

## **CHAPTER 3**

### **PATENT ON MICRO-ORGANISMS, PLANTS, ANIMALS AND HUMAN BODY PARTS**

#### **3.1 Patent on Micro-Organisms**

##### **3.1.1 Concept of Micro-Organisms**

A general definition of a microorganism is an organism that is microscopic and which can be seen only under a microscope, usually an ordinary light microscope. Microorganisms are incredibly diverse and include bacteria, fungi, algae and protists as well as some microscopic plants and animals. Thus, it consists of single a cell or a cell cluster.

The EC Directive on Microorganisms defines it as, “Any microbiological entity, cellular or non-cellular, capable of replication or transferring genetic materials.” EC Directives has also defined biological material as, “Any material containing genetic information and capable of reproducing itself or being reproduced in a biological system.”

Historically speaking, single cell microorganisms were the first form of life to develop on earth approximately 3.4 billion years ago. Further, evolution shows that about 3 billion years in the Precambrian, all organisms were microscopic. So, for most of the history of life on earth, the only forms of life were microorganisms, bacteria, algae and fungi have been identified in amber that is 220 million years old, which shows that the morphology of microorganisms has changed little since the Triassic period.

Most of the microorganisms can reproduce rapidly and microbes such as bacteria can also freely exchange genes by conjugation, transformation, transduction between widely – divergent species. This horizontal gene transfer coupled with a high mutation rate and many other means of genetic variation allows microorganisms to swiftly evolve to survive in new environments and respond to environmental stresses. This rapid evolution is important in medicine, as it has led to the recent development of “super-bugs” pathogenic bacteria that are resistant to modern antibiotics.

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The possibility that micro-organisms might exist was discussed for many centuries before their actual discovery in the 17<sup>th</sup> century, the first ideas about microorganisms were those of the Roman scholar Marcus Terentius Varro, in the 1<sup>st</sup> century BC. He warns against locating a homestead near swamps where there are breeds containing minute creatures, which cannot be seen by the eyes, which float in the air and enter the body through the mouth and nose and cause various diseases. The ancients were unaware of the possibility that disease could be spread by yet unseen organisms. In the cannon of medicine, he stated that bodily secretion is contaminated by foul foreign earthly bodies before being injected. He also hypothesized that tuberculosis and other diseases might be contagious i.e. they were infectious diseases and used quarantine to limit their spread.

All these early claims about the existence of micro-organisms were speculative in nature and not based on any data or science. Micro-organisms were neither proven observed nor correctly and accurately described until the 17<sup>th</sup> century. The reasons for this were that all these early inquiries lacked the most fundamental tool in order for microbiology and bacteriology to exist as a science and that was the microscope.

Antonie van Leeuwenhoek, the first microbiologist, was the first to observe microorganisms using a microscope and that too of his own design. In doing so, he made one of the most important contributions to biology and opened up the field of microbiology and bacteriology. Prior to his discovery of microorganisms in 1675, it had been a mystery as to why grapes could be turned into wine, milk into cheese or why food would spoil. He did not make the connections between these processes and microorganisms but using a microscope he did establish that there were forms of life that were not visible to the naked eyes. His discovery, along with subsequent observations by Lazzaro Spallanzani and Louis Pasteur, ended the long held belief that life spontaneously appeared from non-living substances during the process of spoilage.<sup>1</sup>

In 1976, Robert Koch established that microbes can cause disease. He did this by finding that the blood of cattle that were infected with Anthrax, always had

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<sup>1</sup> Jay James M., *Modern Food Microbiology*, 6<sup>th</sup> Ed., Westport, Conn. AVI pub, 2000

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large numbers of *Bacillus Anthracis*. Koch also found that he could transmit Anthrax from one animal to another by taking a small sample of blood from the infected animal and injecting it into a healthy one, causing the healthy animal to become sick. He also found that he could grow the bacteria in a nutrient broth, inject it into a healthy animal and cause illness. Based upon these experiments, he devised criteria for establishing casual link between a microbe and a disease, which are now known as Koch's postulates. So, it is apparent that new kinds of microorganisms are presently used as medicines and the pharmaceutical industries have also started investing huge capital in order to make research and development programme in the field of biotechnology with reference to microorganisms.

#### **3.1.2 Patent On Microorganisms - A Cross Road**

Microbiologists are forging ahead with more discoveries every day and in turn, are seeking the same protection as inventors in other industries. One such protection is the patent. The US Congress, under the power of the Constitution<sup>2</sup> enacted the patent laws to encourage inventiveness with the ultimate hope of having a positive effect on the society<sup>3</sup>. The Congress intended the patent law to stimulate discovery, thereby promoting the introduction of new and useful products into the society.

“More narrowly the issue was whether a ‘microorganism’ constitutes a “manufacture or composition of matter” within the meaning of the statute.”

Unlike *American Fruit Growers Inc*<sup>4</sup> and *Steinfur Patents Corp*<sup>5</sup>, Chakkrabarty's invention clearly fell within the broad definition of manufacture. Chakkrabarty created new bacteria by using new material-cell- and gene. These cells now form by transporting plasmids from one cell to another. This discovery resulted in a new, useful microorganism which can devour oil.

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<sup>2</sup> Art 1. Sec. 8 of US Constitution

<sup>3</sup> *Diamond v. Chakrabarty* : Scientist Patents Microorganism, Life Forms considered patentable subject – Matter under 35 U.S.C. SS. 101. Ohio, NUL, Rev 1039, 1980

<sup>4</sup> 283, US, 1 (1931)

<sup>5</sup> Ohio, N.U.L. Rev 1039, 1980.

### **3.1.3 Chakrabarty's Legacy: The US Position**

In 1972, Anand Chakrabarty, a microbiologist, researcher to the General Electric Company filed a patent application in relation to a bacterium from the genus *pseudomonas* containing therein, at least two stable energy generating plasmids<sup>6</sup>, each of the said plasmids providing a separate hydrocarbon degradative pathway. It was a man-made, genetically engineered bacterium capable of breaking down multiple components of crude oil. It was asserted that because of this property, which is possessed by no naturally occurring bacteria, the invention could treat oil spills.

The patent claims were of three types:

- First process claim for the method of producing the bacteria
- Second, claims for an inoculum comprised of a carrier material floating on water such as straw and the new bacteria, and
- Third, claims to the bacteria itself.

The Patent Examiner allowed the claims falling into the first two categories, but rejected the claim for bacteria. The decision rested on two grounds:

- that microorganisms are products of nature, and
- that as living things, they are not patentable subject-matter.

Later, the Patent Office Board of Appeals reiterated the examiners' decision on the ground that micro-organisms do not fall within the ambit of patentable subject matter since they are living things. Moreover the Court of Custom and Patent Appeals emphasized that this issue was not whether the claimed bacterium was living or inanimate but whether, it constituted an invention made by human intervention. The Court reaffirmed that the bacterium was not a handiwork of nature rather it was Charabarty's own invention. The four statutory categories of inventions, which can be granted patents are process, machine, manufacture and composition of matter. Therefore, on the question as to in which

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<sup>6</sup> A loop of double stranded DNA that is separate from and replicates independently of the chromosomes, most commonly found in bacteria but also in archaeans and eukaryotic cells, and used in genetic engineering as a vector for gene transfer.

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category would the invention fall, the Supreme Court held that Genetically Engineered oil consuming bacterium could be categorized either as composition of matter or a manufacture. The court read the term manufacture in accordance with its dictionary definition, to mean the production of articles for use from raw or prepared materials by giving to these materials, new forms, qualities, properties or combinations whether by hand labour or by machinery.

The court obviously turned back to legislative intent of the drafters of the US Patent Act to ascertain the rationale behind using general and broad terminology “any composition of matter” or “manufacture.” According to the court, this selection of broad language suggested that the drafters’ goal was to stimulate innovation in a wide range of then unknown technologies and scientific fields, a goal that would be frustrated if Congress was repeatedly required to amend the statute so as to explicitly delineate new categories of patentable inventions. The court observed that the legislative history of the Patent Act connotes that the patentable subject matter includes “anything under the sun that is made by man.” Chakrabarty simply shuffled genes, changing bacteria that already existed. The widest interpretation by the court, let the broadest amplitude to patentability to the living subject matter.

After this historic decision, the US biotech industry flourished and numerous patents have been granted on human made higher life forms such as transgenic crops, mice, fish, cows etc.

During the 1970’s in the US there was a turn around in the point of view of the US courts regarding the patentability of microorganisms based on the argument of “product of nature” doctrine<sup>7</sup> In 1970, the CCAP ignored the ‘product of nature’ objection and held in re Bergstrom<sup>8</sup> that the biological origin of purified natural products does not preclude their novelty and accepted by implication the proposition that such products could be understood as ‘manufacture’ and rewarded with patent protection. Although this line of reasoning was apparently abandoned

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<sup>7</sup> Goertrui Van Overwalle, *Patent Protection for Plants: A Comparison of American Approaches*, 39 IDEA 143, 1999.

<sup>8</sup> 427 F. 2d 1394, 195 U.S. P.Q (BNA) 256 (CCPA 1970)

in 1974 in, re Mancy<sup>9</sup> the ‘product of nature’ objection was rejected again in 1977 in a famous case, Bergy<sup>10</sup>, in which the CCPA, dismissed as “ill considered dictum,” the comments it made in Mancy that seemed to revive the product of nature objection and the Court explicitly accepted that a biologically pure strain of microorganisms is patentable. An important basis for the court’s decision was in understanding that the microorganisms in issue, were ‘man-made’ and could be produced only under carefully controlled laboratory conditions. Finally, it is obvious that ‘the product of nature’ concept was defeated in Chakrabarty and Rote Taube cases. Moreover, this decision later insisted the WTO Member states to adopt microorganisms as a patentable subject-matter in the TRIPS Agreement.<sup>11</sup>

### **3.1.4 The Protection of Microorganisms in Europe**

In Europe, the majority of the Belgian, German and Dutch legal doctrines dismissed the objection that inventions relating to living materials are not patentable. The argument that patent law was tailored to inanimate techniques and those breeders’ products as living material should therefore be excluded from patent protection was never introduced in those countries. Apart from these conditions in Europe, some countries like U.K. recognized patent over man – made microorganisms based on the international and regional legal frameworks i.e. TRIPS Agreement and EC Directives particularly Biotech Directives<sup>12</sup>

With respect to the microorganisms the judgment of the SC of the Federal Republic of Germany based on the ‘Doctrine of Reproducibility;’ by breeding or other processes’<sup>13</sup> In 1975, the SC of the Federal Republic of Germany delivered a judgment in Baker’s yeast case<sup>14</sup> that while referring to the Red Dove case<sup>15</sup>, the microbiological method and the products thereof should not be excluded from patentability for the sole reason that the microorganisms are living organisms thus, recognizing the patentability of microorganism. However, this judgment indicated

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<sup>9</sup> 499 F. 2d 1289, 182 U.S.P.Q (BNA) 303 (CCPA 1974)

<sup>10</sup> 563 F 2d 1031-195 U.S.P.Q (BNA) 344 (CCPA 1977)

<sup>11</sup> Art 27 of TRIPS Agreement.

<sup>12</sup> Goerruri van Overwalle; *Patent Protection for Plants-A Comparison of American and European Approaches*, 39, IDEA, 143 1998-1999

<sup>13</sup> Asia-Pacific Industrial property Center, *Bio Patent*, available at [www.jiii.or.jp/english/apsc](http://www.jiii.or.jp/english/apsc). Accessed on 7<sup>th</sup> September 2011

<sup>14</sup> 11C,137 (1990)

<sup>15</sup> German FSC, GRUR 1969, 677 and IIC 1970, 136 – “Rote Taube” (“Red Dove”)

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further that in order to render patent to the present microorganisms is not only evidence of propagation from the culture but also for reproducibility, in the process of producing the present microorganism from a starting microorganism must be furnished. As a result the patentability of this case was ultimately denied by the SC as failing to meet the above conditions.

Although, it was first made clear by this judgment that microorganisms are patentable subject-matter, in those days it was almost impossible to substantiate reproducibility by breeding process or creating process demanded by this judgment via ordinary breeding means such as screening for natural mutations to produce a new kind of microorganism.

Therefore, in reality a path to obtaining a patent to a microorganism remained long and difficult so long as the “doctrine of reproducibility” by “breeding process” of the Bakers’ yeast case contributed the test for judging patentability of microorganism.

In the another landmark judgment of the SC of the Federal Republic of Germany, in 1998 on the *Lactobacillus Bavarivus*’ case<sup>16</sup> this doctrine of reproducibility by breeding process was followed. However, as far as the new microorganism *lactobacillus bavarivus* of this case was concerned, it was possible to demonstrate the reproducibility of the screening process for the microorganism from the pickle of cabbage, i.e. the creating / growing process of the microorganism. As a result a patent to this microorganism was granted. Obviously, the researcher feels that this was a rare case in which the reproducibility of creating / growing process was demonstrated.

After 1985, the Courts in Europe slightly changed their way of approach in relation with the patentability of microorganisms on the basis of new international frame work in this respect. In 1987, the SC of the Federal Republic of Germany delivered a new judgment on the *Tullwatvirus* case<sup>17</sup> to harmonize it with the practice of EPO, the judgment being quite the opposite to the conventional judgment after the *Red Dove* case<sup>18</sup>. An epoch-making judgment was delivered in

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<sup>16</sup> BpatG, GRUR 1978, 586

<sup>17</sup> 11. C 138, 1970.

<sup>18</sup> *Supra* Note 15

which the patentability of novel microorganism was admitted based on the “propagation ability of the deposited sample.”

The context of judgment for obtaining patent protection on a novel microorganism having a ‘propagation ability’ can be deposited and made public in lieu of showing ‘reproducibility’ of the creating process of the microorganism.

According to the researcher’s understanding the Tullwatvirus case<sup>19</sup> is now considered a clear departure from the conventional doctrine of reproducibility by breeding process which has been an obstacle for a long time for each European country in granting a patent to a living organism.

In fact, the concept that the deposit of the microorganism be required as part of the necessary disclosure very soon became general opinion, although a contrary view was expressed in some cases. Since the deposit is considered a part of the disclosure there is also virtual unanimity that the deposit must have been effected not later than the time of filing the patent application.

It is very significant to indicate that the Budapest Treaty<sup>20</sup> on the International Recognition of the Deposits of Microorganisms for the purpose of patent procedure of 1977, signed among others by the US and nine of the ten countries which have ratified the EPC, put the formalities of deposit and release on an international basis. Although international organizations like EPO cannot become members with equal rights according to Art. 9 of the Treaty,<sup>21</sup> they can affiliate themselves with certain provisions. So far the EPO has not made use of this possibility but has concluded instead separate agreements with individual depositories.

The real problem does not rest in the provisions for deposit, but in the requirements concerning release of the microorganism. It is evident that in giving the microorganism to a third party the inventor gives away much more than with any other invention, he gives away a ready working, fully equipped, complete factory and cannot control what is further done with the microorganism.

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<sup>19</sup> Ibid.

<sup>20</sup> Budapest Treaty 1977.

<sup>21</sup> *Ibid*

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There is an example in this respect, in re Argoudelis<sup>22</sup> where the PTO accepted the deposit of a microorganism in the ATCC as an alternative procedure for meeting the requirements of US Patent Law<sup>23</sup>. Consequently, the Board saw little difference between the concept of screening a microorganism to develop a desired strain and the concept of screening plants to develop a desired variety. Also, in the US the release of microorganisms is possible only after a patent grant. So it is apparent that there is no release without patent protection. This seems in accordance with the patent granting procedure, in which the application remains secret until patent grant.

Most importantly looking at this matter the rulings of Belekerhefe decision are epoch-making, which are as follows:

For a complete description of a microbiological invention rendering here in a process using a microorganism, it is necessary that the microorganisms be deposited at a scientifically recognized culture collection at the time of filing the priority patent application and that the depository and the official file number of the deposit be disclosed in the original specification.

Applicant has to assure by irrevocable declaration to the culture collection that samples of the microorganism will be released upon request at any time to authorities and to courts involved in the patent granting procedure from the date of the first laying open or publication of the patent application. Applicant may require recipients to identify themselves and not to use the sample except in matters pertaining to the German patent law.

Applicant has to ensure that the microorganism is stored in a viable state in the culture collection until an appropriate period after expiration of the patent. In principle, product claims for the microorganism per se are patentable.

Product claims for the microorganism per se are patentable only, if the inventor has disclosed a repeatable method for their reproduction. Isolation of the microorganism from a soil sample or an induced 'mutation'<sup>24</sup> or multiplication of a deposited sample of the microorganism is not repeatable methods. This keeps

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<sup>22</sup> 434 F. 2d 1390 CCPA 1970.

<sup>23</sup> Act 35 of USC, S, 112. Feldman v. Auastrup,186,USPQ,108,CCPA 1975

<sup>24</sup> Any heritable change of the base-pair sequence of genetic material

microorganism which can be found in nature may be free from patent and available to anybody.

