

# Patenting Biotechnological Inventions in Europe and the US

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## I) INTRODUCTION

The patent system is designed to grant inventors and innovators exclusive rights over their inventions for a certain period of time in exchange for public disclosure of their inventions.<sup>1</sup>

Biotechnology is a new technique for industries and specialists and is making astounding progress. Advances in biotechnology are so rapid that many things are now possible, which, even a few years ago, would have seemed unimaginable.<sup>2</sup> It is a type of genetic engineering in medical and veterinary research resulting in modified productions and improved animal breeds.<sup>3</sup> It is the use of microorganisms, mammalian cells and their products for industrial, agricultural, and medical purposes.<sup>4</sup>

This is also a growing discipline with a remarkably strong market. In 2006, global turnover was estimated at \$60 billion, up 15 per cent from 2005.<sup>5</sup>

This rapid development has led to huge problems in biotechnology, particularly in patenting biotechnological inventions. In modern biotechnology, patents are a controversial issue and are more interesting for the public than any other technical field. Advances in biotechnology are bound up in ethical, religious, political and legal issues. Breakthroughs in this area of research invariably reach the headlines in the news. There have been reports on genome sequencing of gene development into protein expression, and enthusiastic discussion on the isolation of stem cell cultures, which makes human cell cloning possible. With public interest aroused, the occasion could arise when a scientific research institution, in order to protect their research investment, would have to consult a patent lawyer for advice. A rapidly increasing amount of genetic code and

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1 See Deming Liu, "Now the Wolf Has Indeed Come! Perspective on the Patent Protection of Biotechnology Inventions in China", 53 *American Journal of Comparative Law* 207, 207 (2005).

2 Noelle Lenoir, "Biotechnology, Bioethics and Law: Europe's 21<sup>st</sup> Century Challenge", 69 *Modern Law Review* 1, 1 (2006).

3 W. Cornish and D. Llewelyn, *Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights*, (Sweet and Maxwell, London, 2003), p.823.

4 Austin (Tex) Bus. J., Oct. 10, 1997, available at 1997 WL 12611805.

5 <http://www.epo.org/topics/issues/biotechnology.html>.

sequencing material is being patented provided that the patent is not so biotechnologically broad that it creates a monopoly or illegitimate patent production based on lack of product or potential product specificity.<sup>6</sup> Consequently, the idea that breakthroughs in genetic knowledge could be monopolized by a few multinational companies is a major cause of concern.

Throughout the world, patent offices, legislators and courts are deeply involved with these issues. Legal answers are more likely to be reached than political or ethical considerations satisfied. The ethics surrounding these issues must not be ignored nor can they be an obstacle to legal provision for potential inventions.

## II) HISTORICAL REVIEW

Inventors have been filing applications for biotechnological patents for over a hundred years. Patent No. 3, granted in Finland on 8 November 1843, introduced a novel method to produce yeast cultures. On 29 July 1873, microbiologist Louis Pasteur obtained a patent from the French Patent Office for his improved yeast-making method.<sup>7</sup>

In the last 50 years, very important biological advancements have taken place. Biological advancements usually require substantial investment for research. Therefore, investors turn to Intellectual Property Rights (IPRs), particularly patent systems, in the hopes of insuring their rights over their investment. In this way, the concerns of biotechnological research, its inventions, and IPRs are closely linked.

The United States was the first in the field with its decisions regarding the patenting of “living matter.” Early patents from the US were granted for bacterial and viral vaccines. Until the 1980s, it was usually agreed that “living things” were not patentable. This policy was revised in the 1980 landmark case of *Diamond v. Chakrabarty*. The invention concerned the discovery of a genetically-altered bacterium, which, when modified, could break down crude oil. As the US Supreme Court famously noted in this case, it now seemed possible to issue patents on “anything under the sun that is made by man.”<sup>8</sup> The Court decided that Chakrabarty’s invention was not a “product of nature” but a “man-made” bacterium, which did not occur naturally in nature. Thus, the court stated, it was “not nature’s handiwork, but Amanda Chakrabarty’s own; accordingly the Court held it was patentable subject matter.”<sup>9</sup> Thus, from then on, an invention involving a living organism could fulfill the criteria to be patentable subject matter, since a genetically modified bacterium, a bioengineered microbe, had been created to provide a useful function – to dissolve oil.

