# DROIT PENALE: INDIAN LAW JOURNAL ON IPR

(A Unit of Droit Penale Group, Prayagraj)

ILJIPR, ISSN: 2582-8762

VOLUME 1 ISSUE 1

## PATENTING OF LIFE FORMS: A COMPARATIVE PERSPECTIVE

*Shivani Bisht, Manika Sharma & Anand Vimal  
Rajiv Gandhi School of Intellectual Property Law, IIT Kharagpur*

### **ABSTRACT**

*A patent is a kind of intellectual property that confers exclusive rights upon an individual who has designed a novel as well as helpful article or up-gradation of an already known article or a unique procedure to make an article. The patenting of life forms began as a crucial concern after 1970 when there emerged bang in biotechnology by the recombinant DNA technology evolution, culturing of tissue and many more. With the help of these machineries, it became achievable for the industries as well as an analyzer to make use of biological resources and to construct economically feasible products in the various areas of agriculture, pharmaceuticals sector, etc.*

*This research paper tries to focus attention on the concern relating to patenting of live forms while correlating the measures pursued in various countries like India, UK as well as US in the pretext of the Agreement on TRIPS.*

### **MEANING OF BIOTECHNOLOGY**

In simple terms, biotechnology can be defined as any procedure the make use of living beings or part of that being either to make or to alter the products or to expand micro-organism for particular use<sup>1</sup> or to develop animals as well as plants for the needs of human beings.

Further, biotechnology is also defined under the Convention on Biological Diversity i.e. CBD as it is any technological operation that makes use of living beings or part of living beings or biological system either to make or enlarge processes or products for a particular use. However, it is the belief of the countries that are developing that biotechnology patenting will carry away their authority over the distribution of pharma as well as agriculture products and will put it in the authority of MNCs and in this way it will have effect upon their political as well as economic supremacy<sup>2</sup>.

---

<sup>1</sup>Article 2 of Convention of Biological Diversity, 1992.

<sup>2</sup>The Patenting of life forms: Problems and Perspectives, 1994 by Dr. T.G. Ajitha.

# DROIT PENALE: INDIAN LAW JOURNAL ON IPR

(A Unit of Droit Penale Group, Prayagraj)

ILJIPR, ISSN: 2582-8762

VOLUME 1 ISSUE 1

## ISSUES INVOLVED IN PATENTING BIOTECHNOLOGY INVENTIONS

To make a new invention patentable it needs to qualify certain criteria, that is, it should be new, should involve an inventive step and must be not obvious to a person skilled in the art. In the field of law on patents, it is a known proposition that patents will not be granted to the naturally occurring subject matter mainly because there is nothing novel in that subject matter.

It is to be noted that due to many evolutions in the field of biotechnology, it is facing many crucial issues which are needed to be resolved.

### 1) Ethical and Moral Issues

Due to the granting of patents on living organisms such as mice, genes, cells of humans and many more it has given rise to various ethical issues relating to the patentability of living organisms. It was argued that granting patents to living organisms will lessen the creation of God to bare substantial objects, will also deteriorate God provided prestige of living creatures by making it their personal property. Further, the European Court took note of this ethical issue in the famous case of *Relaxin*<sup>3</sup>. In this case, the main demand was for patentability of the human gene encodes for Relaxin. It was concluded in this case that even if a single human gene is patented it has no connection with the patentability of life. Moreover, this kind of patent does not provide any privilege to any particular human. It is noteworthy that after the judgment given in the year 2004<sup>4</sup>, European Patent Office those new regulations are more than only explanatory<sup>5</sup>. But, the judgment pending in the case of stem cells<sup>6</sup> might give new supervision on the scope of new regulations<sup>7</sup> as well as Article 53(a)<sup>8</sup>.

### 2) Legal Issues

---

<sup>3</sup>1995 OJEPO 588.

<sup>4</sup>The Harvard Oncomouse case decided in 2004.

<sup>5</sup>Ella O' Sullivan, Impact of Rule 2 (d): Procedure for enlarging animal's genetic identity, Rule 23 (d) on evaluation of ordre public and morality in EPO, Article 53 (a) as well as animal's patentability.

<sup>6</sup>Stem cells/WARF (2006) EPOR 31.

<sup>7</sup>Refer to Rule23B.

<sup>8</sup>Refer to Article 53 (a).