The researcher finds that it is so clear that “product claims” for a microorganism per se, produced for instance by a repeatable method of genetic engineering must be patentable. Also as a matter of fact microorganisms are now patented without any problem so long as they satisfy the rest of the patentability requirements in accordance with the domestic law of each European country.

Moreover, in Japan, in 1997 the Japanese Patent Office published its “Implementing Guidelines for inventions in specific fields.”<sup>25</sup> Inventions in the biotechnology field in the Guidelines were divided into three types, genetic engineering microorganism, plants and animals. Inventions relating to microorganisms include “microorganism per se” as well as those relating to the use of microorganisms.

### **3.1.5 Protection of Microorganisms in India**

In India the position of patentability is parallel to that of US and Europe. The process of creating biochemical, biotechnological and microbiological process is patentable in India.

Inventions pertaining to microorganisms and other biological material were subjected to product patent in India unlike many developed countries. But with effect from 20-5-2005 India has started granting patents in respect of inventions related to microorganisms, though India was not obliged to introduce laws for patenting microorganism per se before 31-12-2004. The grant of patents for microbiological inventions is for a period of 20 years from the date of filing.

The following inventions involving and relating to microorganisms are patentable in India.

- Process for producing new microorganisms
- End products of biosynthesis for example, a new microorganism

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<sup>25</sup> Corina Schiitt: *Patents for Biotechnological Inventions - Current Legal Situation and case law in Europe, US and Japan* available at [www.transfer.ethz.ch/people/IP-Schuett](http://www.transfer.ethz.ch/people/IP-Schuett). Accessed on 25<sup>th</sup> April 2013

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- Synergistic composition containing the microorganism
- Use of microorganisms as for producing antibiotics

The grant of patent in respect of microorganism depends upon the regulations concerning the requirements for the deposition of microorganism under the Budapest Treaty, of which India has become a member and accessibility of that microorganism from the depositories. The microorganism if not being described fully and particularly and is not available to public, the said microorganism is to be deposited before the International Depository Authority under the Budapest Treaty with 3 months of making application in India.

It is therefore advisable before proceeding to file a patent application in respect of the microorganism and other biological material to ensure that the same is not hit by the provision of the Indian Patent Act and the invention is not a mere discovery of what already exists in nature and in case of genetically modified variant of microorganism or other biological material the invention results in enhancing the efficacy of already existing strain of the microorganism or other biological material.

In a land mark case<sup>26</sup>, Indian court has also made a breakthrough in granting patent over a kind of microorganism. The fact of the case is that Domnico AG, a Swiss company applied for patenting the process for preparation of a live vaccine for Bursitis. Bursitis is an infections poultry disease and the invention involved a live vaccine to combat the disease. Controller of Patent refused to allow the application on the ground that the vaccine involved processing of certain microorganic substances. This was only a natural process devoid of any manufacturing activities and hence not patentable under Patent Act. This was in consonance with the prevailing practice that granted patents only to non-living and tangible inventions, that fulfilled the patentability criteria<sup>27</sup>, even though the Patent Act imposed no such limitations. It rejected the contention of the controller that a patent is given only for a process that results either in an article, substance or manufacture. The controller had argued that the dictionary meaning of 'article' is a

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<sup>26</sup> Domnico AG v.controller of patent and Design, Kolkatta. 2002, IPLR 255 Cal. HC.

<sup>27</sup> Sec 2(j) 2(ja) and 2(l) of Indian patent (Amendment) Act 2005.

material thing, item, a thing of a particular class or kind as distinguished from a thing of any class or kind.

Subsequently, the controller said that the definition does not cover living thing. But the Calcutta High Court held that the Indian statute on patents does not put any fetters on patentability of microorganisms developed in a controlled environment in the laboratories. Court also held that the process for creating a vaccine leads to a tradable product containing live material. The court said that if the invention results in the production of some vendible items, improved ones or restores formal conditions of vendible items or its effect in preservation and prevention from deterioration of some vendible product then such an invention would pass the vendibility test. Therefore since the claim process for patent leads to a vendible product, it is certainly a substance after going through the process of manufacture. Finally, court concluded that a new and useful art or process is an invention and where the end product is new article, the process leading to its manufacture is an invention.

This decision on the Kolkatta HC was synchronous with the position in US, most of the European countries as well as Japan, since most processes in the biotechnology field would be patentable irrespective of whether the resultant product is living or non-living. After this decision the Indian law kept pace with the needs of thriving biotech industry The patent Amendment Act 2000 came into force in May 2003, bringing microorganisms within the realm of patentability.

### **3.1.6 Mashelkar Committee Report on Patentability of Microorganism<sup>28</sup>**

Microorganisms are patentable subject matter to the satisfaction of the provision of the Indian Patent Act.<sup>29</sup> Upon, review of Art 27. 3 of TRIPS Agreement and considering the need to give boost to the Indian biotech industry, the committee concluded that excluding microorganisms from patent protection would violate TRIPS Agreement. At the same time the committee recommended formulation of strict guidelines to ensure that only micro-organism modified by substantial human intervention are patented thereby eliminating the possibility of

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<sup>28</sup> Mashalkar Committee Report – Available at [www.mirandah.com/en/.../264-mashallear-report-republished-html](http://www.mirandah.com/en/.../264-mashallear-report-republished-html)? Accessed on 4<sup>th</sup> November 2010

<sup>29</sup> Patent Act 1970, S. 3.

granting frivolous patents. The Act would prevent grant of patent in relation to microorganisms that occur in nature. The Act does not define microorganism which is likely to lead interpretational issues. The committee opined that incremental inventions ought to be encouraged by the Indian patent regime as they may be of tremendous value to the country like India.

### **3.2 Patent on Plants**

Biotechnology involves biological processes which directly or indirectly can control, alter and transfer the genetic information of living organisms in order to achieve a useful end. The world is experiencing a breakthrough in agricultural technology that may soon enable us to harvest crops from deserts, farm tomatoes in many new localities and enjoy entirely new crops such as “Pomato”.<sup>30</sup>

In the mid 1880s, Austrian monk, botanist and plant scientist Gregor Mendel carefully studied the principle of heredity. Experimenting with garden peas, Mendel successfully cross-bred traits such as pea – color plant height and pod size. Mendel showed that differences such as plants height and pod size. Mendel also showed that differences such as plants height or colour could be attributed to the passing of traits and genes, the basic building blocks of life.

In the early 20<sup>th</sup> century agricultural expert Henry Wallace applied the Principles of Hybridization to develop new high yielding seeds. Wallace went on to apply his scientific innovation to a business model as one of the early leaders of Pioneer Hi – Bred International Inc, today a DuPont business. A precursor to prove advanced cross – breeding and eventually biotechnology hybridization is the process of crossing plant varieties to produce crops with more favorable traits or combining genes from two or more varieties of a plant species to produce improved seeds, for example a breeder might eliminate a plant’s thorns by cross-breeding with a thorn – less variety.<sup>31</sup>

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<sup>30</sup> Patricia Lucia Cantuaria Masin, *Providing Protection for Plant Genetic Resources*, 1<sup>st</sup> Ed, Kluwer Law International New York, 2002 at p.4

<sup>31</sup> Shahzad Ahmad ; *Encyclopedia of Environmental Biotechnology*, Vol-2, 1st Ed, Anmol Pub (P) Ltd., New Delhi, 2008,at p.29

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Apart from this, we can now isolate and manipulate the genes that constitute hereditary materials of each species genetic makeup<sup>32</sup>. It is obvious that patents are most commonly preferred by breeders to protect the biotechnological inventions on account of their wide scope of protection.

Moreover, it is noted that in the 20<sup>th</sup> century agriculture has undergone several major transformation, including radical changes in technology. With the stated aim of eliminating hunger, genetically improved “high –yield” varieties were developed for a few of the worlds major crops this process known as Green Revolution, was sponsored by governments and large corporations in the wealthy countries of the North .<sup>33</sup> Along with its miracle seeds for corn, rice and wheat, the Green Revolution ushered in a new style of farming based on the intensive use of chemical fertilizers, pesticides and machinery. These factors considerably increase the quality and quantity of the food production in the market and the multinational corporations too started investing copious amount of capital for the production of new varieties of plants and animals for the agricultural industry. In order to recoup the capital spent by the industries, they compelled the law makers and policy makers to take necessary steps or measures to protect their interest and they intended to get monopoly over the new seeds or crops they produced. For this purpose, later they selected the patent system as a kind of great incentive end which could avoid infringement also.

Indeed, the biotechnology and seed industries are watching the courts with great interest because the decisions could have enormous implications for both industries by potentially changing the landscape of intellectual property rights protection throughout the world. Although utility patents are not the exclusive forms of protection for transgenic ally<sup>34</sup> altered plants and seeds, they are widely believed to provide the broadest protection. Currently plants and seeds (genetically altered and otherwise created varieties) are afforded protection under various types of Intellectual Property statutes and laws including Plant Patent Act

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<sup>32</sup> *Ibid.*

<sup>33</sup> David Hathaway: *Biodiversity, Biotechnology and Patent in Brazil*, Available at [www.academia.edu/.../biodiversity](http://www.academia.edu/.../biodiversity). Accessed on 7<sup>th</sup> Oct 2013.

<sup>34</sup> Transgenic organizing are organizing that contain DNA from another organism insisted by genetic engineers through bio technological process, carrier F. Walter: *Beyond the Hard Mouse*, Current Patent, Practice and the Necessary of Clear Guidelines in Patent Law 73 IND. L.T. 1025 (1998).

(PPA), Plant Variety Protection Act (PVPA), license agreement, utility patents etc.,<sup>35</sup> Despite multiple layers of intellectual property protection available for plants and seeds, industry prefers the courage, provided under the UPTA because it allows for the greatest amount of protection by excluding others from making using and selling patented plants without exemption. Based on this discussion, whether sexually reproducing plants and their progeny seeds are indeed patentable under the Utility Patent statutes and the implications of the Supreme Court's decisions.

In a famous case,<sup>36</sup> the court opined that sexually reproducing organisms are by nature genetically dynamic. The very essence of sexual reproduction is the recombination of genetic material between gametes in each generation. Consequently, in order to accommodate the patenting of sexually reproducing plants under 35 USC the PTO necessarily relaxed the legal requirements of section 112 as well as other sections of the utility statute.<sup>37</sup> Relaxing the legal standards to serve special situation could have legal implications, when considering the issue of patentability for other inventions particularly in light of recent controversies over the patentability of genes, gene fragments and higher forms of life. Also it is evident that patent on plant is not a new concept and the issues relating to patentability criteria started in the early 19<sup>th</sup> century. The researcher wishes to discuss the historical perspective of patent on plants.

### **3.2.1 Historical Aspects of Patent on Plants - US position**

In US, the Congress has power under the constitution, to promote the progress of science and useful arts by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries.<sup>38</sup> However, since the enactment of the first Patent Act in 1790, protecting the efforts of plant breeders and their developed 'germplasm'<sup>39</sup> has been a problem. Early seed companies realized the need to establish a market but because of the ease with

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<sup>35</sup> Darvide C. Scalise and Daniel Nugent's, *International IP, Protection for Living Matter, Biotechnology Multinational Conventions and the Exceptions for Agriculture*, 27 CASE W. RES. INTL. L.83,85 (1995).

<sup>36</sup> *Pioneer v. J.E.M.* 200, F. 3d, 1374

<sup>37</sup> *Exparte "C"*, 27 U.S.P.Q. 2d, 1492, 1502, I, *Exparte Hibberd* 227, US P.Q., 444 – 47.

<sup>38</sup> Art 1 Sec. 8 cl.8 of US Constitution.

<sup>39</sup> Germplasm refers to the genetic material of the plant and the plant breeders and bio technologists' interest because it incorporates their efforts.

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which openly pollinated varieties<sup>40</sup> could be propagated the seed industry had little incentive to invest in extensive research programmes. Because seed naturally produces generation to generation the marketed product once sold to farmers, was available for replanting subsequent crops or for resale to others from a single end sale. Traditionally farmers have engaged in the practice of saving seeds from each years harvest for replanting during successive years a practice that cuts into the seed market with the advent of ‘hybrid technology’<sup>41</sup>, which produces high yield in the first generation cross with subsequent yields declining. The seed industry finally had an incentive to develop new and improved varieties because farmers must return to the seed producer each year for their seed supply.

Hybridization is a process whereby the production of hybrid seed is accomplished as follows parent accomplished lines are developed by repeatedly inbreeding through self – pollination with a single line, so that a “homozygous”<sup>42</sup>line suitable for crossing is developed. When two parental lines are crossed or inter – bred the resulting hybrid plants have a mix of new genetic material that makes them more vigorous in the first generation after cross with accompanying high yields that drop off in subsequent generation, a phenomenon known as hybrid vigor because seed companies often trade only their hybrid seed in the open market. The parental lines can be protected under trade secret law from competitors, seed producers, through “GrowerConfidentiality Agreements”(GCA) on hybrid seed sales. The farmer rather than being able to replant from the previous years crops must return each year to the seed company for additional seed purchases in order to replant with the same results.

In 1930, Congress enacted the Plant Patent Act for the protection of asexually reproduced plants which the PTO administers. However, there was still a need for IP protection for sexually reproducing plants including the self–pollinating” varieties and the parental lines for crops such as corn. The researcher

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<sup>40</sup> Open pollination is natural cross pollination whereby the pollen from the author of one plant is transferred by either insects or wind to the stigma or silk of another plant to complete the sexual reproductive cycle.

<sup>41</sup> Hybrid technology is the cross – pollination of two in bred parental lines resulting in a crop with improved vigor in the first generation with subsequent declining yield in later generation.

<sup>42</sup> Genetically uniform.

would like to discuss about the development of important statutes relating to plant patent.

### **3.2.1.1 Plant Patent Act, 1930**

The need for statutory protection of plant related inventions to promote the progress and development of plant science has long been recognized in this country. Patent legislation was proposed at least as early as 1892, but it was not until the passage of the Townsend Parnell Act was the first legislation anywhere in the world to grant patent rights to plant breeders<sup>43</sup> and was supported by such prominent individuals as Thomas Edison, who stated that nothing that Congress could do to help farming would be of greater value and permanence than to give to the plant breeders, the same status as the mechanical and chemical inventors now have through the law.<sup>44</sup> Through passage of the PPA Congress intended to place agriculture as far as was practicable on the same footing as industry in regards to receiving benefits under the patent system.

It is significant to note that there were two reasons for denying patent protection the Congress had to overcome to pass patent protection for living plants. First was the belief that plants were the product of nature and therefore not subject to patent protection, even those plants bred by man. Secondly, plants were considered not to be amenable to the written description requirement of 35 USC S 112 under the utility patent statutes because they would not sufficiently breed true-to-type generation after generation. A plant breeds “true – to – type” if it has sufficient distinguishing characteristics that are unique to only that plant and these characteristics are reproduced consistently in subsequent generation without human intervention. Thus, the question under section 112 was whether a plant could be sufficiently distinguished by written description from any other plant variety after reproducing generation after generation.<sup>45</sup>

In enacting PPA the Congress recognized that the work of the plant breeder in aid of nature was a patentable invention under the general patent statutes.

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<sup>43</sup> Elisa Rives; *Mother Nature and the Courts are Sexually Reproducing Plants and Their Progeny Patentable under the Utility Patent Act 1952* Available at <https://litigation-essentials.lexisnexis.com.../app?action...> .Accessed on 5<sup>th</sup> June 2014.

<sup>44</sup> *Ibid.*

<sup>45</sup> *Supra* note 7

Congress responses to the difficulty of meeting the written description requirement applicable to utility patents was to relax the requirement in favour of description as complete as is reasonably possible ending with the deposit of examples, in an approved facility. Congress originally enacted the PPA as an amendment to the general patent provision and it was not until the promulgation of the UPTA of 1952<sup>46</sup> that the plant patent provisions were included as a separate chapter of 35 USC.

The PPA provides the plant breeder patent protection to a single claimed plant with a unique characteristic either physiological or anatomical that can be cloned by grafts, buds or cuttings resulting in a new plant with the same characteristics.<sup>47</sup> Protection which excludes all others from making, selling, or reproducing a patented plant continues for twenty years from the date the patent application is filed. However sexually reproduced plants and their progeny plants produced from seed were not recognized for protection under the PPA. It was not until the passage of the PVPA in 1970 that Congress recognized the patent like protection for sexually reproducing plants and seeds.

### **3.2.1.2 Judicial Contributions: Innovative Approaches and Liberal Interpretations**

In this part the researcher would like to emphasize the fact that the judiciary in US and some other countries had taken positive view point prior to Chakrabarty's decision. Thus, it is evident that prior to Chakrabarty's decision, the concept of product of nature influenced considerably in the judicial decision makings and policy frameworks.