In the 1987 case of *Ex parte Allen*, the Board of Patent Appeals and Interferences ruled that polyploid oysters containing three sets of

6 John Salinas Lopez, “Should Genetic Code Be Patented?,” Law and Society Review at UCSB, Vol.1 (2002) Genetic Code 57.

7 <http://www.epo.org/topics/issues/biotechnology.html>.

8 447 U.S. 309 (1980).

9 *Ibid.* at 310.

chromosomes instead of two were patentable subject matter.<sup>10</sup> The decision resulted in the United States Patent and Trademark Office (USPTO) making an announcement that thereafter it would consider “non-naturally occurring, non-human multicellular living organisms, including animals, to be patentable subject matter within the scope of the Statute.”<sup>11</sup> Only one year later, in 1988, the first patent on a mammal was granted in the U.S. for the Harvard mouse (US Patent 4,736,866). Many patent applications in the U.S. have followed for genetically modified animals. The same case underwent a very complex process before it was finally granted a patent in 2004. The European equivalent to the US *Chakrabarty* case was the “*Rote Taube*” decision.<sup>12</sup> In this case, the patent application was refused because of difficulties in reproducing the invention but it was accepted that a process of animal breeding based on classical crosses and selection could be patentable material.

In 1973, the European Patent Office established the European Patent Convention (EPC), based on established national laws. Biotechnology, although a developing new field that is making discoveries that could never have been foreseen, is dealt with by a traditional body of law.

In July 1998, EU Directive 98/44/EC on the legal protection of biotechnological inventions, known as the “Biotech Patent Directive” was adopted. Its purpose was to clarify the distinction between what is patentable and what is not.<sup>13</sup>

### III) IMPORTANCE OF PATENTS IN THE FIELD OF BIOTECHNOLOGY

The major reason that inventors apply for patents is to protect their control over the technologies that they have invented. However there are also other reasons. A large patent portfolio is considered to be an indication of a strong company and can put companies in an advantageous position to attract investors and collaboration partners. Although there is the opposing argument that the costs of patenting and the requirement to disclose technical information are disproportionately large in comparison to the benefits, it is nonetheless clear that biotechnological inventions are patented extensively. In addition to this, companies derive great advantages from cross-licenses and the ability to undermine competitors. So the main object seems to be, not the protection of the technology *per se*, but the restriction of competition.

Patents are the most appropriate way of protecting biotechnological inventions. Other methods of protection, such as trademarks and trade secrets, are less relevant for biotechnological inventions because of the ease with which drugs can be copied through chemical reverse engineering.

<sup>10</sup> 2 USPQ 2d, 1425 (PTO Bd. Pat. App. & Int., 1987).

<sup>11</sup> USPTO, April 21, 1987.

<sup>12</sup> BGH, Beschluss vom 27.03.1969 – X ZB 15/67 (BPatG).

<sup>13</sup> <http://www.epo.org/topics/issues/biotechnology.html>.

#### IV) PATENTABLE SUBJECT MATTER

According to Article 27.1 of the WTO Trade Related Intellectual Property Rights (TRIPS) Agreement, “patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.” These requirements are arranged in all national legislation schemes in different provisions. Besides, these traditional requirements in the field of biotechnology there may be other requirements for the patenting procedure. Investors planning to obtain patent protection for biological inventions may confront different legal systems, patent authorities, substantive and procedural requirements, since the field is territorial in nature

##### A) Most relevant provisions regarding biotechnological inventions

1) Europe: European Patent Convention Art. 52-57, 83, 84; Rules 23 b-e, 28 and Directive 98/44/EC

2) US: Title 35 United States Constitution Section 101-103, 112, 287(c)

##### B) Prerequisites of patentable subject matter

For a living thing to be patentable, it must meet two prerequisites of patentable subject matter. The living thing must be an “invention” within a “patentable class.” In all national legislation schemes, these prerequisites must be in place for a patent to be granted for a biotechnological invention. Each of them will be examined by focusing on the legislation separately.

##### 1) First prerequisite – the distinction between Inventions and Discoveries

The specific definition of an invention is not included either in the United States Patent Act or in the European Patent Convention and discoveries are excluded from patentability.<sup>14</sup>

###### a) The United States

To be eligible for a patent, an invention must fit within one of the statutory categories of patentable subject matter established in Section 101 of the US Patent Act:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.<sup>15</sup>

The case of *Diamond v. Chakrabarty* was the first time a court made

<sup>14</sup> Convention on the Grant of European Patents (5 October, 1973, Munich; as amended for the last time 10 December, 1998) Art. 52. Patentable inventions are described by giving the list of exclusions that “shall not be regarded as inventions: (...) (a) discoveries, scientific theories and mathematical methods; (b) aesthetic creations; (c) schemes, rules and methods for performing mental acts, playing games or doing business, and programmes for computers; (d) presentations of information.