## DROIT PENALE: INDIAN LAW JOURNAL ON IPR

(A Unit of Droit Penale Group, Prayagraj)

ILJIPR, ISSN: 2582-8762

VOLUME 1 ISSUE 1

Until the 1980s no patents were granted for living organisms merely for the reason that they were treated as only the discovery of the things which were not seen before or which were dimly seen. This proposition was mentioned in the well-known case of *Funk Brothers v/s Kalo Inoculant Company*<sup>9</sup>. The main claim in this case was for the patent of a combined culture of Rhizobia which has the capacity of inoculating plants seed. The court here remarked that one who finds or discovers a hitherto of the not known aspect of nature<sup>10</sup> does not have a claim to its monopoly. If at all there has to be an invention from that discovery it has to be evolved from the law of nature and must mature into novelty and helpfulness. Finally, in this case, it was also remarked that maybe it was the outcome of skill but definitely, it was not the outcome of the invention<sup>11</sup>.

But in 1980, the first case came in which court granted patents to the living organisms. The case was *Diamond v/s Chakrobarty*<sup>12</sup>; in this case, the Supreme Court remarked that bacteria that are genetically altered are considered to be patentable. The court made a remarkable statement that anything made by man under the sun will be a patentable subject matter. It was observed that it is the work of man which falls under section 101, 35 USC<sup>13</sup> and not the work of nature. After this case, there was a flood of cases related to patenting of living organisms.

Then in the year 1985, another case came that is *Re Hibberd*<sup>14</sup>, in this case, patentability was provided to maize plants and in this way patentability also extended to plants. Similarly, in the case of *Ex parte Allen*<sup>15</sup>, patents were granted to animals as well. In all the above cases the major criteria were to see the extent of interference of human beings while making products.

The main problem also was to make a differentiation between inventions and discoveries as there is a very thin line between the two. This difficulty arises at the time when the technique of DNA was evolved to isolate the genetics materials. Here, the court relied on the Diamond Case and also confirmed the patent to Oncomouse for learning cancer drugs. The only test was the interference of human beings and never went into the concern of *ordre public*<sup>16</sup> as well as morality.

---

<sup>9</sup>333 U.S. 127 (1948).

<sup>10</sup> The Principles of Intellectual Property, EBC Publishers, (2009) by N.S. Gopala Krishnan and T.G. Ajitha.

<sup>11</sup> Ibid at p. 127.

<sup>12</sup> 447 U.S. 303 1980.

<sup>13</sup> Refer to section 101 of U.S.C.

<sup>14</sup>227 USPQ 2d (BNA) 443.

<sup>15</sup>2 USPQ 2d (BAN) 1425.

<sup>16</sup> The Patent War: The Battle to own Technology of World, John Wiley and Sons Inc. (1994).

# DROIT PENALE: INDIAN LAW JOURNAL ON IPR

(A Unit of Droit Penale Group, Prayagraj)

ILJIPR, ISSN: 2582-8762

VOLUME 1 ISSUE 1

## 3) Issues related to Environment

There are some issues regarding coming technologies which have strong impact on biological diversity and strong danger to the health of human beings. The danger to the health of human beings is due to Genetically Modified Organisms i.e. GMOs and these GMOs had also brought irregularities especially concerning the environment. On this point, it is important to respect the Precautionary Principle. In the well-known case of Oncomouse/Harvard case<sup>17</sup>, regarding the known danger to the environment, the court contemplated the aim of the invention. As per the rulings of the court, this invention aims to furnish models for the test of animals that are to be used only in the labs by the high expertise staffs and under the known conditions. There is no intention to discharge it into the public environment. The court observed that the only proposition that such unmanageable action is protectable cannot be used for determining whether patent to be conferred on it or not. Therefore, we can say that the environment qualities are for executive or legislature to enact<sup>18</sup>. Moreover, Parliament can lay down safety, health as well as environment measures which are to be satisfied by the applicant who is willing to get GMO's patented.

## PATENTABILITY REGIME OF BIOTECH INVENTIONS IN US AND UK

The parameters and standards of novelty and non-obviousness for granting a patent for biotechnological inventions are different from other technology or pharmaceutical inventions. For the former, the difficulty lies in the distinction between discovery and invention. The subject matter for biotechnological patents is that it must be the purest and isolated form of DNA sequences.