#### **Blue Mold Decay Resistant Orange<sup>48</sup> – Decision:**

The analysis began with the 1931 Orange case on March 10, 1925, Brogden and Crowbridge received US latter's patent. Presumably, the patent was issued without fanfare. It was predicated on the discovery that impregnation of the rind of oranges with very small amounts of borax rendered the orange resistant to 'blue mold decay', Patent claim 26 covered, "Fresh citrus fruit of which the rind or skin

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<sup>46</sup> *Supra* note 41

<sup>47</sup> *Ibid*

<sup>48</sup> American Fruit Grows INC v. Brogdex 283, US 1 (1931)

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carries borax in amount that is very small but sufficient to render the fruit resistant to blue mold decay". Both District Court and the Court of Appeal held that this claim was valid and infringed, the defendant used the borax impregnation proves but argued that claim 26 defined nothing more than natural fruit. The patentee argued that since the product was a combination of natural fruit and the borax carried by the rind or skin, the complete article was not found in nature and was properly patentable. The US Supreme Court reversed the Court of Appeals and found that the product was not patentable.

The court seemed to hold that to avoid application of the "product of nature doctrine" the product must possess a new and distinctive form, quality or property, it must exhibit a change in name, appearance or general character. Though the courts actual decision concluded that borax impregnated orange was not a new article of manufacture but only a product of nature, there was little logic in this decision. The Court of Appeals view that such oranges were not found in nature, in the patented form seemed unrefined. Nevertheless the principle of law that products of nature were not patentable remained firm and accepted.

The US Supreme Court once again had taken a good view in an another case.<sup>49</sup> The fact of the case is that Inoculants Company dealt with US patent number 2,200,532 issued on May 14, 1940, the patent concerned an inoculants for leguminous plants. The inoculants contained six non-inhibitive strains of bacteria of the genus 'rhizobium'.<sup>50</sup> None of the six strains was affected by the others with respect to its ability to fix nitrogen in legumes. In its broadest sense it claimed a mixture of six bacteria for use in fixing nitrogen in legumes. The patentee took all six strains which were known to aid in nitrogen fixation and combined them into a single inoculants, which he packaged and sold. The Seventh Circuit of Appeal in reversing the District Court held the claim valid. The Supreme Court reversed reasoning that the inventor did no more than take six strains of rhizobium which existed in nature and aggregate them.

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<sup>49</sup> Funk Brothers' Seed Co. v. Kalo Inoculants Co. 161, F. Zd, 981 (7th Cir 1947).

<sup>50</sup> Any of various bacteria, of the genus Rhizobium, that form nodules on the roots of legumes and fix nitrogen.

Finally, the court opined that the discovery of the fact that certain strains of each species of these bacteria can be mixed without harmful effect to the properties of either is a discovery of their qualities of non – inhibition. It is no more than the discovery of some of the Handiwork of nature and hence is not patentable. The aggregation of select strains of the several species into one product is an application of that newly discovered natural principle may have been the application of its hardly more than an advance in the packaging of the inoculants. Each of the species of root-module bacteria contained in the package infects the same group of leguminous plants which it always infected. No species requires a different use. The combination of species produces the new bacteria, no change in the six species of bacteria and no enlargement of the range of their utility. Each species has the same effect it always had. The bacteria perform in their natural way. Their use in combination does not improve in any way in their natural functioning. They serve the ends nature originally provided and act quite independently of any effort of the patentee. So it is well evident that in this case court successfully applied the product of nature doctrine. In writing, the majority opinion Justice Douglas seemed to reaffirm the orange rind case in it interestingly however he did not cite it.

### **3.2.1.3 The Exception to the Product of Nature**

#### **Non-Living Subject Matter**

In the years following Funk Brother<sup>51</sup>, the court gradually developed exceptions to the products of nature doctrine. If the products of nature were altered from the standpoint of purity, crystalline phase optical isomer- admixture with diluents or critical percentage ranges needed for operability, the court would allow composition claims<sup>52</sup> Put another way, if any one of the physical or chemical attributes of the naturally occurring compound composition or product of nature were changed in any way to provide a claim which pertained to novel subject – matter and had new utility, the claims were allowed. In order to illustrate this point

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<sup>51</sup> *Ibid.*

<sup>52</sup> Edmund v. Sease; from Microbes to Corn Seeds to Oysters to Mice: Patentability of Life Forms, Available at [www.Nationalaglawcenter.org](http://www.Nationalaglawcenter.org). Accessed on 2<sup>nd</sup> May 2013.

the researcher wants to note a famous case<sup>53</sup>, in this case, the invention was crystalline vitamin B-12 Merck successfully convinced both the patent office and the courts that crystalline Vitamin B-12 never existed before albeit Vitamin B-12 per se had existed previously. Essential to Merck's theory was the fact that crystalline Vitamin B-12 had properties different from those of Vitamin B-12 as it exists in nature.

Neither the courts nor the patent office or the public had any objection to creating exceptions to the products of nature doctrine as long as the patented subject – matter was non-living. For example, even if chemical compounds existed in nature, they nevertheless were routinely held patentable, if they existed in a different form after man's intervention.

#### **3.2.1.4 Patent on Plant Variety Protection Act of 1970: Another Path-breaking Statute Relating to Plants**

The Plant Patent Act which only confers patent protection to sexually reproduced plants was of little help to the establishment and promotion of developing seeds and agricultural industry due to the fact that most agricultural crops reproduce sexually and multiply by seed. It is not economically feasible to propagate agricultural cash crops such as soybean, cotton, wheat, barley, oats and rice through asexual reproduction. So the PPA did not provide the protection necessary to promote the agriculture industry. Because of many of these cash-crops are not amenable to hybridization techniques, are self-pollinating and are grown in the open, so the breeders cannot employ state laws to protect their interests.

The PVPA administered by the Plant Variety Protection Office through the US Department of Agriculture provides “patent-like protection” to novel varieties of sexually reproduced plants which parallel the protection afforded asexually reproduced plant varieties under chapter 15 of the Patent Act under PVPA, a plant breeder is issued a certificate of protection for novel and distinct varieties that breed true-to-type through sexual reproduction.<sup>54</sup> Certificate holders have the right during the terms of the plant variety protecting to exclude others from selling the

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<sup>53</sup> Merck & Co. v. Chase Chemicals, 273, F. supp. 68 (DN J.A. 1967)

<sup>54</sup> Elisa Rives: Mother Nature and the Court are Sexually Reproducing Plants and their Progeny Patentable: Under the utility Patent Act 1952 Available at [www.NationalAgLawCenter.org](http://www.NationalAgLawCenter.org) Accessed on 5<sup>th</sup> June 2014.

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variety or offering it for sale or of reproducing it or importing it or using it in producing a hybrid or different variety of their form.

In respect of differentiating both Funk Brothers and Chakrabarty, court tried to draw a thick line between the method of combination and difference in the consequential result that accentuates the court's point in Chakrabarty. In Funk Brother's the combination of the six species produced no new bacteria. The range of the bacteria's utility was not enlarged nor was the natural manner of the bacteria's performance altered. The bacteria acted independently of the patentee and basically served the same ends that nature provided. In contrast, Chakrabarty produced a new bacterium with markedly had different characteristics from any found in nature and are having potential for a significant utility quite separate by any of the organisms used in the combination. Therefore, through examining Chakrabarty's claim in light of the precedent cited in *Flook*<sup>55</sup>, the majority reached a logical conclusion in favour of patentability.

The majority in Chakrabarty addressed the government's argument in reference to the PPA and PVPA. The court rejected the government's assertion that the words manufacture and composition of matter includes living things neither in the 1930 PPA or the 1970 PVPA, would have been necessary. According to the court two factors neither of which is the fact, plants are alive excluded them from patent protection prior to these Acts. First there was the belief that plants were products of nature. This belief was derived from *Ex parte Latimer*<sup>56</sup> which rejected a patent claim for the fibre of pine seeds because it was considered as a product of nature. *Latimer* illustrates what the law was prior to the 1930 PPA. The second obstacle to patent protection as viewed by the majority was that plants were thought not amendable to the written description requirement of the patent law. As noted by the court since the new plant may differ from old only colour or perfume differentiates by written description was often inexpressible. In the 1930 PPA, the legislature rewarded the description to read as complete as is reasonably possible. The majority may have found alternative support for rejecting the governments

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<sup>55</sup> *Parker v. Flook* (1978), 437 US 584

<sup>56</sup> *Ex parte Latimer*, 1889, Dec. Commir. Pat 123

assertion in that the purpose of the 1930 PPA was to extend the patent system to a non-industrial area ignoring completely the fact that plants were alive.

The 1970 PVPA did not land much support to the government's position. The court explained that this Act was merely an exception of the 1930 Act. The court reasoned that prior to the Act, sexually as opposed to asexually reproduced plants were excluded from patentability because they would not be reproduced true to type through seedlings. By 1970, this type of reproduction was possible consequently, patent protection was extended.

The government argued that the Act specifically excluded bacteria with an explanation and that this cannot be read as supporting the conclusion that the exception was intended to preserve an assumed pre-existing patentability of bacteria. The court also acknowledged that the legislature gave no reason for the exclusion and offered two explanations. One reason was possible agreement with *in re Arzberger*<sup>57</sup> which held that bacterias were not considered as 'plants' for the purpose of the 1930 Act. A second reason may have been the congressional recognition that prior to the 1970 Act the patent office had issued patents for bacteria, under Section 101.

Under the PPA the written description requirement is relaxed in contrast to the UPTA which requires the deposit of an example in an approved facility. Thus, instead of requiring a detailed written description to enable one skilled in the art to make and use the invention as required under the general utility statute, the PPA allows access to a deposited example that can be replicated by asexual reproduction.

Nevertheless, another decision this time by the BPAI in *Ex parte Hibberd*<sup>58</sup> seemed to open the door to the PTO for accepting plants and seed patents under 35 USC. The issue addressed by the BPAI in *Hibberd* was whether Congress intended to restrict the scope of the utility patent Act by providing exclusive protection to plants and seeds under the PVPA and tissue culture under the PPA. In other words could plants, seeds and tissue culture be patented under both the general utility

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<sup>57</sup> *Arzberger*, 112 F. 2d, 884 (CCPA 1940)

<sup>58</sup> *Ex parte Hibberd* 227, USPQ, 443, 447 (Bd. Pat. App & Int. 1985)

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patent statutes and the PVPA and PPA respectively. The subject – matter on appeal in Hibberd involved technology designed to increase free tryptophan<sup>59</sup> levels in maize seed, plants and tissue culture. The PTO examiner rejected claims drawn to seed and plants as inappropriate subject-matter under 35 USC sec 101, because the claims comprise subject-matter within the purview of the PVPA.

In the present situation the plant breeder is seldom regarded as an “inventor” although he is actually an innovator of the highest type. The production of new plant often require more patience, skill, ingenuity, resourcefulness, knowledge and observation than the making of a mechanical invention/<sup>60</sup> Thus, in respect of patentability criteria either the PTO or the courts in US relaxed considerably and tried to protect the interest of the seed industries and individual breeders also<sup>61</sup>.

In 2001, the US, Supreme Court in a famous case confirmed that plants are patentable subject – matter under 35 USC Sec.101. The court stated that Congress never intended for the PPA and the PVPA to be the exclusive means for protecting plants and that utility patents could also be awarded to seed developers. Comparing the utility patent statute to the PVPA, the court noted that it is more difficult to obtain a utility patent for a plant because of requirements such as non-obviousness that are not present in the PVPA. Hence, because of the heightened requirements for receiving a patent, “utility patent holders received greater rights of exclusion than holders of a PVPA certificate. It is also evident that the old trend based on PPA has also considerably changed, which is reflected in a case<sup>62</sup> where tuber-bearing plants were specifically omitted from the PPA, because they reproduce through the same part of the plant that is sold as food. Some early patents were granted for non-food tuber propagated plants indicating that the concern with tuber propagated plants was that the tuber might be the product that is actually sold and

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<sup>59</sup> An essential amino acid having an indole side chain , it is present in many foods especially chocolate, oats bananas and milk, it is essential for normal growth and development and is the precursor of serotonin and niacin, any specific form of this compound, or any derivative of it.

<sup>60</sup> Cole Nursery Co. v. Youdeh Perennial Garden, Inc., 31 USPA (BNA) 94 ND Ohio, 1936, Exparte Moore, 115, USPA (BNA) 145 (PTO Bd App. 1957), Noel J. Byrne Fifty Years of Botanical Plant patents in the US, 3, EIPR, 222, 1981.

<sup>61</sup> *Ibid.*

<sup>41</sup> J.E.M Ag Supply Inc v. Pioneer Hi-Breed Intl Inc,122 s ct 593 (2001)

<sup>62</sup> Imazio Narsery Inc v. Dania Green House, 69, F. 3d, 1560 (Fed Cir. 1995)

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consumed as food. Newly discovered plants found in the wild by a plant explorer were also excluded as being a discovery and not an invention. The PPA was amended in 1954 however to provide for patent protection for any plant found in a cultivated state, “including cultivated spores, mutants, hybrids and newly found seedling.”<sup>63</sup>

It is very clear that during the 1970’s in the US, there was a turnaround in the point of view of the US courts regarding the product of nature doctrine. In 1970, CCAP ignored the product of nature doctrine. In 1970 the CCAP ignored the product of nature objection and in a particular case the court held that the biological origin of purified natural products does not preclude their novelty and accepted by implication, the proposition that such product, could be understood as manufacture and rewarded with patent protection.

So it is evident that after Chakrabarty’s decision almost all the seed industries in US started filing patent applications for their newly introduced crops or seeds. The Monsanto like seed giants are presently introducing huge varieties of new crops in the seed market and obtaining patent also in order to get monopoly over their seeds and crops.

#### **3.2.2 Patent on Plants in Europe**

In the 1960’s European Patent Law was considered unsuitable for protecting new plant varieties that were created using traditional breeding methods.<sup>64</sup> Although plant varieties were not considered suitable for patenting, it was recognized that there was a need to provide an alternative form of protection.

The Strasbourg Convention provides that contracting states are not bound to provide patents for plant and animal varieties. In 1973, EPC was signed creating a regional arrangement that allows patent protection to be obtained in 19 Member States by filing a single patent application at the EPO. For legislative simplicity, the EPC adopted the wording of the Strasbourg Convention and specifically excluded plant varieties from patentability since they are protected under the

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<sup>63</sup> Re Bergstrom, 427, F. 2d 1394, 195 USPQ (BNA) 256 (CCPA 1970)

<sup>64</sup> IPRIA, The University of Melbourne, Implications of the Exclusion of Plant and Animal Subject-matter from Innovation Patent, Available at [www.ipria/publications/submissions/plant/-animal-Exclusion.pdf](http://www.ipria/publications/submissions/plant/-animal-Exclusion.pdf). Accessed on 15<sup>th</sup> Feb 2010.

UPOV Convention and National Plant Breeders Rights Laws. At the time when these legislative instruments were developed the potential importance of biotechnologies could not have been foreseen.

While the exclusion of plant varieties according to the EPC provision<sup>65</sup> might seem to prohibit the patenting of plants in any form, the practice of the EPO has been to narrowly interpret this exclusionary provision as functioning to prevent conflict between patent and PVR systems. The EPO considers that the purpose of the EPC, exclusion was that European patent should not be granted for subject-matter under which patentability was excluded by the prohibition of dual protection under the UPOV Act.<sup>66</sup> Article 2 of the 1961-1972 and 1978 UPOV Acts ban state parties from providing protection both by means of a “special title of protection” and a patent for the same botanical genus or species.

EPC stipulates that plants are not patentable subject matters<sup>67</sup> This article reflected the fact that some of the main countries of the EC, which are member states of the UPOV Convention had already stipulated a special law for the protection of new plant varieties in compliance with the provisions of UPOV.

Most interestingly, new plant varieties can be protected by either a special law or patent law. However, the same botanical genus or species can be protected by only one of these laws under what is called prohibition of double protection. Incidentally, some member countries such as Italy and Hungary fulfil the protection by breeders’ rights as stipulated in the UPOV by introducing special regulations which are identical to the provisions of UPOV, into existing patent law. Therefore, a patent directed to a new plant variety under the UPOV is quite different in relation to its protected subject and its manner of protection under a plant patent based on regular patent law.

### **3.2.2.1 Claiming Patent Protection for Plants and Judicial Contributions**

There is now a system of protecting new plant varieties under the UPOV and in addition the breeders rights have been also enlarged and strengthened by the

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<sup>65</sup> Art 53 of the EPC

<sup>66</sup> UPOV Act 1978

<sup>67</sup> Art. 53 (b) of EPC 1978 reads, “plants or animal varieties or essentially biological processes for the production of plants or animals” are not patentable.

revised UPOV of 1991 in conformity with the advancement of new biotechnology such as Genetical Engineering. However, since the subjects under protection by the UPOV are confined to plant varieties, inventions directed to non-variety plants that do not meet the requirement of variety as defined under the UPOV as well as inventions directed to 'plants in general' such as an insect-resistant plant or a herbicide – resistant plant, which can be created by means of GE, that apparently fall outside the definition of variety cannot be effectively protected.<sup>68</sup>

Plants bred by traditional breeding methods such as artificial mating often cannot fulfil the disclosure requirements including the showing of reproducibility thereof or the patentability requirements. In contrast, plants produced by genetic engineering can readily meet these requirements. The production of plants by using new biotechnology such as genetic engineering involves enormous investment costs for the research and development thereof, and if only a narrow scope of rights restricted to an individual variety is granted, it would not be possible to fully recover the investment costs.