<sup>15</sup> 5 U.S.C. Section 101.

a decision to change the paradigm of enquiry for biotechnological inventions. The meaning of the statute was clarified in a broad sense for biological inventions in the *Chakrabarty* decision. The U.S. Supreme Court decided in this case that “anything under the sun that is made by man” is patentable subject matter.

According to the court decision, what is needed to evaluate biotechnological patent claims is to determine whether a product is of a living nature, or is of human invention, rather than of making one’s judgment based on whether the product is living or inanimate. Applying this criteria means natural products can be seen to be biologically active substances or chemical compounds and not merely as products of nature.

Thus, the issue is already settled. As long as the living matter applications under 35 USC Section 101 are a product of human ingenuity – viruses, single cells or multicellular organisms, they, can, like plants and non-human animals be considered to be living matter.

A common issue arising from biological inventions is the problem of novelty and the distinction between discovery and invention. Pure products of nature are not patentable. In order for the subject matter of natural origin to be patentable under 35 U.S.C. Section 102, a human being must impart a new form, a new quality, at least one new property, or combinations thereof, to the original product existing in nature. The main issue regarding patentability of biotechnological inventions concerns the extent to which they are made publicly available and how the claimed inventions are different from what is found in nature. Products, which have a higher purity or activity from the original, have distinguishing physical properties or a different physical form may be patentable.

### **b) Europe**

*“Discoveries (...) shall not be regarded as inventions.”<sup>16</sup>*

Similarly in Europe, just as there is in the US, there is a legal objection to allowing patents for living things. This view is based on the “product of nature” doctrine. If a new property of a known article or of a previously recognized substance existing in nature is found, it is a “discovery” and not patentable as such.<sup>17</sup> However, if an applicant proves that a substance found in nature can be put to a new use (for example, a micro-organism X is proved to be useful in diagnosing Y disease) or if another technical effect is established, then such a “living thing” and its use may be patentable as an invention.<sup>18</sup> Thus, the concept that ‘discovery’ is necessary in order for a patent to be granted is interpreted narrowly under the EPC as well as other exclusions.

A leading decision on patentability of naturally-occurring substances and the distinction between discovery and invention was made by the

<sup>16</sup> EPC, Convention on the Grant of European Patents, Art.52 (2) (a).

<sup>17</sup> Guidelines for Examination, Part C, Chapter IV, Section 2.3; [http://www.european-patent-office.org/legal/gui\\_lines/index.htm](http://www.european-patent-office.org/legal/gui_lines/index.htm).

<sup>18</sup> *Ibid.*

German BpatG (Bundespatentgericht) in the *Antamanid* case.<sup>19</sup> The decision made clear that substances occurring naturally are patentable if they are new and have been isolated by technical means. It also has to be publicly available in that form and that it could not have been found without technical intervention. An isolated gene, which is identical to the gene found in nature, may be patentable if the gene sequence has never been isolated before.

Article 3 of the Directive makes it clear that once the criteria have been met, the biological products or material, or a process by means of which it is produced, processed or used, is patentable. The isolated element of the human body is only patentable in its natural state. The factors that make the element so are the technical processes used to identify purity and classify it and to reproduce it outside the human body, techniques which human beings alone are capable of putting into practice and which nature is incapable of accomplishing by itself.<sup>20</sup>

When it comes to human beings, there is the commonly accepted approach that such intervention and human parts should not be patented.

Therefore, it would seem important to exclude unequivocally from patent ability, processes for modifying the germ line genetic identity of human beings and processes for cloning human beings.<sup>21</sup>

Art. 52(1) of the EPC defines patentable inventions as:

European patents shall be granted for any inventions which are susceptible to industrial application, which are new and which involve an inventive step.<sup>22</sup>

In Article 52(2), the second part of the article lists subjects which shall not be regarded as inventions. Discoveries are strongly excluded from patentability in this article.