Erythropoietin [EPO] is a glycoprotein that stimulates the growth of red blood cells in our body and was used to treat anemia. Suddenly EPO became the most valuable patent and led to a patent infringement-war in a landmark case of *Amgen v/s Chugai pharmaceuticals*<sup>19</sup>. Claim asserted by Amgen was on the purified and isolated recombinant EPO sequence while the counterclaim was concerning the DNA sequence encoding it. Amgen substantiated their claim by asserting that it was the first one to

---

<sup>17</sup>Harvard/ Onco-Mouse OJEPO (1990)476.

<sup>18</sup>Rahul, "Patenting Life forms", NUJS, Kolkata.

<sup>19</sup> 808F. Supp. 894 (D. Mass. 1992).

## DROIT PENALE: INDIAN LAW JOURNAL ON IPR

(A Unit of Droit Penale Group, Prayagraj)

ILJIPR, ISSN: 2582-8762

VOLUME 1 ISSUE 1

successfully achieve the DNA sequencing and purified EPO concurrently. However, the Japanese company, Chugai Pharmaceuticals contended that an inventive step was used in the process of isolation. The court acknowledged that the mere knowledge of how to isolate is not sufficient for novelty. It ruled that since the plaintiff was the one to isolate the gene its invention was not prior art but novel in character.

The issue of non-obviousness and inventive step is also of major concern in the biotech patenting regime. It is pertinent to mention here that the EPO was isolated in 1970; much before the patent claim of Amgen but the DNA sequencing was not known till the latter prepared it. Unconditional obviousness is not a pre-requisite for biotechnological inventions all that is required is that the entire invention including the potential and implication, should not be obvious to any person ordinarily skilled in the art to which the invention relates. The concept of inventive step in biotech inventions means the full deliberation of isolated DNA sequence encoding EPO and the screening and inquiring method employed to achieve the desired results. Hence the standards of granting patents for biotech inventions are higher as compared to the other technological inventions.

The House of Lords in *Biogen v/s Medeva*<sup>20</sup> highlighted the significance of genetic engineering patents. Biogen had a patent on the technique of producing HBV antigens based on existing research work and filled for infringement when Medeva publicize to market HBV vaccine. A new way of doing things already know can also constitute an inventive step provided the same was not in the contemplation of others. The courts in the aforementioned case held that the inventive step was merely a marketable aspiration or a chance taken by biogen which the others did not take. Biogen acted on the available research and methodology and lacked in non-obviousness, hence its patent was nullified.

On comparing the two decisions given by US and UK courts a clear distinction in patenting standards can be outlined. In both cases, the starting point of the invention was known to the world before the invention but in Amgen's case, the court acknowledged that the scrutiny process and scientific methodology adopted were non-obvious just because the results were not successfully achieved before Amgen. However, in Biogen case, the court completely discarded the existence of an inventive step holding that the entire work including the procedure used was the result of knowledge already known in

---

<sup>20</sup> (1996) UKHL 18.

# DROIT PENALE: INDIAN LAW JOURNAL ON IPR

(A Unit of Droit Penale Group, Prayagraj)

ILJIPR, ISSN: 2582-8762

VOLUME 1 ISSUE 1

the scientific community and declared it to be obvious. Hence it would be correct to imply that the UK courts adopted a stricter approach because Biogen cannot be allowed to dominate all the obvious methods to achieve desired results.

A literal interpretation of a patent document should not be adopted which is to say that a party can be held liable for infringement even when his interference is not per se part of the disclosure<sup>21</sup>. Hence the already available knowledge can form the basis of a patentable claim in an invention concerning a product or a process. This approach was further accredited by the courts in *Ancare New Zealand case*<sup>22</sup>; here ruling touched the length and breadth of obviousness and inventive step. It was held that an obvious idea or method which appears to be bizarre or illogical in the scientific community does not constitute an inventive step. A practice that is followed in one part community, however ineffective or useless it might appear to others, cannot be a subject matter of the patent. In addition to that if patents are granted for such obvious practices then we will end up granting a monopoly on regular and general methods obstructing future growth, invention and technological advancement.

The decision of US court in *KSR Intl' Co. v/s Teleflex Inc.*<sup>23</sup> had far-reaching effects on the patenting scheme in the US. In this case, court emphasized that the difference between the prior art and patent claim along with the degree of skills a person ordinarily possesses in that subject matter should be considered strictly. Therefore, cascading of the prior art will not lead to a new invention and it would be treated as obvious. In this case, the plaintiff had an adjustable pedal fixed with electronic control; on the other hand, the defendant added an electronic sensor to the pedal which helped in the transmission of information on the computer. The Supreme Court noted that when an invention is made available to the market, the shortcomings or advancements in the invention are likely to be done by the market competitors and this process propels a range of variations. If a person ordinarily skilled in that art can predict and realize these variations then the subject matter does not come within the ambit of patentability.