In view of this, a trial decision to admit the patentability of a general plant as explained below was made by the EPO in spite of the provisions of EPC, Art 53(B) that denies patentability of plant varieties.<sup>69</sup> Furthermore, an instruction the form of a directive was delivered by the EU to admit the patentability of the aforementioned general plants.

A trial decision permitting the patentability of non-variety plants in the EPC is that a plant patent first admitted under the EPC was a trial decision on a propagating material case is known as the *Ciba-geigy* case<sup>70</sup>, which was decided by the Technical Board of Appeals in the EPO. The fact of the case is that the patent claim which concerned a chemical seed coating was initially denied on the ground that the claims involved the patenting of plant varieties. The Board of Appeal reversed the decision. The claims included the following:

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<sup>68</sup> Asia Pacific Industrial Property Center: *Bio Patent*, Available at [www.jipic.or.jp/english/apic](http://www.jipic.or.jp/english/apic) Accessed on 7<sup>th</sup> Nov 2011

<sup>69</sup> *Ibid.*

<sup>70</sup> *Ciba-geigy*, 1979-85, EPOR Vol. C. 758

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Claim 13 – propagating material for cultivated plants treated with an oxide derivative according to same formula

Claim 14 – propagating material according to claim 13 characterized in that it consists of seed.

The Board of Appeal held that, “if plant varieties have been excluded from patent protection because specifically the achievement involved in breeding a new variety, is to have as its own form of protection, it is perfectly sufficient for the exclusion to be left restricted in conformity with its wording to cases in which plants are characterized precisely by the genetically determined peculiarities of their natural phenotype”. In this respect there is no conflict between areas reserved for national protection of plant varieties and the field of application of the EPC. On the other hand, innovations that cannot be given the protection afforded to varieties are still patentable if the general prerequisites are met.”

According to Art 53 of EPC, plant varieties are not patentable. The Board of Appeals noted that the claims embraced plants propagated from material (eg. seeds) that had been treated with an oxide derivative to confer herbicide resistance. The object was the claims was not considered to be a plant variety and therefore the patent was allowed. The Board of Appeal stressed that, “no general exclusion of inventions in the sphere of animate nature can be inferred from the EPC. Thus, in spite of the existence of Article 53(b), this decision thereafter was frequently cited as strong grounds for supporting the patentability of a general plant created for instance by a genetic engineering method, and hence not limited to a plant variety.

A similar case dealt with by the Board of Appeal was a hybrid plants case<sup>71</sup> Here the Board of Appeals granted Lubrizol patent protection for the method of modifying plant cells with certain Ti-Plasmids<sup>72</sup>, as well as plants produced from them. The Board stressed in this case that exclusions from patentability were to be “construed narrowly. It noted that the generic group of plants produced by the

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<sup>71</sup> Lubrizol, 7320/87, Lubrizol Hybrid plant (1980) EPOR 173.

<sup>72</sup> Ti-Plasmid is a plasmid carried by the crown gall bacterium, *Agra bacterium tumefactions*, part of which (T-DNA) becomes integrated into the chromosomes of infected tissue. Crown gall is a plant tumour caused by the bacterium *Agra bacterium tumefactions*.

process described in the patent application could not be considered new variety because it failed to meet the requirements of a plant variety distinctness, uniformity and stability. Furthermore the process by which the group of plants were produced could not be considered “essentially biological” because it involved variety of human intervention. In this case it considered steps such as the use of cell culture to maintain heterozygous parents as a technical process and not a biological one. On the other hand plants produced through conventional breeding such as crossing and selection are considered biological and as such not patentable. Therefore since the claim did not relate to the category of plant variety or a process essentially biological, a patent was allowed to Lubrizol.

Another EPO decision of great importance is the one to the Plant Genetic System’s case.<sup>73</sup> This EPO decision has given a new horizon to Article 53 of the EPC by interpreting it in a unique way Plant Genetic System<sup>74</sup> was granted a patent in respect of its claims concerning a transgenic plant having a foreign nucleotide<sup>75</sup> sequence incorporated into its genome and methods for making and using the transgenic plant. Green peace opposed the patent under Art. 53(a) and 53(b). Under Art 53(a) it argued that it was immoral to patent plant genetic resources because they were part of the ‘heritage of humankind’ and thus should remain intact for future generation and available to all without restrictions. Regarding 53(b) Green Peace argued that said article clearly states that plant varieties, their seeds and the process to make them are not patentable.

When analyzing the case the Board of Appeals found that there was no ground under Art 53(a) to prevent patenting. As the said article does not provide any definition of morality, the Board of Appeals held that it was to be interpreted as to exclude only “inventions, the exploitation of which is’ likely to breach the public peace or social order or it seriously prejudice the environment”. The Board found that there was no evidence in the claim or in the case that could prove that the exploitation of the inventive plant would seriously prejudice the environment. Therefore, it concluded that the Plant Genetic System’s claim was not contrary to

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<sup>73</sup> Plant Genetic System Glutamin Synthetase Inhibitors. Decision EPO T. 356/93, Plant Genetic Systems Offices Journal, EPO 1995 at 545.

<sup>74</sup> Plant cells resistant to glutamine syntheses inhibitors made genetic engineering.

<sup>75</sup> *Ibid*

public morality and therefore it did not fall within the scope of Art 53(a) of the EPC. In this regard the researcher says that, “the scope of patentability is expanded while the role of moral standards in the operation of the patent system is being increasingly limited.

According to the Biotech Directive, plant and animal varieties are not patentable<sup>76</sup>. It also says that inventions which concern plant or animals shall be patentable if the technical feasibility is not confined to a particular plant or animal variety<sup>77</sup>. Further, it allows the patenting of plant genetic resources by stating that biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature.<sup>78</sup>

Thus, if the new plant introduced has already existed in nature, cannot entitle patent protection, this is otherwise known as product of nature. The product of nature doctrine influenced the European courts considerably. Indeed, at that point of time, the first objection raised by the legal doctrine was that breeders’ products, even those artificially bred were not the result of a creative process and hence were not inventions as such. In other words, breeders’ products were products of nature and were “non-inventions” or as the Germans put it “Nicht-Erfindungen”,<sup>79</sup>

In Germany, the product of Nature (Naturstoff) objection had only a few followers who opposed patent protection for culture methods, breeding methods and breeders’ product barring their objection on the fact that these inventions were largely the result of ‘nature’s works with minor human intervention.

In Belgium, the old doctrine examined the basic scope of the reproducibility requirement but did not determine whether the requirement should be applied to plant inventions. More recent doctrine has raised the problem of the non-reproducibility of plant inventions. On one side, rigid interpretation of the

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<sup>76</sup> Art. 4(1)(a) of Biotech Patent Directive 98/44.

<sup>77</sup> *Ibid.* Art. 4(2),

<sup>78</sup> *Ibid.* Art 3(2)

<sup>79</sup> Geertrui Van Overwalla; *Patent Protection for Plants; A Comparison of American and European Approaches*; 39, IDEA, 143, 1998-1999. Available at SSRN.com/abstract =1718614. Accessed on 14<sup>th</sup> Oct 2012.

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reproducibility requirement expresses that, the process of making which led to the first specimen of the new variety should be repeatable since such repetition was not possible practice, plant patent protection should be excluded. On the other side, a more flexible interpretation' of the reproducibility requirement allows, that it is sufficient for additional 'copies' of the first specimen of the new variety to be obtained by another process, specifically multiplication process of sexual or asexual reproduction. In most cases, this requirement can be met meaning that plant patent protection should not be found on the basis of non-reproducibility.<sup>80</sup> The general requirement that an invention should be reproducible derived from the German requirement of industrial utility, an unrepeatable process is not industrially applicable and hence not patentable.

Finally, it is understood that, in Europe the ongoing debate over reproducibility was tackled by the German Federal Supreme Court. In Rose breeding case, the court reasoned that the reproducibility requirements did not have to be strictly applied in cases of process protection for multiplication methods and held that a repetition of the process of making was not necessary. But in seven years later in Rote Taube,<sup>81</sup> the court changed its policy and held that a person skilled in the art must be able to repeat the process of making a new organism before patent protection should be granted. The court intended for this strict reproducibility requirement to apply to process protection both for the process of making a new organism and for multiplication methods for a new organism as well as to product protection for the new organism.

Transferring this reasoning of the German Federal Supreme Court in its microorganism cases to the question of plants patent would suggest that "product protection" for plants is always possible because this approach removes the most critical impediments to patenting plant, the repetition of the process of making. Process protection for such products seems possible only if the process of making can be repeated which is most common in the context of modern genetic modification techniques that can be accurately described and repeated with few problems by persons skilled in the art. As a result, when a patent application for a

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<sup>80</sup> *Ibid.*

<sup>81</sup> BGHZ, 52, 74, 72 GPUR 692, (1969).

plant invention contains product claims and process claims, the product claims are in principle always admissible if the requirement of patentability criteria are met, while process claims are only admissible if the process can also be repeated. Thus it is very clear that the patentability of plants and seeds are currently feasible without any rigid legal obstacles.

### **3.2.3 Patentability of New Plants in Canada**

Currently, the greatest number of life forms being developed are plants exemplified by inventions such as the new protein rich and oil rich crops, a new strain of wheat with improved qualities for baking and various plants with enhanced abilities to grow in hostile conditions such as poor soil, poor weather, a post-infested environments. In addition new forms of genetically engineered a soybean, cotton, rice, corn, oil seed-rape sugar beet, tomato, and ‘alfalfa’ crops”<sup>82</sup> have been produced and expected to enter the market place.

The great profit potential of new plant life forms has led inventors to seek some form of proprietary protection. As a result, intense pressure has been brought to bear upon the patent system to incorporate these new life forms or its protective sphere.<sup>83</sup>

Canada does not yet enjoy the luxury of specific plant protection legislation. This may change in the future as the Canadian government has recently taken a legal framework entitled, Plant Breeders Rights Act (PBRA). However, the rights granted to the inventors under this law are not as extensive as the rights available under the current patent legislation. Thus inventors seeking full and certain proprietor protection in Canada for their new plant life must rely on the current Patent Act.

Unfortunately, the accessibility of such patent protection in Canada remains unclear. This lack of clarity was enhanced by the Supreme Court of Canada’s decision in Pioneer Hi-Bred,<sup>84</sup> which rejected a patent application for a new strain of soybean. Legal commentaries addressing this decision have expressed the

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<sup>82</sup> A plant principally of *Medicago sativa*, grown as a pasture crop or a type or breed of this plant.

<sup>83</sup> Randy W. Marusyk, *The Patentability of New Plant Life Forms in Canada*, Hein online 16 can Bus L. T. 340 1990.

<sup>84</sup> Pioneer Hi-Bred Ltd v. Canada, Commissioner of Patents (1989) 60 D.L.R. (4<sup>th</sup>) 223, S.C.R. 1623.

opinion that multi cellular plant patents are now prohibited in Canada. In spite of such claims, this common argues that the decision in Pioneer Hi-bred should not be treated as indicating that all new forms of plant life are excluded from patent protection in Canada.

But the recent pressure to grant patents for new life forms in Canada began with the Patent Appeal Boards' decision in *Re Application Abitibi*.<sup>85</sup> Indeed the Board established some early guidelines that were directly relevant to new varieties of plant life when it stated that 'algae' is a form of plant life of which more than 35,000 species have been described. Thus, by including algae in its list of patentable life forms, the Board indicated that it was willing to extend patent protection to any new plant varieties derived from any plant species.

The first test case to address the patentability of new multi-cellular plant life forms began with Pioneer Hi-Breed's filing for a plant patent on May 18, 1983. The application involved a new strain of soybean (variety 0877) developed through intense selective cross-breeding, improving the plant's oil content, maturation rate, yield, seed toughness and disease resistance. The application was rejected by the patent examiner as "the variety of soybean plant disclosed and claimed in this application does not fall within the statutory definition of invention as given by section 2 of the Patent Act."<sup>86</sup> Moreover, the examiner relied on section 12-03-01(a)<sup>87</sup> of the manual of patent office practice to determine the scope of section 2. The examiner thus concluded that the interpretation of "invention" as given in sec 2 has always excluded new varieties of plants and seeds. The examiner's decision was appealed to the Appeal Board and Commissioner of Patents. After careful examination of the Canadian Courts' interpretation of Section 2 of the Patent Act, the Board concluded that, "the Canadian Courts have not taken a very broad wording of section 2 at face value. They provide direction that restrictive meanings be given to section 2. As a result without receiving an alternative direction from

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<sup>85</sup> *Re Application of Abitibi Co.* (1982) 62 C.P.R. (2d) 81.

<sup>86</sup> Section 2 says that "invention means any new and useful art, process, machine, manufacture or composition of matter or any new and useful improvement in any art, process, machine, manufacture or composition of matter.

<sup>87</sup> Sec 12.03.01(a) reads as, "subject – matter for a process for producing a new genetic strain of variety of plants or animals or the product thereof is not patentable. This exclusion does not include a micro-biological process or product thereof.

the courts, Section 2 of the Patent Act could not be expanded to encompass new multi-cellular life forms such as plants.

An appeal to the Federal Court of Appeal was equally unsuccessful.<sup>88</sup> The Court of Appeal also expanded on the Board's reasoning for rejecting of the application and the court said that, "the alleged invention is capable of being described, pursuant to section 36(1) of the Act, so as "to enable any person skilled in the art or science to which it appertains, to make it .... Indeed, the material filed by the appellant in support of application shows that the new variety of soybean was developed through cross-breeding and selective-breeding and that the selection steps of the development involved a degree of luck, 'an element of good fortune.'"

Finally, the Court of Appeal concluded its judgment by pointing out that plant breeding was a well-established industry when the Patent Act was originally enacted by Parliament, and that if Parliament had meant to extend statutory proprietary protection to such new plant strains it could easily have done so. Thus the court is implicitly stating that other methods such as genetic engineering, with its much higher rate of reproducibility for someone skilled in the art may satisfy the section 36(1) requirement.

On further appeal, the Supreme Court of Canada affirmed the Federal Court of Appeal's decision and approved the reasoning with respect to section 36(1). If a new plant life form fulfills the traditional requirements of the Patent Act, it would be eligible for patent protection/ Pioneer Hi-Bred's application did not satisfy these requirements and it is for this reason alone that it did not warrant patent protection.

### **3.2.4 Patent on Plants - Indian Position**

Since 1970, India did not allow patent on seeds or plants and had no system of protection for plant varieties. Indian policy was based on the concept that plant varieties and seeds were the common heritage of humankind. Indian Patent Act specifically excludes plants and animals in whole or any part thereof including seed varieties and species and essentially biological processes for production of plants and animals from the ambit of patent protection. In the case of plant varieties .TRIPS Agreement provides option to Member countries for protecting

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<sup>88</sup> Pioneer Hi-Bred Ltd v.Canada, Commissioner of Patents, (1987) 14.C.P.R(3d) 491.

them by patents or by an effective sui generis system or by combination of patent and sui generis. India chose not to give patent to plants and to protect plant by the sui generis system. Sui generis system grants an exclusive rights to the innovator of a plant variety for producing, processing, stocking commercializing, importing or exporting the propagating material of the protected variety. This system is governed by the Protection of Plant Varieties and Farmers Right Act 2001 (PPVFR). This Act constitutes India's attempt complying with the obligations under Article 27.3 .b of TRIPS concerning the protection of plant varieties.

### **3.2.5 Problem of distinguishing between Plant Varieties and Plant Patent**

While disagreement continues among nations regarding the appropriate means of providing patent protection for plant varieties, there has been widespread acceptance of the practice of providing patent protection for plants and seeds and methods of making or using plants or seeds, that are not limited to specific varieties as well as genetically modified plants.<sup>89</sup> The law of many countries seem to suggest that a sui generis form of protection is appropriate for plant varieties whereas utility patents are appropriate for larger classes of plants.<sup>90</sup> The difficulty then arises in delineating between the types of inventions in order to determine which form of protection is the most appropriate one.

According to UPOV, a plant variety is defined as a plant grouping within a single botanical taxon of the lowest known rank, which grouping can be defined by the expression of the characteristics, resulting from a given genotype or combination of genotypes.<sup>91</sup> Given the variability in plant groupings within different taxon such a definition of plant variety is sure to vary in breadth from one plant taxon to the next. Consequently, the delineation of inventions suitable for sui generis protection from those suitable for utility patent protection becomes increasingly challenging.