## 2) Second prerequisites

### a) *Ordre public* and morality

This area is exclusive to EU Patent Law. EPC Article 53 (a) and (b) bring further restrictions on biotechnological patents. As stated in part (a) it excludes inventions contrary to “*ordre public*” or morality and in (b) excludes “plant or animal varieties or essentially biological processes for the production of plants or animals.”

EU Directive 98/44/EC and its 1:1 implementation into Rules 23b-e of the EPC further specifies exceptions to patentability that are in conflict with “*ordre public*” or morality. Excluded is cloning of human beings, modification of the human germ line, using human embryos for industrial or commercial purposes and genetic modification of animals that causes

<sup>19</sup> BpatG, Beschluss vom 28.07.1977 – 16 W (pat) 64/75 “Naturstoffe.”

<sup>20</sup> Recital 21.

<sup>21</sup> Recital 40, the Directive.

<sup>22</sup> EPC Article 52(1).

them suffering without substantial medical benefit.<sup>23</sup>

*Although EPC Art. 53(a) explicitly states that inventions contrary to the “ordre public” or morality are patentable, the meaning of these two terms are not clarified.*

The concept *ordre public* has an untranslatable character.<sup>24</sup> It was originally used in continental Europe. In some documents, the concept of *ordre public* means public security and the physical integrity of the individual and environment,<sup>25</sup> but it is more than that. Briefly, *ordre public* means the proper order of the whole society.<sup>26</sup>

Although according to EPC Art. 53(a), inventions contrary to morality are excluded from patenting, the grounds regarding morality are uncertain and flexible, for what is seen to be contrary to morality changes with time and place. Sometimes attitudes even vary in a particular country at a particular time. Moreover, there is the belief that “morality issues are marginal, or even irrelevant to patent law,” that patents have more in common with finance, than morality.<sup>27</sup> However, there is a great public concern over this matter, particularly over patenting biotechnological inventions, since there is the fear that they may damage society.

### **Morality after the Directive**

The European Union adopted a Directive on the Patenting of Biological Inventions in 1998. It came into force on 6 July 1998 as Directive 98/44.<sup>28</sup> Member States had to implement this Directive before July 2000. However, there was some opposition to the Directive in Europe. For instance, Netherlands applied to the Court of Justice for a modification while Germany, France, and Austria did not implement the Directive before 2004.<sup>29</sup>

First of all, the Directive defined the distinction between what is patentable and what is not. For example, an invention relating to individual human, animal or plant genes and gene sequences, and their functions, can be patented as long as the other patentability criteria are fulfilled.<sup>30</sup>

In the first draft of the Directive, there was no reference to morality regarding patenting. In the course of time public concerns were voiced and the Directive became a focus for the consideration of the ethical and social dimensions of biotechnology.<sup>31</sup> Those evaluating the patenting of biotechnological inventions were of the view that the patent system, as it stood, was an inappropriate instrument to deal with ethical questions because the existence of a patent cannot control how an invention is exploited.<sup>32</sup>

23 D.Schertenleib, E.I.P.R. 2004, pp.203-213 (general review on patentability of living organisms in Europe).

24 Cornish and Llewelyn, supra note 3, at 224.

25 See Guidelines for Examination, supra note 17.

26 P.W. Grubb, Patents for Chemicals, Pharmaceutical and Biotechnology, Oxford Un. Press (2004), p. 281.

27 Ibid.

28 OJ Official Journal 1998 L 213/13.

29 Grubb, supra note 26, at 278.

30 <http://www.epo.org/topics/issues/biotechnology.html>

31 Lionel Bently and Brad Shermann, Intellectual Property Law (2004), Oxford Un. Press, Oxford, p. 439.

32 Ibid, at 439.



In the view of the evaluators, the means to control biotechnological inventions should be the responsibility of a different regulatory system.

After discussions, the Directive compromised, accepting that inventions must be unpatentable should their commercial exploitation be contrary to *ordre public* or morality. There are institutions and organizations in the world which play a key role in deciding on ethical issues. One such institution is the Nuffield Council on Bioethics in the UK, which examines ethical issues raised by new developments in biology and medicine.<sup>33</sup> The Nuffield Council supports embryonic stem cell research when it can be proved that such research is not contrary to public welfare or morality.<sup>34</sup>