In the light of foregoing discussion, it can be implied that the Courts have not followed a consistent or static approach when it comes to the standards of non-obviousness. The varying standards of non-

---

<sup>21</sup> Kirin-Amgen Inc. v. Roche Diagnostics [2002] RPC.

<sup>22</sup> Ancare New Zealand Ltd.'s patent Privy Council [2003] RPC 8.

<sup>23</sup> 550 U.S. 398 (2007).

# DROIT PENALE: INDIAN LAW JOURNAL ON IPR

(A Unit of Droit Penale Group, Prayagraj)

ILJIPR, ISSN: 2582-8762

VOLUME 1 ISSUE 1

obviousness are an issue of concern when it comes to biotech patents. In the US the earlier trend was inclined towards the private interest to speed up technological advancement. However, with the decision of KSK Intl' obtaining patents has become more cumbersome as now we have a wide range of prior art. The courts in the UK are steady in their approach and have reiterated their proclivity towards the public interest.

## INDIA'S STANDING ON PATENTING IN BIOTECH INVENTIONS

The Indian Patent Act, 1970 (hereinafter mentioned as the Act, 1970) has been amended on various occasions. In 2002, the Act, 1970 was amended to include biotechnological, biochemical and microbiological processes. The Act, 1970 envisaging all the amendments to date complies with the provisions of TRIPS, for instance, section 3 has been modeled on Article 27 of TRIPS. However, in the absence of rigid definitions in TRIPS India has a window of elasticity to develop. Section 5 of the Act, 1970, has an oblique implication on biotech inventions as this section deliberately excludes product patents on substances capable of being used as food, medicine or drugs and substances prepared or produced by chemical procedure, however, process patents are granted for them. On further inquiry it is apparent that the lack of a proper definition of micro-organism may be an issue of concern hence the guiding provisions in TRIPS is the only recourse for this problem<sup>24</sup>.

Section 2 (1) (ja) of the Act, 1970, defines an inventive step in the light of technological advancement or economic significance or both to make an invention non-obvious. This definition in the context of biotech patenting should be of secondary considerations to maintain the scientific qualitative value of an invention. The parameters of the inventive step as mentioned in the draft manual of Patent Practice and procedure<sup>25</sup> are much more in line with the industrial needs, for instance, surprising effects, commercial success, affordable product, the ease with the proposed technology, etc.

Biotechnological and life forms patenting is a subject matter which has a long journey ahead of it. With the advancing technology and research methodology, the horizon and ambit of the biotech inventions in India will see a boom in the coming years. To provide a safe market for such inventions the standards

---

<sup>24</sup> Basheer Shamnad, India's tryst with TRIPS: The patent (Amendment) Act, 2005, The Indian journal of law and Technology, quoted in JIPR January 2008.

<sup>25</sup> Draft manual of Patent and Procedure, 2008.

# **DROIT PENALE: INDIAN LAW JOURNAL ON IPR**

(A Unit of Droit Penale Group, Prayagraj)

ILJIPR, ISSN: 2582-8762

VOLUME 1 ISSUE 1

and requisites of granting patents will have to be given a degree of predictability. These consistent set of principles will help the inventors and their investors to successfully claim a patent for their invention and commercially exploit the patent. The fluctuating set of values in the patenting regime will impact the market structure and obstruct the economic development of the country as well. Hence the authorities must be sensitized towards granting or rejecting patent applications.

## **CONCLUSION**

In this modern era, many inventions are taking place, particularly in the area of biotechnology. Now, since granting of patents have evolved as a strong weapon of the Intellectual property, protection in the area of biotechnology has to be taken. The main difficulty in granting protection of a patent in the field of biotechnology is that of the need of requirement of obviousness as well as the degree of art.

Many judicial pronouncements in the UK as well as in US that reveals different standards of granting the patent in the biotechnological inventions. The varying standards of granting patents in the biotechnology field will surely be going to affect the investors and also the expansion of the industries. Eventually, we can say that it is affecting the growth of technology development and because of this scientific advancement as well as the economic advancement of our country is getting affected. Therefore, the judiciary and patent offices have to be very careful and active while determining intellectual concerns in the field of patenting biotechnological inventions.