A broad claim to a plant that encompasses many different plant varieties would likely be patentable. For example, wide hybrid crosses between two

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<sup>89</sup> JEM A.G. Supply Inc v. Pioneer Hi-Bred International Inc. 534, US 124 (2001)

<sup>90</sup> Amy Nelson, *Is There an International solution to IP Protection for Plants?* 37, Geo, Wash, Int'l Rev. 997. (2005)

<sup>91</sup> Art 1 of UPOV

distantly related plant taxon comprising numerous plant varieties may reproducibly lead to plants with unique distinguishing characteristics. The resulting population of plants would likely be entitled to utility patent protection as it would encompass multiple plant varieties. In contrast crosses between more closely related plants taxon would likely produce relatively homogenous plant varieties which would only be entitled to protection under a *sui generis* system<sup>92</sup>

Drawing a clear line between what is eligible for patent protection and what is eligible for *sui generis* protection is potentially quite difficult. It is also unclear whether the ineligibility of plant varieties for utility patent protection would extend to related claim such as to plant parts or to methods of plant breeding or simply to claims to the plant varieties themselves. Moreover, by this reasoning genetically modified plants whose patentability rests on a particular transgene would be entitled to a utility patent protection whereas, a specific plant variety comprising the same transgene would be entitled only to a *sui generis* form of protection. The TRIPS Agreement also leaves to each country's discretion whether to protect new plant varieties by means of patent or by effective *sui generis* system or by any combination there of.<sup>93</sup>

Another problem may arise if a country that allows plant breeders to obtain both utility patent protection and protection under a *sui generis* system. If a breeder first obtains a plant breeder's right, he can then market his seed during prosecution of a utility patent application and label the seeds as "patent pending."<sup>94</sup> A farmer who purchases the seed will not know if a patent will ever be issued for the purchased variety before he has to make a decision on whether or not to save seed. Consequently, in a country, where utility patents and *sui generis* protection are available farmers may avoid the practice of saving seed to avoid being sued for patent infringement even if many of the varieties are ultimately protected only under the *sui generis* system.<sup>95</sup> Hence, the farmer's exception provided by *sui*

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<sup>92</sup> *Ibid.*

<sup>93</sup> Art. 27 of TRIPS Agreement 1995

<sup>94</sup> Marking of products as "patent pending" is a routine practice for patent applicants in order to put potential infringers on notice.

<sup>95</sup> For example, a farmer might have to decide whether or not to save seed while the patent application is still pending in the patent office. Due to the fear of a lawsuit for infringement the farmer would likely to choose not to save seed. If in the end no patent is obtained for the plant variety but, instead only *sui generis* protection is obtained then the farmer has needlessly given up his right to save seed.

generis system may be meaningless in a country also providing utility patent protection.

In the light of the foregoing problems, it seems unduly cumbersome to have multiple system of plant variety protection within a particular country and it would appear much more desirable for countries to maintain a single form of intellectual property protection for plant varieties.

### **3.3 Patent on Animals**

The modern biotechnology is a significant change in as well as enhancement of human kinds ability to manipulate and control nature. The rapid development towards considering all life forms as patentable subject – matter except human beings, results in patenting of transgenic animals. Also of great concern is the extent to which human biological material is being taken into private ownership. There have been patent applications for human genes and human cell lines.<sup>96</sup> Human genes have been inserted into animals and there is the prospect of human animal hybrids. Also another aspects which are important to consider under biotechnology is patentability of genes and DNA sequences. Patenting of genes would be essential since it would provide an incentive for the manufacture of new and improved therapeutic drugs and its applications in different areas of biotechnology.

It has also been reported that male mice have been modified to produce rat sperm, one species being used to modify another. It seems that this technique could at least in theory be used to make another animal produce human sperm. Moreover the flounder has a gene which protects against freezing. This gene has been transferred into a tomato to make freezing of tomatoes possible. So it is apparent that such kind of tomatoes contain an animal component other transgenic tomatoes are being produced and distributed which take about twice the normal time to open apparently to increase the time they can be displayed on shop shelves before going bad. This tomato is resistant to an antibiotic and there are fears that this resistance can be passed on to human beings.

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<sup>96</sup> Manfred Davidmann: *Creating, Patenting and Marketing of New Life Forms of Life*, Available at [www.solhaam.org/articles/clm.505.html](http://www.solhaam.org/articles/clm.505.html). Accessed on 24<sup>th</sup> July 2010.

Also, it seems that about 50 transgenic pigs were sold for human consumption in Australia. Rat genes have been transferred to pigs in an attempt to increase their reproductive capacity. More so, US scientists had inserted human growth hormone gene into the body of pig in order to make it of big size. GM Salmons have been produced which apparently grow quickly to something like 40 times of their normal weight.

Stem cell research and the advent of Dolly, the cloned sheep opened the eyes of the researchers. Animals have however been cloned early in 1960's and humans since the early 1990s the latter by the use of techniques of embryo splitting, less spectacular than the nuclear transfer technique which cloned Dolly from an adult somatic cell'.<sup>97</sup> Although still extremely unreliable as a technique, the Dolly method of cloning was a scientific breakthrough of immense significance in mammals, not least in terms of its implications for demography and reproduction.

### **3.3.1 Patenting of Transgenic Animals**

Unlike patenting of other life forms, these animal patents raise more and more legal, moral and ethical issues. In spite of the issues, animals are patented today that leads to access its patentability. The main issue is regarding the scope of these patents, besides the problem of adequate disclosure in animal patents. The claims of the animal patents are extremely broad which indicates the lack of well – defined scope of this patent and are not supported by the description. Another important issue is the crucial quality of animals like plants, that set them apart from other invention in their self-reproducing tendency. This distinguishing characteristic has raised many complex issues in extending the coverage of the patent statute to animals especially within the agricultural industry. All these raised doubt relating to the implication of these facts in the current patent system.

There are claims to the process for creating transgenic animals and this had already been determined as patentable. Besides the products animal itself could be patented now whether the term 'manufacture'<sup>98</sup> and the phrase 'composition of

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<sup>97</sup> Any normal cell of an organism that is not involved in reproduction, a cell that is not on the germline

<sup>98</sup> 35 USC Sec 101 states that an invention be either a process, machine, manufacture or composition of matter. A 'manufacture may be defined as the production of articles for use from raw or prepared materials by giving to these materials, new forms, qualities, properties or combination whether by Gent labor or by machinery .... American Fruit Growers Inc v. Brogdex Corpn.283, US – 1, 11, 1931.

matter”<sup>99</sup> within the context of the patent law are significantly broad to include transgenic animals. How the patentability criteria are fulfilled by the transgenic animals in order to become eligible for patent protection? These are the matters to be examined for the analysis of patentability of transgenic animals. Hence, the researcher wants to analyze the legal development of patenting transgenic animals the patentability criteria in transgenic animals and the scope of animal patent.

### **3.3.2 Legal Development of Transgenic Animal Patent**

Before the intervention of the policy makers Courts in some countries had been making some sort of innovations in respect of determining the patentability of animals or transgenic animals. Initially court in US admitted the doctrine of ‘product of nature’ in a very famous case<sup>100</sup> wherein the patent application claim covered fresh shrimp from which the head and sand vein had been removed. The patent examiner rejected the claim on the ground that the product did not differ from ordinary shrimp of commerce. The patent applicant agreed that the removal of the sand vein rendered his deveined shrimp different from those ordinarily available. Citing *America Fruit Growers*<sup>101</sup>, the Board of Appeal stated,

“The claim has also been rejected as in substance defining a product of nature under the authority of the decision in case of *American Fruit Growers* case. Applicant is not claiming the whole shrimp. However, the part he is claiming is still in its natural state, which has been changed in no manner. We consider this ground of rejection to be sound.”

Presumably, a shrimp with some parts removed still had all of its remaining parts intact as they existed in nature Nothing which remained was unchanged in its general character from its natural state. This decision seems more defensible than the *Orange Rind*<sup>102</sup> case there however, man intervened only to eliminate something from the shrimp, cores, the flesh of the shrimp remained natural. Thus

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<sup>99</sup> Composition of matters refer to all composition of two or more substance s and all composite articles whether they be results of chemical union or mechanical mixture or whether they be gases fluids, powders or solids, *Shell Dev. Co. v. Watson*, 149, f. Supp 279, 280 (1958).

<sup>100</sup> *Ex parte Grayson* (Deveined Shrimps case 51 USPQ (BNA) 413 PTO Bel. App. (1941).

<sup>101</sup> *Ibid.*

<sup>102</sup> *Ibid.*

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there was no novel combination and it was a product of nature. So in this case “less quantity” of human intervention concept was defeated by “products of nature” doctrine.

In another classic case<sup>103</sup> the court had not appreciated the patentability over dwarf chicken. In this case, the patent applicants discovered in chicken a gene for dwarfism, which allowed product of dwarf breeding hens. These dwarf hens could be mated with normal rooster. The resulting eggs produced normal and desirable heavy meat offspring. Cost savings resulted, since the dwarf hens were used solely for breeding purposes and did not consume much feed. In the patent application, Claim – 1 covered the process for producing normal chickens from dwarf hens Claim-2 related to the product the process itself, i.e. a normal chicken descended from a dwarf hen. These claims were rejected because they lacked utility and they related to non-statutory subject – matter. The Patent Office Board of Appeals and the Patent Examiner held that claim -1 did not cover a ‘patentable process’ within the meaning of 35 US C 101<sup>104</sup> and that a thing occurring in nature (i.e. a normal chicken produced by the process prescribed in claim – 2) was not an ‘article of manufacture’.

Thus, in a classic case of sidestepping the Court of Customs and Patent Appeals avoided the whole issue of patentability of a living organism and rejected the patent application on the basis of defects in the claim under 35 US S. 112.<sup>105</sup> The law requires that patent claims particularly point out and distinctly claim the subject – matter which the applicant regards as his invention. However since there is some inherent uncertainty in breeding practices for some time, the patent office used this “sidestep” to avoid more difficult substantive issues.

#### **3.3.3 Post Chakrabarty Scenario in Patent on Animals**

The US courts new dimensional approach paved the way to obtain patent over life forms. In Ex parte Allen<sup>106</sup> the Board of Patent Appeals and Interference again was called upon to interpret and expand the Chakrabarty decision in 1987.

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<sup>103</sup> Merat (Dwarf Chicken case) 519, F. 2d 1390 (CCPA 1976).

<sup>104</sup> *Ibid.*

<sup>105</sup> US Patent Act 35 of US.

<sup>106</sup> Ex parte Allen (Oyster’s case) 2 U.S.P.Q 2d (BNA) 1425. (Pat. App. & Int. 1987.)

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This case obviously tested the strength of Chakrabarty for the first time. Ex parte Allen involved a patent application for a man made non-naturally occurring 'strain' of "pacific polyploidy oysters" and a method of inducing polyploidy in oysters. These oysters made sterile by induced polyploidy grew much larger than normal oysters<sup>107</sup>The examiner rejected the application on the grounds that.

1. The polyploidy oysters are living organisms, thus falling outside the scope of the patent statute, and
2. The oyster do not satisfy the non-obviousness test for patentability because the organism is not sufficiently different from those produced by other known means.

The Board of Patent Appeals reversed the Examiner's Determination on the first ground holding the Chakrabarty makes it clear that the patent statute encompasses man made life forms. Therefore pursuant to the Supreme Court decision in Chakrabarty, Board held that the polyploidy oysters were 'non-naturally occurring' "manufactures" or "combination of matters" within the scope of sec. 101. The Board however upheld the examiner's finding that the polyploidy oyster failed to meet the non-obviousness test for patentability and thus denied the patent. The Federal Circuit affirmed the Board's decision.

On April, 7, 1987, four days after 'Allen' was decided the PTO<sup>108</sup> issued a statement reflecting the policy for which Ex Parte Allen stood. The PTO issued a rule announcing that non-naturally occurring, non-human multicellular organisms including animals are patentable subject-matter within the scope of sec. 101.<sup>109</sup>The

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<sup>107</sup> Polyploid was induced by applying hydrostatic pressure to fertilized oyster eggs at a specified intensity for a specified duration thereby producing increased growth. Polyploid refers to a numeral change in a whole set of chromosomes, polyploid can be induced by some chemicals which can result in chromosome doubling.

<sup>108</sup> Commissioner of Patent and Trade Mark issued this disputed notice immediately following the decision in Ex parte Allen, 2 USPQ 2d (BNA) 1425. (Bd. Pat. App & Int. 1987).

<sup>109</sup> The full text of the PTO's appeared as follows. 'Animals patentability: - 'A decision by the Board of Patent Appeals and interferences in Ex Parte Allen 2, U.S.P.Q 2d 1425 (Bd. App & Int. April 3, 1987) held that claimed polyploidy oysters are non-naturally occurring manufactures or compositions 35 USC S.101. The Board relied upon the opinion of the Chakrabarty's decision as it had done in Ex parte Hibbard 227, USPQ 443 (Bd. App & Int. 1985) as controlling authority that congress intended statutory subject-matter to "include anything under the sun, that is made by man". The PTO now considers non-naturally occurring, non-human multi-cellular living organisms including animals to be patentable subject matter within the scope of 35 USC Sec. 101.

The Board's decision does not affect the principles and practice that products found in nature will not be considered to be patentable subject-matter under 35 USC Sec. 101 and 102. An article of manufacture in nature will not be considered patentable unless given a new form, quality, properties or combination not

rule expressly relied upon the decision of Chakrabarty, Ex parte Hibbard and Ex parte Allen. The 1987 PTO statement officially allowed patent application to be filed for Genetically Engineered animals. By 1990 more than seventy five patent applications for multi-cellular living animals were pending. The back log has created an estimated seven years delay from patent application filing date to probable patent issue date. Nevertheless, the seventeen years exclusively right begins with the issuance of the patent met the filing date of the application. In spite of the delay, the PTO issued the first patent for transgenic animal i.e. Harvard Mouse in 1988.

### **3.3.4 Harvard Mouse Case: A Historical Breakthrough**

Seven years after the Chakrabarty's decision in 1988, Harvard University had filed a US patent application for a transgenic non-human mammal, specifically a mouse that was genetically altered to increase its susceptibility to cancer by incorporating a cancer promoting "onco-gene" into each of its cells. The mouse could be used for 'Carcinogenicity testing and for testing new drugs for the prevention and treatment of cancer'<sup>110</sup> The Harvard Onco-Mouse patent<sup>111</sup> issued in 1988 non-human mammal<sup>112</sup> containing a recombinant activated oncogene sequence that was introduced into the mammal or an ancestor of the mammal, at an embryonic stage. Here the claims include both product and process. Dupont, the patent licensee currently sells "onco mice" for \$100 (dollar) per mouse. This

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present in the original article existing in nature in accordance with existing law, examples are, Funk Bros Seed Co. v. Kalo Inoculants' co. 333, USS 127. 76 USPQ 280 (1948), American Fruit Growers v. Broadex, 283, US 1, 8 USPQ 131 (1937), Ex parte Gravon, 51, USPQ 413, (Bd. App. 1941).

A claim directed to or including within its scope a human being will not be considered to be patentable subject-matter under 35 USC 101. The grant of a limited but exclusive property right in a human being is prohibited by the constitution. Accordingly it is suggested that any claim directed to a non-plant multi cellular organisms which would include a human being within its scope include the limitation, non-human to avoid this ground of rejection. The use of negative limitation to define the metes and bounds of the claimed subject-matter is a permissible form of expression, in re Wakefield, 422 F. 2d, 897, 164. USPQ 636 (CCPA 1970).

Accordingly the PTO is now examining claims directed to multi-cellular living organisms, including animals. To the extent that the claimed subject-matter is directed to a non-human non-naturally occurring manufacture or composition of matter, a product of human ingenuity" such as claims will not be rejected under 35 USC 10 as being directed to non-statutory subject-matter, April 7, 1987, 1077 OFFICIAL GAZETTE PAT OFFICE 24, (April 21, 1987).

<sup>110</sup> This transgenic animal could be used as an experimental model for human cancers because significant members of the transgenic mice develop a type of breast cancer within a few days/months/years.

<sup>111</sup> US Patent No: 4, 736,866.

<sup>112</sup> In general a mammal is an animal possessing the following combination of characteristics four-chambered heart, end endothermy or warm-bloodedness, insulating layer of hair or fur, differentiated teeth behavior modifiable by experience embryonic development in the mother's uterus and offspring nourished by milk.

transgenic animals. patent sparks debates over the “PTO statement”<sup>113</sup> which leads to the Animal Legal Defence Fund (ALDF) and other ‘interest’ groups challenged the legality of the PTO statement issued by Commissioner Quigg, and they had filed a case<sup>114</sup> against the decision taken by the PTO.

ALDF’s decision is the case as a vehicle to discuss the underlying controversy surrounding animal patents and to examine the implications of the case in terms of the future direction of the controversy. The controversy surrounding transgenic animals patents set the stage for ALDF v. Quigg. The plaintiff in ALDF, animal rights group, farming groups and individual farmers challenged the issuance of animal patents by attacking the validity of the PTO’s 1987 rule. The Federal Circuit however did not reach the issue of whether the rule constituted valid law, as it held that the plaintiffs did not have standing to bring the suit.

The main issue in this case is whether the PTO’s 1987 rule constitutes valid law and it is necessary to analyze arguments of plaintiffs whether they have challenged transgenic animals patent. The controversy in ALDF originated when the plaintiffs challenged the rule on both procedural and substantive grounds. The plaintiffs filed suit in the District Court for Northern District of California challenging that Donald Quigg, then Commissioner of Patent and Trade Mark, issued the rule in violation of the public notice and comment period requirement of the Administrative Procedure Act (APA) and 5 USC Sec. 553 (b) and (c)<sup>115</sup>. The plaintiffs also claimed that Quigg had violated another provision of the APA by exceeding the statutory authority granted to him under the Patent Act. Thus, the plaintiffs’ complaint stated two causes of action. The defendants filed a motion to dismiss the complaint for failure to state a claim upon which relief may be granted.