### **b) Plant and Animal varieties**

EPC Article 53 (b) states that patents shall not be granted on “plant or animal varieties or essentially biological processes for the production of plants or animals.” Upon first impression, it seems that even a living thing may qualify as a “manufacture” or a “composition of matter” and as such would meet the statutory subject matter requirements in the United States.<sup>35</sup> The EPC, however, expressly excludes all living inventions such as “plant or animal varieties” from patentability and distinguishes them from microbiological<sup>36</sup> ones. The term “variety” creates a difficulty in this case since its definition is still vague. This exception does not infer “general exclusion of inventions in the sphere of animate nature”<sup>37</sup> and is interpreted narrowly meaning that if an invention does not deal with a single plant or animal variety it can still be patentable provided other requirements are satisfied.<sup>38</sup>

### **c) Patentability of therapeutic and diagnostic methods**

According to Art. 52(4) of the EPC “methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body shall not be regarded as inventions which are susceptible to industrial application.”

In the US, therapeutic and diagnostic methods carried out on humans are patentable. However, medical activities “which means the performance of a medical or surgical procedure on a body,” may be limited by 35 U.S.C. Section 287 (c). Remedies cannot be sought against a medical practitioner or a health care entity with respect to such medical activity. However, the level of regulation is different and the final outcome and the implications are the same, since Europe and Japan exclude methods for treatment and diagnosis from patentability by law and the US limits the enforcement of such patents. These medical treatments should not be monopolized and

<sup>33</sup> <http://www.nuffieldcouncil.com>.

<sup>34</sup> *Ibid.*, at 440.

<sup>35</sup> *Diamond v. Chakrabarty*, 206 UPSQ 193 (Sup.Ct.1980).

<sup>36</sup> “Microbiological” is defined as involving mono-cellular organisms, bacteria. See Guidelines for examination, *supra* note 17.

<sup>37</sup> Implementing Regulations to the Convention on the Grant of European Patents, Rule 23(c).

<sup>38</sup> Katrina McClatchey, The European Patent Office and the European Patent: an Open Avenue for Biotechnologists and “Living Inventions”, 2 *Okl. J. L. & Tech.* 25 (2004).



the practitioners should be free to use such methods for the benefit of their patents.

### **C) The Essential Requirements**

#### **1) Novelty**

The first and clearest requirement is that nothing can be patentable which is not new.<sup>39</sup>

It is widely known that the requisites for novelty and inventive application are not easily applied to patenting procedures for biological products and processes. This has been a continued discussion in many countries, mainly in the United States and the European Union, and has been dealt with by new regulations and policies on the issue.

Patents on genes have been reviewed on many grounds. A common complaint is that genes are naturally occurring entities that exist in living organisms and thus are not invented but discovered. This argument does not bear any weight in science or in law.<sup>40</sup> The DNA sequences used by biologists are ‘new’ in the sense that they have never existed in that form before and also they are always modified to an appreciable extent. The law has recognized for some time that the DNA we use is created and not discovered.

Specifically on the subject of genetic patents, a joint statement of the USPTO, EPO, and JPO<sup>41</sup> confirmed that genes are patentable. More recently, the new European Biotechnology Directive<sup>42</sup> and the Examination Guidelines of EPO also support this view.

In the United States, under Section 102 of the statute, what is claimed as an invention must be new in order to be eligible for a patent.<sup>43</sup> The novelty bar calls for the examination of the relevant “prior art,” which contains the teachings of printed publications.

Section 102(a) requires that the applicant has invented the claimed invention prior to its use by others in the United States and prior to its patenting or description in a printed publication anywhere in the world.<sup>44</sup> Section 102 (f) further specifies that the applicant must have been the true first inventor, and may not have derived the invention from others.<sup>45</sup>

As Section 102 shows, the novelty requirement is treated simultaneously with newness.<sup>46</sup> In the substantive law of both systems, the novelty requirement is based on the idea that the inventor cannot patent something that already exists in the public domain. In court decisions, the concept of novelty is generally discussed in conjunction with the product of nature doctrine.

39 Philip w. Grubb, *Patents for Chemicals, Pharmaceuticals and Biotechnology*, Oxford, 2004, 4<sup>th</sup> Edition p.58.

40 Denis Schertenleib, *The Patentability and Protection of DNA-BASED Inventions*, (2003) E.I.P.R., p.126

41 Reported in 7 *Biotechnology Law Review* 159 (1998).

42 Art.3.2 Directive 98/44 on the Legal Protection of Biotechnological Inventions.

43 35 U.S.C. Section 102 (a), (e), (f), (g)

44 35 U.S.C. Section 102 (a).

45 35 U.S.C. Section 102 (f).

46 35 U.S.C. Section 102.

For example, in *Funk Brothers Seed Co. v. Kalo Inoculant Co.*,<sup>47</sup> a patent application was invalidated on the basis of lack of novelty, since the company's claim was for a mixture of six naturally occurring bacteria which trigger nitrogen-fixing functions in leguminous plants. This was not the same as the *Chakrabarty* case, where the bacteria was new and human-engineered. In its decision, the court reasoned that each bacterium is a "manifestation of the laws of nature, free to all men and reserved exclusively to none."<sup>48</sup>

In Europe, the main point of the novelty requirement is that the invention has not been previously made available to the public. Within the realm of human genetics, novelty is proven if the total genes or a larger gene section, including the partial sequence, has previously been made known.

In the case of the isolation of gene sequences with no known function, even where there is a structural partial identity between the claimed and the known gene sequence, an inventor can acquire a use patent on the basis of the description of a new function.<sup>49</sup> The emergence of novelty does indeed depend on the value of this knowledge for technical activity, rather than upon the purely intellectual information. On this basis, a use patent is not granted for the means of attainment of the use, but for the previously unknown use itself.<sup>50</sup>

This fact is important in view of the high production rate of gene sequences by the Human Genome Project. Some of these are available from public databases, but now it is enough that this fact will not invalidate the novelty requirement for related technological developments in the future. On the other hand, if the new use has benefits for medicine, the court's definition has been changed to compensate for the exclusion from patentability for methods of medical treatment.

Significantly, it is now possible to patent second and additional non-medical uses.<sup>51</sup> The basic assumption in patent law is that the discovery of a use for a previously unknown thing or substance may found claims to the thing or substance itself, whatever it is subsequently used for.<sup>52</sup> As a result, the second inventor can be acknowledged just for the new use claims. The Directive does not in any way affect the concept of current patent law, according to which a patent may be granted for any new application of a patented product.<sup>53</sup>

As a result, the sequencing and isolation of the gene itself is relatively straightforward. The inspirational work comes in with the exploration

47 *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948).

48 *Ibid.*

49 Andreas Oser 'Patenting (Partial) Gene Sequences Taking Particular Account of the EST Issue,' 30 IIC 1-18 at 11.

50 *Plant Growth Regulating Agent/BAYER*, 1990 OJ EPO 114, at 115.

51 In *Friction Reducing Additive/MOBIL OIL*, 1990 OJ EPO 93, the enlarged Board of Appeals concluded that a new use of a known compound may reflect a newly discovered technical effect. ('If that technical feature has not been previously made available to the public by any of the means set out in Art 54(2) EPC, then the claimed invention is novel, even though such technical effect may have taken place in the course of carrying out what has previously been made available to the public').

52 William Cornish, *Intellectual Property: Patents, Copyright, Trademarks and Allied Rights*, (4<sup>th</sup> ed) p 186.

53 Recital 28.

of the functional aspects. Therefore, the patent system may be giving out rewards incommensurate with achievement in such a case that is peculiar to the state of the technology. Protecting initial discoveries with a broad monopoly assumes that these discoveries comprise the major breakthroughs. For inventions in human biotechnology, this is not necessarily true.

## 2) Inventive Step/Non-Obviousness Requirement

This requirement is called the inventive step in Europe, and non-obviousness in the US. The critics of patenting say that generally there is a lack of inventive activity in innovations. They usually originate primarily from manipulation or combination of genetic material already existing, or, more definably, it is just the isolation of organisms and substances that occur naturally in nature. The most frequent argument against biotechnological inventions and processes is that they are discoveries, rather than inventions. However, the biotechnological institutes and organizations are still making investments in this field as they see the patent system as the only way of achieving the protection for their innovations, once they have become known to the competitors.

The American requirement for non-obviousness states that the invention is not patentable, if considered as a whole, it would be obvious to any person having ordinary skill in the art. This test is similar to the inventive step test in Europe, which focuses on the idea that inventions should be examined as a whole product. It involves a fact-oriented determination, where failed attempts by others to achieve the claimed invention are important.<sup>54</sup>

With special importance for biotechnology inventions, factors of “reasonable expectation of success” and “unexpected properties” were introduced.<sup>55</sup> If the prior art stimulates motivation for the invention and enables an expert in the art to invent something with a reasonable expectation of success, the living invention will be considered obvious as a result and cannot be patented. On the other hand, the invention can be non-obvious if the applicant can justify that his invention has an unexpected yield and superior purity.