In granting the defendant’s motion to dismiss the court concluded that the rule is an interpretive rule as that term is used in 5 USC Sec. 553 (b) and is thereby exempted from the public notice and comment requirements of the APA. Further more because

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<sup>113</sup> *Ibid*

<sup>114</sup> Animal Legal Defence Fund v. Quigg, 710, F. upp.728 (N. D. Cal 1989).

<sup>115</sup> The PTO did not publish the Rule in the Federal Register prior to its promulgation nor did it invite public comment.

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the PTO is authorized to issue such rules or “notices” and because the Rule neither abridges nor enlarges the rights of anyone the PTO could not, as a matter of law have exceeded its statutory authority in promulgating it<sup>116</sup>. Finally, the court concluded that this action neither raised the status of prior precedent nor the validity of any animal patents actually issued.

The plaintiffs appealed the District Court’s order of dismissal before the Court of Appeals for Federal Circuit. ALDF’s challenge of the Rule on substantive grounds alleged that the Commissioner in issuing the Rule exceeded the patent Act’s grant of authority. Specifically, ALDF alleged that the PTO Commissioner issued the Rule in violation of Sec. 706(2)(c)<sup>117</sup> of the APA, which concerns the action a reviewing court must take when confronted with an agency that exceeds its statutory jurisdiction. The plaintiffs sought as relief for this alleged violation, a court declaration that animals are not patentable subject-matter and an injunction against the issuance of any animal patents. The arguments of the plaintiff (Animal Rights groups, Farmers) were denied by the Court by holding that plaintiffs lack standing.

#### **3.3.5 View of Animal Rights Group**

ALDF alleged as its injury that its purposes and activities as well as those of its members had been and would continue to be frustrated and adversely affected by the Commissioner’s new rule. Accurately, they objected to Quigg’s refusal to provide the public with notice of and an opportunity to comment on, the Rule prior to its promulgation. Federal Circuit ruled that ALDF lacked standing calling its allegations, “patently insufficient under controlling precedent”. Although the court recognized that for the purpose of standing, a plaintiff’s injury need not be economic in nature, it concluded as the Supreme Court held in *Sierra Club v. Morton*<sup>118</sup> that the APA does not permit organizations or individuals to use the judicial system to vindicate their own value preferences. The Federal Circuit

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<sup>116</sup> The Court agreed with PTO’s position and found that the decision cited within the rule under the law at the time, the rule was promulgated and that they continued to be the law. Moreover the court found that those decisions held precisely what the rule stated, “that non-naturally occurring non-human multicellular living organisms including animals are patentable subject-matter under 35 USC sec. 101.” The district court granted the defendant’s motion on the grounds that the ‘Rule’ was interpretative of prior decisional precedent and was thus expressly exempt from the notice and comment requirement of APA.

<sup>117</sup> 5 USC Sec. 706(2)(c).

<sup>118</sup> *Sierra Club v. Morton* 405, US 727 1972.

held that ALDF's claim that it would expand more money on its activities as a result of the Rule failed to distinguish ALDF from any other member of the public with a particular concern for protecting animals.

Since the District Court granted the defendant's motion to dismiss for failure to state a claim, the Federal Circuit had to assume the truth of the injury, even though the alleged injury of the animal rights group was clearly insufficient to achieve standing. Turning then to the element of causation, the court determined that the injury alleged by the animal rights groups, was not fairly traceable to the Commissioner's interpretation of Sec 101. The court reasoned that the need for independent action of the third parties to invent and prosecute animal patent applications, severs any link between ALDF's injury and the Commissioner's action. The Court determined that the animal rights group must be denied standing because the alleged injury required the additional acts of third parties.

### **3.3.6 Farmers' View Points**

Another group of individuals ALDF comprised of individual farmers and farming associations alleged that the Commissioner's interpretation of Sec. 101, caused them economic injuries by forcing them to pay increased costs in the form of royalties on patented transgenic animals and decreasing their profit, due to their inability to complete in the production of such animals.<sup>119</sup> In response to this claim, the defendant contended that the plaintiffs' injury was speculative as it depended upon the independent actions of third parties and was therefore not controlled by government action. The court agreed with the defendant and found that the alleged injury was not fairly traceable "to the defendant's actions."

The court also rejected as speculative the farmers' claim that they would be forced to pay increased royalties as a result of the availability of animal patents. The court reasoned that the farmers could not be forced to purchase the transgenic animals and to pay royalties on them. Similarly, the court rejected the plaintiffs' contention that their costs of operation would increase as a result of such royalties

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<sup>119</sup> In attempting to establish causation, the farmers cited cases recognizing that an injury could result from government action affecting the acts or decisions of a third party, who then either caused or threatened to cause injury to the plaintiffs. The plaintiffs cited two Supreme Court cases in support of this point. (1) *Blum v. Yaretsky*, 457 US. 991, 1996 n. 6, 1999-2001 (1982) (2) *Blum v. Yaretsky*, 457 US. 991, 1996 n. 6, 1999-2001 (1982) (2)

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as equally speculative. The court noted that the ability of a market participant to affect the price of patented animals depends upon whether competitive patented or unpatented animals are available. Because the court would need to engage in this type of market speculation to link the plaintiffs' injury to the defendant's action the court held that the farmers failed to show a sufficient line of causation for the purposes of standing.

The Chief Judge, Nics explained that the farmers alleged injury from increased competition could only result from the development and commercialization of transgenic animals not merely from the grant of a patent. Therefore, he reasoned that enjoying the issuance of animal patents would not prevent their development. In arriving at the conclusion the Chief Judge, Nics traced the progressive expansion of Sec. 101 to encompass non-naturally occurring non-human multi-cellular organisms including animals also. She found that the Rule clearly corresponds to the interpretation of Sec. 101 as set forth by the Board in *Ex parte Hibbard*<sup>120</sup> and *Ex parte Allen*<sup>121</sup>, in reliance upon *Diamond vs Chakrabarty*<sup>122</sup>, and therefore constituted no change in the law by the Commissioner.

As the animal rights group offered no factual basis for their claim that the issuance of patents would result in increased animal suffering, the Federal Circuits' denial of standing to the animal rights groups in ALDF was warranted. Indeed, the patenting of animal fails to raise any novel animal cruelty issues. Stressing transgenic experimentation and not animal patenting, is the real focus of opposition in the present controversy. In spite of the fact that the farmers and the farm groups', claim of economic injury was stronger and more tangible than that of the animal rights groups, it was still highly speculative. Even though the courts' determination that the farmer's injury was inadequate for purposes of standing and timing of ALDF was also premature for the farmers as that a patent is yet to be issued for a transgenic farm animal. Under the Federal Circuit reasoning in the ALDF case, it is difficult to imagine any situation in which the plaintiffs could

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<sup>120</sup> *Ibid.*

<sup>121</sup> *Ibid.*

<sup>122</sup> *Ibid.*

achieve standing.<sup>123</sup> The irony of the situation created by the ALDF holding is that the only people who would have standing to challenge the validity of animal patents (i.e. researchers and Biotech companions) would have no incentive to do so as they are the beneficiaries of the Rule. Thus ALDF illustrates an impasse for animal patent opponents attempting to obtain relief through the judiciary.

Since the plaintiffs were denied standing the Federal Circuit decision in ALDF did not resolve whether the PTO's 1987 Rule permitting the patenting of transgenic animals is valid law. The case merely determined that the plaintiffs did not have standing to challenge the Rule and that the Rule was not subject to the public notice and comment requirements of the APA. Thus due to these procedural obstacles, the case did not reach the merits of the controversy.<sup>124</sup> The District court in this case stated that the action did not raise the question of whether any actual animal patent issued pursuant to *Ex parte Allen and Chakrabarty*, exceed the PTO's authority under Sec. 101. The court indeed considered it an important question and acknowledged sensitivity to its possible ramifications, but the court also stated that it had no opportunity to decide the question.

### **3.3.7 Post Harvard Mouse Development**

Since 1988, in which Harvard mouse have been patented there has been approximately 660 animal patents with one-third of those patents belonging to foreign companies for use with biomedical and medical research. In addition to Harvard's onco-mouse, there have been numerous other mice patented, examples of these include an 'Alzheimer's mouse' and HIV 'mouse'. Besides mice, animals such as Beagle dogs, cats, sheep pigs, cows, macaquo monkeys, fish, chimpanzees, birds, rabbits and many others have all been patented. Some recent examples of patented animals include the transgenic mouse that comprises of a genomic human 'Tau transgene' which received a patent on Jan. 9, 2001.<sup>125</sup> An example of a non-mouse patented animal would be the patent of a transgenic cow that secretes

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<sup>123</sup> One reading of the decision is that ALDF did not have the right to intervene in the prosecution of another's patent and that only an owner of an animal patent would have standing to challenge the rule. As neither animal rights group nor farmers are likely to ever own an animal patent, these groups will probably never be able to achieve standing to challenge the validity of transgenic animal patents.

<sup>124</sup> The question of whether transgenic animals should be patented implicates broad policy issues rather than the narrow procedural issue of statutory interpretation of the APA, than the Court in ALDF addressed.

<sup>125</sup> *Re Harvard College's Materials Patentable* 2002.SCC 76. FN 28155 Available at [www.Bioetica.org](http://www.Bioetica.org). Accessed on 6<sup>th</sup> Dec 2014.

foreign proteins into its milk. On Feb. 7, 2007, there was a patent given to transgenic mammals that express mutant GP III a protein.<sup>126</sup> The race continued and patents were also granted on goat and cattle expressing diverse protein. As per the observation, now it is possible to build a farm of transgenic animals to which patent protection is offered. Thus, one small mouse sparked one of the largest advances of technology as we know it today. Patenting transgenic animals is gaining importance in the course of time, as the time goes on more and more specific and useful transgenic animals are evolving while the science and technology is expanding day by day.

### **3.3.8 International Perspective**

Most of the countries agreed the potential benefits of transgenic animals and acknowledged their importance by granting them patent protection. But this is not so in many other nations where one could see the staunch opposition of patenting of animal biotechnology till today. The researcher wants to discuss about the existing legal structure in respect of transgenic animals patent position in US and Europe.

#### **3.3.8.1 U.S. Position**

In the US, transgenic animals as such can fulfill the requirements for patentability. Most significantly, the decision of Chakrabarty, Ex parte Allen, the PTO's statement on April 7, 1987 and Harvard Mouse patent shows that animals that did not occur in nature could be patented. Thus, transgenic animals in the US at present, are patentable subject matter.s

It is obvious that transgenic animals can be patented as products – by – process, Sec. 103(b) of the Act<sup>127</sup> provide that the products of biotechnological processes fall within the scope of the patent on the process. Transgenic animals are subjectively considered as ‘manufacture’ or composition of matters or the process whereby it was modified. It is noteworthy that patent on the gene will not, by operation of law extend to the animals in which it is inserted and expressed. The US inventors can apparently apply for patents on transgenic animals as such. Thus,

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<sup>126</sup> *Transgenic Animals*, Available at [www.wpi.edu/pubs/E-project/Available/E-project-/IP.pdf](http://www.wpi.edu/pubs/E-project/Available/E-project-/IP.pdf). Accessed on 12<sup>th</sup> Feb/2012.

<sup>127</sup> 35 USC Sec. 103(b).

they usually attempt to acquire a patent on one modified animal, a group of animals, a variety and in case such will prove to be possible in the future that a race has been created through the biotechnology. The patent regime of US allows the patent office to grant patents for genetically modified animals as well as their offspring. The PTO sometimes granted patent for transgenic animals produced by sexual reproduction and some claims explicitly include such animals within this scope. Other patents implicitly include such sexually produced offspring.<sup>128</sup>

### **Human Related Inventions**

In the US an invention must be useful pursuant to Article 101 of the Act, Utility in principle is also related to the benefits that are derived from an invention for the society. The PTO applies this doctrine very restrictively with respect to inventions consisting of transgenic animals. But the PTO's only moral restriction on patentability of living subject-matter deals with human-animal chimeras, but the distinction between what is human and what is animal in this regard, remain unclear. The various patents granted for animals containing human genes seem to suggest that the PTO will not consider an invention a human/animal chimera as long as its genome consists mostly of naturally occurring non-human genes. Although at least a Federal Court's decision seems to suggest that the doctrine of beneficial utility may be invoked more often with respect to biotechnological inventions such as transgenic animals, this is not very likely. Thus human related inventions are not patentable in the US but there is much uncertainty, perhaps owing to the constitutional mandate, which aims at the progress of science and useful arts.<sup>129</sup>

### **Enablement Criteria**

The US law provides for the deposit of biological materials in order to fulfill the enablement requirements.<sup>130</sup> But in case of transgenic animals, deposit as such will most likely not lead to de facto full disclosure.<sup>131</sup> In the US patent

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<sup>128</sup> In principle, animal produced by propagation are produced through a process that is subjected entirely to the laws of nature and are themselves product of nature But however PTO and Courts have applied the doctrines of laws of nature and products of nature restrictively.

<sup>129</sup> US Constitution Art 1 Sec 8 cl. (8).

<sup>130</sup> 35 USC Sec. 112 and 114.

<sup>131</sup> This is because the expression of genes within animals may not be observable externally. Also practical problems may arise, such as the storage and maintenance of the animals.

applications at the PTO were confidential until the law was changed in Nov. 1999 to require publication of 18 months after the earliest filing date.<sup>132</sup> This is because under the US patent law the PTO issues patents, to the one who invents first. But in case of deposit of transgenic animals, one may doubt how this would be arranged without demanding that the applicant deposit numerous animals. Thus, there are some problems with respect to disclosure and enablement of inventions consisting of transgenic animals. Thus under the US patent law, single transgenic animals and groups of animals belonging to a forming the same fact race can be patented.

### **Transgenic Animal Patent Reforms Act, 1988**

*The Congress has responded to the high level of public interest and emotion* surrounding the patenting of life forms with numerous bills. The Act provides for an exemption which allows farmers to reproduce patented transgenic farm animals through breeding for use in the farming operation or for sale.<sup>133</sup> The farmers exemption does not apply however if the germ cells, the semen or the embryos of the patented transgenic animal are sold without the permission of the patent owner.<sup>134</sup> Farm animals are defined as animals used or intended for use as food or fiber.<sup>135</sup>

The granting of patents for transgenic animals by the patent office is unaffected by the proposed Act but the rights which patent owners obtain are limited by the farmer's exemption. The farmer is allowed to breed farm animals and sell the offspring of that breeding but the farmer becomes an infringer, if he enters into direct competition with the patent holder by selling the embryos, germ cells or semen of the patented animal. But, it is very clearly understood that later the Congress is not having much interest in enforcing all those proposed legal measures in order to avoid overlap between patent Act and proposed Acts.

#### **3.3.8.2 Position in European Union**

In European Union also, transgenetic animals can be patented as products and the process by which they are produced is also patentable because these

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<sup>132</sup> 35 USC Sec 122(9).

<sup>133</sup> Proposed 35 USC Soc 271 (g)(1) (Bill).

<sup>134</sup> *Ibid.* Sec. 271 (g)(2).

<sup>135</sup> *Ibid* Sec. 271(g)(3)(B).

animals fulfill the requirements of patentability in EU.<sup>136</sup> In the EU, EPC Articles, 53(b) and 64(2), Directive 98/44, Art 2 (1)(b), in conjunction with Art 4(3) and 4(1)(b), 2(2), and 8(2) and the decision in Onco-Mouse/Harvard and Novartis-11, make it clear that animals fall within the scope of the patents on the processes from which they are derived.. The European Patent Office (EPO) studied the Onco Mouse deeply and did not resolve its decision until 2004. Later the EPO applied the standards of the EPC which contained two main relevant provisions which are Art 53(a)<sup>137</sup> and Art 53(b).<sup>138</sup> The EPO concluded that Onco Mouse was not included in “animal variety” and did not fall in the exclusion of Art. 53(b), what the EPO meant by *ordre public* morality and for this they have developed a ‘utilitarian balancing test’ which aimed to access the potential benefits of Onco-Mouse against the negative aspects. The EPO thereby concluded that the usefulness in the advancement of cancer research outweighed the moral concerns in the suffering caused to the animal.<sup>139</sup>

In the EU, animals are also protected by the patents on the genes that are inserted in to be expressed in them. In this regard, the EU offers more probabilities for animal patents. It is obvious that, the inventor of a gene has the certainty that all animals in which it is incorporated will be within the scope of his patent/ More so, processes of sexual reproduction that are carried out with a slight human intervention may be subject to patent law, as may be products (animals) thereof.

### **Enablement Criteria**

Like the US patent Law, the European patent Law also provides for the deposit of biological material in order to fulfill the enablement requirements Directive 98/44, Art. 13(2) provides therefore, for the issuance of samples of the

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<sup>136</sup> Articles 1, 2(1)(a) and 4(2) of European Directive, 98/44.