The approach of the United States Court of Appeal for the Federal Circuit (hereinafter the “Federal Circuit”) to DNA-based inventions is applied in a manner that lowers the standard bar for patentability, thus expressly making the quality poorer. As noted earlier, non-obviousness precludes patentability if, given the prior available technology (known as the “prior art”), the invention would have been obvious to someone of “ordinary skill in the art.”

In the 1990’s, two cases, *In re Deuel*<sup>56</sup> and *In re Bell*,<sup>57</sup> the Federal

54 Indre Kelmelyte, Can Living Things Be Objects Of Patents?, 2 International Journal of Baltic Law 8 (April 2005).

55 Laurie L. Hill, The Race to Patent the Genome: Free Riders, Hold Ups, and the Future of Medical Breakthroughs, 11 Tex. Intel. Prop. L. J. 221 (Winter 2003).

56 51 F. 3d 1552 (Fed. Cir. 1995).

57 991 F. 2d 781 (Fed. Cir. 1993).

Circuit has, however, rejected arguments by USPTO patent examiners who are skilled in the art of biotechnology, that knowing a general method for identifying genes through the use of nucleotide probes, as well as the complete or partial amino acid sequence of a protein, renders the DNA base sequence for that protein obvious.<sup>58</sup> The Federal Circuit has justified its decisions by arguing that, with respect to patent claims to DNA sequences, the non-obviousness determination must focus on the DNA molecules as chemical compounds rather than on the method for isolating the DNA.<sup>59</sup> Thus, according to the Federal Circuit, any given DNA sequence (whether a full DNA sequence that encodes a gene or a mere sequence fragment) is obvious only if the prior art actually recites a similar or identical sequence and not simply a method for isolating the sequence.<sup>60</sup> In this regard, DNA sequences can be non-obvious no matter how easy or routine it is to isolate the sequences.<sup>61</sup>

The biotechnology Patent Protection Act was signed into law in 1995. This made sure that those patentable processes resulting in a patentable composition of matter are patentable.

The European inventive step requirement is explained in EPC Article 56. It states that the invention must not be obvious to a person skilled in the art. The Board of Appeal of the EPO has developed an approach, called the “problem-solution approach,” to assess whether an invention involves an inventive step. All EPO branches apply this approach to decide whether an invention involves an inventive step. This approach consists of three steps: closest prior art, objective technical problem and obviousness.

- The first step, closest prior art, consists in assessing what it is the most promising starting point from which a skilled person could have arrived at the invention.

- The second step determines the technical problem which the claimed invention aims to solve. This implies determining the feature(s) distinguishing the claimed subject-matter from the closest prior art, determining the technical effect(s) of the distinguishing feature(s), and finally the objective technical problem is how to adapt or modify the closest prior art to obtain the identified technical effect.<sup>62</sup> “Alleged advantages to which the patent proprietor/applicant merely refers, without offering sufficient evidence to support the comparison with the closest prior art, cannot be taken into consideration in determining the problem underlying

<sup>58</sup> Indeed, the USPTO patent examiners have gone so far as to say that “when the (amino acid) sequence of a protein is placed into the public domain, the gene is also placed into the public domain because of the routine of cloning techniques.” *Ex Parte Deuel*, 33 U.S.P.Q.2d 1445, 1447 (Bd. Pat. App. & Int’l 1993) (citing the views of the USPTO examiners).

<sup>59</sup> *bid.* at 1559 (“The USPTO’s focus on known methods for potentially isolating the claimed DNA molecules is also misplaced because the claims at issue define compounds, not methods.”) (citing *In re Bell*, 991 F.2d 781, 785 (Fed. Cir. 1993)).

<sup>60</sup> Arti K. Rai, “Intellectual Property Rights In Biotechnology: Addressing New Technology,” p. 834

<sup>61</sup> See Rebecca Eisenberg & Robert Merges, Opinion Letter as to the Patentability of Certain Inventions Associated with the Identification of Partial cDNA Sequences, 23 AIPLA Q.J. 1, 32 (noting that the Federal Circuit’s approach “would seem to make all novel DNA sequences patentable, however trivial the scientific advance that led to their identification. This position collapses the novelty and non-obviousness requirements for DNA sequences.”).