<sup>137</sup> Art 53(a) excluded patents for invention the publication or exploitation of which would be contrary to *ordre public* or morality.

<sup>138</sup> Art 53(b) excluded patents on “animal varieties or essentially biological processes for the production of animals.”

<sup>139</sup> However the EPO did make a small adjustment in the original application, the claim referred to animals in general, but in course of proceedings, the patent was amended and finally maintained with claims limited to mice. This same utilization approach was used in 1992 by the EPO in the moral issue of Upjohn mouse. The patent subject in review was filed by the Upjohn pharmaceutical company and was on a transgenic mouse in which a hair – loss was present. The mouse’s objective to test hair-loss products to possibly treat human baldness and wool production techniques. The EPO weighed the positive and negative of the case and decided that the suffering of the mouse outweighed the possibility of hair-loss cures.

material immediately after its deposit to interested parties.<sup>140</sup> In the case of the deposit of transgenic animals, one may doubt how this would be arranged without demanding that the applicant deposit numerous animals. Similar to the US patent regime, deposit as such will most likely not lead to de facto to full disclosure. Therefore, under EU also, there are some problems with respect to disclosure and enablement of inventions consisting of transgenic animals. These problems lead to a lack of internal and external disclosures.

### **The Landmark Decision of Harvard Onco-Mouse Case<sup>141</sup>**

In this case, the invention was a method for producing a transgenic non-human mammal having an increased probability of developing neoplasm by introducing an activated onco gene sequence into a non-human mammal at a stage not later than the eight-cell stage. The applicant also claimed onco-mouse, the transgenic non-human- mammal resulting from the above method.<sup>142</sup>

The Board of Appeals view that the mere fact that a claim was not a ground to refuse the patent considering the application as not complying with the requirement for sufficient disclosure unless there existed some serious doubts on the invention based on verifiable facts.<sup>143</sup> Finally, the Board concluded that the description of producing onco-mouse is adequate and sufficient disclosure to practice the invention on other non-human mammals. In EU, both genetically modified animals and their offsprings are patented. The term applied in Directive 98/44, that propagation and multiplication are however broader and this includes

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<sup>140</sup> In Europe, patent applications become part of the prior art, also Art 93 provides for immediate publication when applications are filed. This is because under European patent Law the EPO issues patent to the first one to file the application in other mammals.

<sup>141</sup> T 19/90 (1990) O.J. EPO 476, Tech Bol. Appl.

<sup>142</sup> Applicant in support of their claim cited Genetech's case, where the invention described a general method to express polypeptide in bacteria and claimed the method to be applicable to all other class of species or bacteria. There was opposition to the patent contenting that the claim was too broad. It was argued that the inventors were claiming a method for producing transgenic non-human-mammal by disclose the method for producing the mice. It was also argued that the inventor did not disclose the method of practice the invention in other mammals.

<sup>143</sup> The Board considered Genetech's case as cited by the applicants as relevant to the present case. The Board identified the similarity between the two cases. The Board was convinced that the invention clearly indicated how a skilled person could practice the invention by incorporating an activated onco gene into the genome of a non human mammal as disclosed in case of mouse. The Board viewed that the invention described the method of incorporating and expressing an onco gene to produce onco-mouse. It ensured that the invention could be practiced successfully on mice to claim other non-human mammal the inventor need not have described with reference to particular non-human animal. The description with reference to mice was, enough to achieve the invention on other.

clones of the animals concerned, whereas the term multiplication in the said Directive specifically addresses the reproduction of the patented animals.<sup>144</sup>

More so, the European Patent law provides for detailed and specific exceptions for both breeders and farmers under the Directive.<sup>145</sup> But the exhaustion rule is triggered, only if the material is acquired in the EU. Under the European Patent Law, the third parties have opportunities to express their options with respect to the patenting of a certain inventions.<sup>146</sup> Thus, it can be concluded that the concern of the third parties are likely to be heard during or shortly after, the review of a patent application filed under the EPC.

### **3.3.8.3 Position in Canada**

This is one among the nations which rejected the patenting of transgenic animals. Significantly, Canada rejected the claims to transgenic animals on the basis that they were not inventions but approved the claim on the process for obtaining such animal. The patent Act, states that “inventions means any new and useful art, process, machine, manufacture or composition of matter or any new and useful improvement in any art, process, machine, manufacture or composition of matter.”<sup>147</sup>

### **Harvard College v. Canada<sup>148</sup> - The Patentability Criteria**

In 2002, a 5:4 split decision of the Supreme Court of Canada rejected claims to genetically modified Harvard onco mouse. The majority held that the term invention under the Patent Act did not include a higher life form. Also, the court held that “composition of matter” and “manufacture” elements of the definition did not include conscious, sentient living creatures. The court enthusiastically invited the parliament to amend the Patent Act, if such creatures were to be accorded patent protection. But claims for other aspects of the invention, including the cell creatures and plasmids were held to be properly patentable subject matter.

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<sup>144</sup> Art 8 of Directive 98/44.

<sup>145</sup> *Ibid* Art 10 and 11.

<sup>146</sup> EPC Art 99(1) provide for an opposition procedure that can be initiated by “anyone” until nine months after the patent is granted.

<sup>147</sup> Canadian Patent Act, S. 2.

<sup>148</sup> *Harvard College v. Canada* (Commissioner of Patents) 2002, 21 C.P.R. 4, 417 (S.C.C.)

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The formal history of the SC's Onco-Mouse decision began on 21 June 1985, when the President and Fellows of Harvard College applied for a Canadian Patent over 'transgenic animals' genetically engineered to be susceptible to cancer. Harvard applied for a patent to cover the process of inserting the cancer causing genes into the mice, but also to cover the resulting mouse and for that matter, any non-human mammals genetically engineered to develop cancer. The whole organisms or product claims were rejected in 1993 by the Canadian Patent Office because the examiner determined that whole organisms were outside the scope of the definition of "invention" under Canadian Patent Act. The examiner did however grant the process claims the case went to Federal Court of Appeals.

A claim to the process for creating such a mouse had already been determined as patentable, the issue before the Federal Court of Appeals in the case, was the patentability of genetically altered non-human for use in carcinogenicity studies that is the mouse itself. The court held that the onco-mouse and its offsprings were composition of matter within the meaning of "invention" in Sec. 2 of the Patent Act. They reasoned that the laws of nature did not disqualify a product from patentability, so long as some inventiveness or ingenuity was involved regardless of some characteristics. There was nothing within the term "composition of matter" to suggest that living things should be excluded from the definition. The patent was granted for all transgenic zn-human mammals with the onco-gene.

The Canadian government appealed and the case went to the SC. The SC, majority held that the mouse as a higher life form does not qualify as a manufacture or as a "composition of matter" under the Canadian Patent Act. The main question in this appeal is whether the words manufacture and composition of matter within the context of the Patent Act are sufficiently broad to include higher life forms.

Critically the dissenting opinion in this case cited the onco mouse decision in questioning whether patents on genes and cells, reproduced as part or whole organisms, could be protected without creating *de facto* property right over whole organisms. Further, they added that "the crux of the issue is whether the Federal

Court of Appeal's decision can stand in light of this court's ruling plants as higher life forms are unpatentable. A purposive construction that limits the scope of the respondents' claims to their "essential elements" leads to the conclusion that the gene claims and the plant cells claims should not be construed to grant exclusive rights over the plant and its entire offspring.<sup>149</sup>

In spite of the Supreme Court's decision not to allow patents claims for higher life forms, such as the "Harvard Mouse", virtually all biotechnology inventions are still patentable in Canada. Biotechnology inventions can be protected through patent claims directed at subject-matter, the Supreme Court refers to as 'lower life forms'.<sup>150</sup> Thus, the inventor can obtain patent protection for the building blocks that make up a genetically altered plant or animal such as the gene sequence with a use, the genetically altered egg and the resulting cell lines.<sup>151</sup>

#### **3.3.8.4 Position in India**

Obviously speaking, biotechnology patent law is an outcome of judicial pronouncement in the United States and EU but in India the emergence of biotechnology patent law is a result of ratifying international conventions. India usually made amendments in patent law in order to fulfill the obligations under TRIPS Agreement. Under Indian Patent Act, animals, plants or part thereof, not only of the natural origin but such living entities of artificial origin such as transgenic animals and plants or any part thereof are also not patentable.<sup>152</sup>

The question may arise whether genes are considered as biological or chemical material and whether they would be interpreted as part of plants or

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<sup>149</sup> As with the Harvard Mouse case, where the majority of the court invited parliament to amend the Patent Act to include higher life forms if it so chose, the majority in the Monsanto case found that agriculture and biotechnology inventor are protected under the patent Act, and parliament could amend the Patent Act to distinguish between inventions concerning plants and other inventions or with respect to biotechnology if it so chose.

<sup>150</sup> The SCC in Harvard Mouse case did not define higher life forms". The court has only given the practical guidance regarding higher and lower life forms in biotechnology patent and confirms that the genetically altered mouse egg did fall under the definition of "composition of matter" and is patentable subject-matter, and is presumably classified as a "lower life forms".

<sup>151</sup> In Canada, the current patent laws and biotechnology patent claim drafting practice provide successful protection for the vast majority of biotechnology inventions. It is however unfortunate that the court did not deliver more clarity decisions in harmonization with industrialized worlds regarding patentability of genetically altered plants and animals.

<sup>152</sup> Patent Act 1970 (Amended in 2002) Sec. 3(j) reads as, "plants and animals as a whole or any part thereof other than microorganisms but including seeds, varieties and species and essentially biological processes, for production or propagation of plants and animals are not patentable."

animals and if they can be patented or not. More so, the Indian Patent Office's Manual 2008, does not explicitly elucidate the same but under the unity of invention when a GM gene sequence/amino acid sequence is novel, involves an inventive step and has industrial application, some kinds of claims can only be patented, having ratified the TRIPS Agreement which mandates for patent protection to biotechnology inventions. In India, microorganisms are now patentable, but the real position or stand of India is not very clear with regard to the patenting of non-naturally produced animals. If the sustainable amendments are made then animals/transgenic animals can be patentable in India and hence it would lead to opening lot of research and also this leads to many religious ethical and legal especially environmental issues considerably.

### **3.4 Patent on Human Body Parts**

With current biotechnology, it is possible to snip, insert edit and program genetic material, the very blue print of life including human being. The journey of the patent regime in granting monopoly reached the human biological materials within no time after the patenting of animals. It is evident that patents are granted to human cells, genes and DNA. The technologies involved for getting these results are recombinant DNA technology, gene splicing and gene manipulation.<sup>153</sup> These technologies are used for the isolation and purification of human cells and gene sequences. These developments require the utilization of human body parts, both for experiments and for transplantation and present certain major-medico legal problems.

Moreover, the human "totipotent cells",<sup>154</sup> have the potential to develop into the entire human body. In view of this potential, such cells are not patentable because the human body at various stages of its formation and development is excluded from patentability. Similarly, a method of culturing or propagating human totipotent cells are also excluded from patentability as a claim to a method, also provides protection for the product of such a method. But the situation started,

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<sup>153</sup> Manfred Davidmann: *Creating, Patenting and Marketing of New Forms of Life*, Available at [www.solhaam.org/articles/clm.505.html](http://www.solhaam.org/articles/clm.505.html). Accessed on 24<sup>th</sup> July 2010.

<sup>154</sup> The ability of a cell to produce differentiated cells upon division

gradually changing and the judiciary also looked this matter through utilitarian's eye and decided the cases for the economic interests of the innovators as well.

### **3.4.1 Rule in John Moore v. Regents of University of California<sup>155</sup>**

In this interesting case, a human cell line was claimed to be patented for the first time in the history of patent law. The fact of the case is that a cell line isolated from the spleen cells of John Moore was patented by his doctors. By granting patent on the cell line, the USPTO set in motion the patenting of human gene material, it is pertinent to note that the researchers or the doctors who were granted the patent and the huge profits from it. What the patent office did was expressly recognizing the proprietary right and also the monopoly right over the human cell line, that too for a research done without the consent of the donor or the persons from whom the cells were taken.

When Moore learned of the use of his cell lines without his permission, sued the defendants under various causes of action. Two of these were, breach of fiduciary duty and "conversion", the use of property of another for commercial benefit without the owner's authority. The case from the legal perspective has two important aspects. The first one, refers to the authorization that should have been obtained from Moore and the second one is the susceptibility of patenting body parts. The California Supreme Court of Justice, which rendered a decision partly in favour of Moore, based its decision on three basic principles. (1) An adult in full use of his faculties has the right to decide whether or not to submit to a medical treatment based on his "right to have control over his own body," (2) the patient's consent shall be sought and (3) the physician has the obligation to give all the necessary information for the patient's decision.

The California Supreme Court rule was that Moore's consent was not obtained and the doctors were in breach of their fiduciary duty. But, the court rejected his argument that he has a right over his cells as they are unique from others. They stated that the 'lymphkines' used by the defendants were of the same basic molecular structure in all human beings. This argument is difficult to accept

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<sup>155</sup> 793 p. 2d 477 cal. 1990. 51. Cal. 3d 120. (1990)

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because it is only the uniqueness of the cell line derived from him made it valuable. It proves that this case is closely related to the development of medicine and biotechnology applied to medicine, which requires human body parts both for research and for transplantaon resulting in certain major medico-legal problems.

The Moore decision reflects an unwillingness to recognize the infringement of human dignity that results from international fraud. No judgment was made on the consequence of or the problems caused by the absence of informed consent. The decision given by the court did not concern the legal regime that governs informed consent in biomedical research. This decision will become increasingly important as biomedical research advances in the 21<sup>st</sup> century. This is a judgment by the US Court and is not binding in other jurisdictions. However, the case has serious implications regarding the patenting of human genetic material. Such patenting is beginning to be accepted in the US and is a matter which could arise in any other country. Thus, it is essential to revisit the Moore case in order to analyse these issues, which were not sufficiently dealt with by the California Supreme Court and also to explore the case from the point of view of patent.

#### **3.4.2 Patenting of Human Genetic Material**

Patents are said to serve the goal of fostering the development of innovation promoting the economic growth, dissemination of knowledge by providing innovators an incentive or reward to risk their time and the costs of R & D. However this view is a matter of controversy, some scholars question the notion that patent necessarily lead to innovation and that they are an incentive to research. In fact, however that human genetic material has been granted patent in numerous cases, in Chakrabarty,<sup>156</sup> the US Supreme Court held that a genetically engineered bacteria was patentable as a ‘new and useful’ manufacture or composition of matter thereby opening the floodgates for gene patenting in the US. A patent claim human genetic marital DNA was made for the first time in Amgen v. Chugai.,<sup>157</sup> Similar claims were made in re Bell<sup>158</sup> and re Deuel<sup>159</sup> but

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<sup>156</sup> *Supra*, note 3

<sup>157</sup> Amgen v. Chugai, 18 USPQ 2d, 1016 fed cir. 1991.

<sup>158</sup> Re Bell, 991, f. 2d 781 (fed. Cir. 1993).

<sup>159</sup> Re Deual, 51, F. 3d, 1552 (Fed. Cir. 1995).

settled outside the court. This already shows the stand that human genetic material was patentable.

In the *Relaxin*,<sup>160</sup> case for the first time in Europe the EPO issued a decision on whether or not a gene coding was patentable. This is for a human *Relaxin*. The patent was granted and the patent office held that patenting of human gene did not go against ethics, as patenting gene was not tantamount to patenting a human being. Following the *Relaxin* decision, in *Biogen v. Medeva*,<sup>161</sup> a patent application was made for human genetic material and subsequently granted. It is now a settled matter of law in the US and recently in the EU that human genetic material is patentable. Many other countries support this but have not incorporated expressed provision in their domestic statutes. However there are also countries which oppose the patenting of human genetic material.

Particularly in the *Moore* case,<sup>162</sup> for the first time in the history of patent law a patent was claimed on a human cell line. A cell line in tissue culture, is defined as the cells growing in the first or later subculture from a primary culture or a clone of cultured cells derived from an identified parental cell type. The distinction between cells taken directly from the body and cell lines is that while primary cells typically reproduce a few times and then die one can sometimes continue to use cells for an extended period of time by developing them into a cell line a culture capable of reproducing indefinitely. In the case of *Moore*, a patent was obtained for a cell line using cells taken from *Moore's* body. The court held that the patented cell line and the product derived from it would not be *Moore's* property. It stated that this was so because the patented cell line is both factually and legally distinct from the cells taken from *Moore's* body. Since then, there have been numerous instances, where cell lines have been patented across the world.

### **3.4.3 Doctrine of Product of Nature and Product of Man**

The main object of the patent law is to reward for the inventive efforts of the inventors and not the discovery of natural occurring raw materials. Intangible intellectual property in the body such as a gene patent or a cell line, receives much

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<sup>160</sup> *Relaxin* (1995) EPO R. 541.

<sup>161</sup> (1997)RPC 1

<sup>162</sup> 793, F. 2d, 479 (cal. 1990) 51 Cal. 3d, 120 (1990).

more protection than do physical body parts. The “inventor” or the discoverer of intellectual property in the body is granted broad protection, unlike the individuals who are seen as applying the raw materials such as the blood tissue and other body parts necessary to conduct such research.

The decision of the court in Moore’s case,<sup>163</sup> clearly indicates that under the US law, cell line is an invention and therefore a non-natural human made product, different from John Moore’s cells, which are the product of nature. The cells were the product of nature until human intervention, whereupon they turned into a product of a man and developed new abilities to grow in the different media. This is the direction in which the US and the EU laws have been developing, though it is not explicitly accepted in other parts of the world.

It is very significant to note that the court in the Moore case did not acknowledge the fact that the cells used for making the cell – line were Moore’s property and Moore alone had the right to determine and direct the use of his cells. Thus, using his cells for research without his consent raises issues relating to property and privacy.

#### **3.4.4 Property Right Over Body Parts**

The definition of property is sufficiently broad to include “every species of real estate and personal and everything which one person can own and transfer to another. Under existing legal system, a quasi property is recognized with regard to dead bodies and embryos. Even cell lines have been recognized as property.<sup>164</sup> Therefore, by drawing an analogy from these cases even extracted dead cells of John Moore can be considered a property. Under existing law in the US, Moore has the right to control his body exclude others from it and dispose of it in any way that the law prescribed. This right to dispose off property includes the right to direct the use of excised cells and tissue, while the right to exclude, includes the right to refuse medical treatment. A person of sound mind and adult years has the right to determine in exercising control over his body whether or not to submit for lawful medical treatment.

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<sup>163</sup> *Supra* note 155

<sup>164</sup> *Pasteur v. United States* 814, F. 2d, 624 (Fed Cir. 1987).

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According to the UK Gene Watch there are about two dozen patents covering gene processes related to HIV and countless of others covering every major organ. There are also patents granting ownership over genes and gene sequences in teeth, sperm, blood, ears, tongue and the immune system. Upto 2007, around 20 percent of the genes that make up human DNA are patented. In a famous case<sup>165</sup> in which, the rights of the persons who gave their body parts and biological materials for research was later patented. The plaintiff in this case, the parent of two children who were affected with 'Cana van disease', which is a rare genetic disease more prevalent among Ashkenazim Jews, that is both incurable and fatal. The parents wanted to find a cure for this and for that they sought help of a researcher, Dr. Reuban Matalon to study about the disease. For that they supplied him with blood urine and tissue samples. They even gave the pieces of their children's brain, after their death. They identified more than hundred families who were suffering from the disease and convinced them to provide blood urine and tissue samples too, thereby creating a Cana van Registry. They gave him financial support for the research too. In 1993, Matalon and his research team successfully isolated the gene responsible for 'Cana van' disease. In 1994, a patent application was filed and in 1997 the US PTO issued patent (No. 5.679, 635) to the Moami's children's Hospital listing Matalon as the inventor. Through patenting, defendants acquired the ability to restrict any activity related to the Cana van disease gone including without limitation, carrier and pre-natal testing gene therapy and other treatment for Cana van disease and research involving the gene and its mutations. Although the patent was granted in 1997, the plaintiff only came to know about in 1998, when MCH revealed their intention to limit 'Cana van' disease testing through an operation of limiting, licensing of the patent. The plaintiff filed suit against the defendants, Dr. Matalan and MCH alleging some causes of action, which are (1) lack of informed consent (2) breach of fiduciary duty (3) fraudulent concealment (4) conversion (5) misappropriation of trade secrets and (6) unjust enrichment. The court rejected all the allegations except unjust enrichment. Firstly, the court rejected the claim for lack of informed consent for the reason that there was no duty on researchers to disclose their economic interests. They distinguished Moore vs Regent of the University of

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<sup>165</sup> Greenberg, 264, F. supp. 2d, 1064 (S. D. Fla. 2003).

California,<sup>166</sup> on the ground that the researcher was the physician in that case but in this case there was no relationship in that sense.

The Court dismissed the plaintiff's claim for breach of fiduciary duty based on similar reasoning finding that there cannot be automatic fiduciary relationship when a researcher accepts medical donations. Although, the court dismissed or rather distinguished the ratio given by Moore in the claim for lack of informed consent, the Greenberg Court relied upon Moore to reject the plaintiff's claim for conservation holding that the plaintiff's body tissue and genetic information were donations to research without any expectations of return and thus conversion does not live as a cause of action.

The court, relying on the Moore decision, rejected the contention of the plaintiff that the bodily material and the genetic information that they have provided is not the property of the person.. Further, it stated that any property right in blood and samples will disappear, when the sample is voluntarily given to a third party. In the present case the parties went for a settlement agreement, because of which there was no plead of trial in the court.

### **3.4.5 Ownership over all Biological Materials: Isolated from Body**

A great issue may arise in future with regard to use of human biological materials or the ownership of human biological materials came in the case of Washington University v. Catalone<sup>167</sup> In this case, the plaintiff Washington University filed a declaratory judgment action seeking to establish ownership of biological specimens of blood DNA and prostate tissue that were contributed by patients and housed in the Genito–Urinary Repository for the purpose of prostate cancer research. They claimed their biological specimen from Washington University on the basis of the withdrawal provisions in the consent form and transferred them to Dr. Catalone. The District Court rejected all the claims made by the defendants by refusing to recognize the property rights of the patients over their biological material stored, in the GU Repository. On the contrary, the court held that the plaintiff, Washington University has the ownership of all the biological materials

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<sup>166</sup> *Ibid.*

<sup>167</sup> J. Mark Waxman: *Who Owns My Tissue?*, Available at <http://www.deldmag.com/intellectual-property-and-biological-materials.aspx>. Accessed on 1<sup>st</sup> Dec 2009.

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including but not limited to blood, tissue and DNA samples of the GU Repository. The court considered the defendants as donors donated to Washington University, in spite of the defendant's argument that they had always intended to keep the ownership rights.

The court reached this conclusion by interpreting the consent form, which the defendants had signed. It focused on the language of the consent form stating that they were making a gift of the biological materials for the research purposes. Even though the court focused on the language of the consent form, it failed to take notice of the limiting provisions in the same form with the same magnitude given to the gift provision. The question of ownership of human biological material was the primary issue in the case. Although the court was reluctant to grant rights to the donors, they are not forthcoming budge from the age old principles even though confronted with the latest issues happening in the society. The courts and also the patent authorities are granting monopoly rights, through patents on the one side and on the other side, the rights of the person, who gave their own body materials are detached from their privileges.

In the 2010, case of Association for Molecular Pathology v. USPTO,<sup>168</sup> widely known as the Myriad case, after one of the co-defendant Myriad Genetics a group of Genetics physician and researchers represented by the American Civil Liberties Union Challenged patent claims relating to two human genes, (1) Breast Cancer susceptibility Gene 1 and 2 (BCSG – 1 and BCSG2). Judge Robert Sweet of the US District court for the Southern District of New York jolted the biotechnology world by holding the claims invalid. Taking clear aim at the isolation and purification doctrine, the court cited legal commentators and scientists in the field of molecular biology and genomics have considered this practice a lawyer's trick that circumvents the prohibitions on the direct patenting of the DNA in our bodies but which in practice reaches the same result.

The Decision of the US District Court would ordinarily have little chance of hauling down the doctrinal frame work of Modern Gene Patenting, that quickly changed however, thanks to an unexpected development in appeal, the US

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<sup>168</sup> Myriad case, Fed. Cir. No. 2010, 1406, 6 ct. 29 (2010)

government entered the pray as amicus curiae to argue that isolated genomics DNA is not patentable after all.<sup>169</sup>

### **3.4.6 Patentability of Human Embryonic Stem Cells**

Human totipotent cells have the potential to develop into the entire human body. In view of this potential, such cells are not patentable because the human body at various stages of its formation and development is excluded from patentability.<sup>170</sup> Similarly, a method of culturing or propagating human totipotent cells are also excluded from patentability as a claim to a method also provides protection for the product of such a method.

Following the recent decision of the court of justice of the EU, in the case<sup>171</sup> the patent office amended its practice on the patentability inventions involving human embryonic stem cells. The EPO will now recognize that where the implementation of an invention requires the use of cells that originate from the process which requires the destruction of a human embryo the invention is not patentable even if the claims of the patent do not refer to the use of human embryo. This is irrespective of when the destruction took place. In other words, if an invention uses a human embryonic cells line that was at some point derived by the destruction of a human embryo then it is excluded from patentability, by virtue of Patent Rules,

The C J E U also ruled that the term, “human embryo” must be interpreted broadly to include any organism that is “capable of commencing the process of development of a human being.” But also confirmed that invention that are useful to the human embryo are not excluded from patentability. The office will continue to grant patents for such diagnostic or therapeutic interventions upon the human embryo, provided they meet the other legal requirements.

Obviously, induced pluripotent cells which are obtained from the – differentiation of an adult cell by the forced expression of certain genes are clearly

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<sup>169</sup> Christopher Beanchamp; *The Pure Thoughts of Judge Hand. A Historical Note on the Patenting, of Nature*. Available at. [www.law-nyu.edu/sites/default/files/ECM-PRO-07130.pdf](http://www.law-nyu.edu/sites/default/files/ECM-PRO-07130.pdf) Accessed on 4<sup>th</sup> Feb 2013.

<sup>170</sup> Examination Guidelines for Patent Application Relating to Biotech Inventions in the IP Office – July 2012.

<sup>171</sup> Oliver Brustle v. Greenpeace C.V. C -34/10.

not obtained from human embryos and cannot go on to form a human being. Therefore, these cells are not subject to the exclusion of patentability.

### **3.4.7 Human – Animal Chimera Patent**

Chimeras are mixed species creatures, whose genetic code chromosomes and cells have been derived from two or more individuals of different species, includes human also and generally patent on these hybrid is prohibited, if there is a mixture of human genes. But now an Australian company succeeded in obtaining patent on the methods of “human–animal chimeras.”<sup>172</sup>

The EPO granted a patent to the Australian company Amrad on 20th January 1999, for a method to produce human–animal chimeras. However, as recently as October 2000, when Greenpeace disclosed an application for a similar patent on such mixed species creatures, the EPO claimed that such patents would never be granted as they would be against public order and morality. But at that time the patent explained below, which Green peace has now discovered, had already been granted.

Furthermore, back on February 2000 the EPO has been heavily criticized for granting a highly controversial patent on human–animal embryos. All those examples show that we are not dealing with occasional “errors’ but with a pattern, EP, 380646 – the latest patent scandal. This patent covers method of producing non-human and animal embryonic animal’ by mixing human and animal embryonic cells, human stem cells are integrated into animal embryos. As a result, the created chimeras are non-human but they may contain, human organs, body parts nerve cells even human genetic codes.<sup>173</sup>

The Chimera creating process starts by isolating a substance, the objective of which is to stimulate the growth of embryonic stem cells. The patent covers methods to isolate cells from humans and animals, their propagation in the lab and the use of these cells to create a Chimera. More so, concerning the origin of these cells the

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<sup>172</sup> *Humans Patents on Human Genes, Cells on Human including procedures on Human Embryos and Human-Animal Chimeras* – Available at <http://www.gene.ch/genet.2001/may/misg00044/html>. Accessed on 8<sup>th</sup> Jan 2013

<sup>173</sup> Antony Barnett: *Patent allows creation of Man – Animal Hybrid – special Report on the Ethics of Gene*. Available at <http://www.guardian.co.uk/science/2000/Nov/26/genetics.theobserver>. Accessed on 27<sup>th</sup> Feb 2012.

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patent states, “The embryonic stem cells are derived from humans, mice, birds, sheep, pigs, cattle, goats or fish etc.” The patent does not disclose the purpose of such animals, nor whether such experiments have actually taken place, but the patent does underline that the patented method is to be used to breed and cultivate human stem cells in the laboratory as shown by the method, wherein the animal embryos are derived from mice, birds, pigs, sheep, cattle goats or fish.”

A method of producing a non-human chimeric animal, comprising introduction into said animal at the pre-implantation embryo stage, animal embryonic stem cells which have been isolated in accordance to claim 1 to 13.<sup>174</sup>

The patent includes the creation of a being, comprising an animal embryo into which human stem cells have been introduced. EPC law stipulates that the process of creating a being also includes the being itself, that if the subject matter of the European patent in a process, the protection conferred by the patent shall extend to the products directly obtained by such process.<sup>175</sup>

The patent which does not give concrete medical uses was obviously intended to give the company broad monopoly rights in the process and chimeric creatures. Apparently the EPO did not consider this patent to be against public order or morality as stipulated in the EPC that European patent shall not be granted in respect of invention. The publication or exploitation of which would be contrary to *ordre public* or morality.<sup>176</sup> Moreover, such kind of process to produce chimeras from germ cells or totipotent cells of humans and animals are obviously, also excluded from patentability.

Following the logic of patent law, this means that other processes would well be patented. The present case uses “pluripotent” cells rather than totipotent ones. Therefore, such a patent could also be granted according to the new EC Directive under which chimeras could be understood as patentable ‘biological material’. Biological material, here means any material containing genetic information and capable of reproducing itself or being reproduced in a biological systems.<sup>177</sup>

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<sup>174</sup> *Ibid.*

<sup>175</sup> Art. 64(2) of EC Directive

<sup>176</sup> Art 53 of EC Directive

<sup>177</sup> Art 2(1) of EC Directive.

### 3.4.8 Cloning

A clone is a cell or individual that has been created from and is genetically identical to another cell or individual. Presently, there are three known methods for creating clones:

- (1) Somatic cell nuclear transfer
- (2) The creation of cell lines and
- (3) Embryo twinning.

While somatic cell nuclear transfer occur only in the laboratory the latter two types of cloning may either take place naturally or be artificially induced.

The first US patent for reproductive human cloning has been issued by the US PTO. The patent was granted on April 3, 2001, but lay unnoticed until the patent watch project discovered that it contains claim applicable to cloning of both humans and non-human animals. The owner of the patent is listed as being the University of Missouri, but inspection of files lodged with the PTO reveals that financial interest in the patent is shared with Brotransplant Inc. of Charlestown, Massachusetts.<sup>178</sup> Specifically, claims 19 and 20 of the patent are directed to a “method for producing a cloned mammal and include steps of nuclear transfer into a mammalian oocyte<sup>179</sup> and the step of implantation of the so-formed embryo into a recipient, maternal mammal to produce a cloned mammal”. The methods of the invention are defined as broadly covering all mammals, and specifically include those made from human ‘oocytes’. Also the description of the patent, places the public on notice that “the present invention encompasses the living cloned products produced by each of the methods described herein patentees have the right to until April 1, 2003 to present such product claims. However, even in the absence of such a claim broadening the patent owners now have rights over the product, i.e. any cloned human embryo or person been under the process via operation of the statute 35 USC sec. 271 (g)<sup>180</sup>, which extended process claims to cover materially unaltered products of patented

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<sup>178</sup> Andrew Pollack: *Debate on Human Cloning Turns to patent, May 17, 2002* Available at [www.ncbi.nlm.nih.gov/pubmed/12056440](http://www.ncbi.nlm.nih.gov/pubmed/12056440). Accessed on 7<sup>th</sup> Sep 2013

<sup>179</sup> A cell that develop into an egg or ovum; a female gametocyte

<sup>180</sup> Process Patent Amendment Act of 1988

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processes. It appears from the record that the inclusion of humans within the scope of mammals may have been intentional in that the following transpired.

- (1) The patent Examiners recognized the broad expense of the claims as covering a scope of cloning all “mammals”.
- (2) The PTO never demanded the inclusion of a “non-human” disclaimer.
- (3) Nowhere in the patent was a word “non-human” used
- (4) The patent does contemplate the use of human oocytes.
- (5) The patent owners filed for and received an official “certificates of correction” on the patent after its issuance but took no action to “correct” the omission of non-human.<sup>181</sup>

Significantly, the patent represents a desire on the part of the patentee to commercialize human cloning and perhaps also indicates a new willingness on the part of the PTO to grant patent claims covering such processes. To date, however, no clear ethical guidelines have ever been placed into patent law and moreover, the coming up commercialization of human cloning processes militate laws banning such techniques unqualified, need to be passed.

In certain easier occasions the PTO has rejected other patent applicants, who have filed for human cloning process based upon an unofficial policy dating from a pre-Dolly – 1987, PTO memorandum. However, no patent rules or laws have ever been promulgated which would certainly rule out the commercialization of humans. Although the EPO has issued rules which ban the patenting of human cloning and the commercialization of human embryos and fetuses, the rules have become law in many EU nations<sup>182</sup> but no similar laws exist in the US. It is noteworthy that the TRIPS Agreement explicitly allows for any nation to prohibit patenting of inventions which are contrary to morality and ordre public.<sup>183</sup>

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<sup>181</sup> Antonio Regaldo: *The University of Missouri receives patent in human Cloning method* The WALL STREET Journal, Available at <http://islet.org/forumo25/messages/22874.htm>. Accessed on 23<sup>rd</sup> Dec 2012.

<sup>182</sup> *Ibid.*

<sup>183</sup> Art 27. 2 of TRIPS Agreement 1995