<sup>62</sup> [http://en.wikipedia.org/wiki/Closest\\_prior\\_art](http://en.wikipedia.org/wiki/Closest_prior_art).

the invention and therefore in assessing inventive step”.<sup>63</sup>

- The third and the last step concluded by the “could-would approach”. The question is the climax to assess whether the invention involves an inventive step. Is there any teaching in the prior art, as a whole, that would, not simply could, have prompted the skilled person, faced with the objective technical problem formulated when considering the technical features not disclosed by the closest prior art, to modify or adapt said closest prior art while taking account of that teaching (the teaching of the prior art, not just the teaching of the closest prior art), thereby arriving at something falling within the terms of the claims, and thus achieving what the invention achieves?<sup>64</sup>

- The key point of the third step is that the skilled person should not have arrived at the claimed invention by changing it. Whether he would have done so because the prior art incited him to do so in the hope of solving the objective technical problem or in expectation of some improvement or advantage is the question.<sup>65</sup>

### 3) Industrial Applicability/Utility Requirement

#### a) The United States

In order for an invention to satisfy the 35 USC Section 101 utility requirement, it must be useful. In 1995, the utility examination guidelines were published by the USPTO. These guidelines stated that the utility should be both specific and credible.

The Federal Circuit issued a patent law decision in September 2005 that inevitably rendered hundreds of pending patent applications worthless and that will raise the bar for proving gene sequence and protein-related inventions useful.

The Federal Circuit ruled against the patent applicants in *In re Fisher* by upholding the decision of the USPTO Board of Patent Appeals and Interferences that bars patent protection for gene fragments that do not have a “specific and substantial” utility. The court had its first opportunity to comment on the USPTO Revised Utility Examination Guidelines of 2001 with the presentation of the *Fisher* case. Focusing on the patentability of research tools, it found that none of the claims made by Fisher to ESTs met the requirements of the specific and substantial utility tests.

#### b) Europe

The European Patent Office (EPO) showed that, in these jurisdictions, an invention shall be considered to be susceptible (or capable) of industrial application “if it can be made or used in any kind of industry, including agriculture.” The general understanding is that the term “industry” shall be interpreted in the broadest possible sense.

<sup>63</sup> Investigates the “could-would” question when determining if the skilled person is prompted to combine two prior art references.

<sup>64</sup> [http://en.wikipedia.org/wiki/Closest\\_prior\\_art](http://en.wikipedia.org/wiki/Closest_prior_art).

<sup>65</sup> Ibid.

With regards to utility, the EU Directive has included a provision that needs clear specification of the function, Recital 23 reads:

Whereas, in order to comply with the industrial application criterion it is necessary in cases<sup>66</sup> where a sequence or partial sequence of genes is used to produce a protein or part of a protein, to specify which protein or part of a protein is produced or what function it performs.

#### **4) The Disclosure (written description) requirement**

##### **The United States**

The disclosure requirement is not covered in European legislation, but is in the United States. The Patent Act embodies a written-description requirement to ensure that an applicant has actually invented what is claimed and that the public will be in possession of the claimed invention after the expiration of the patent.<sup>67</sup> The new guidelines issued by the USPTO, the Guidelines for Examination of Patent Applications, under 35 U.S.C. Section 112, “written description” requirement, set forth the methodology for determining the adequacy of a written description.<sup>68</sup>

For each claim, the examiner should first determine what the claim as a whole covers and give the claim its broadest reasonable interpretation.<sup>69</sup> The entire patent application is then reviewed to understand how the applicant provides support for each element of the claimed invention and determine whether the applicant has demonstrated possession of the claimed invention. Such a review is to be conducted from the standpoint of one of skill in the art at the time the application was filed. Information that is well known in the art need not be described in detail in the specification.<sup>70</sup>

In contradiction to the non-obviousness requirement, the Federal Circuit has used the written requirement in a manner that somewhat raises the patentability bar.<sup>71</sup>

#### **V) THE ONCO MOUSE CASE**

The following case is given as an example to illustrate the importance of patenting biotechnological inventions and also to discuss the problems therewith.

The history of the Harvard Onco-mouse began in the early 1980s after the successful development of a “transgenic non-human mammal, all of whose germ cells contain a recombinant activated onco-gene

<sup>66</sup> Soames, C.J. and Kowalski, Inventive Step and Genomics, 3 Nature Review 729.

<sup>67</sup> 35 USC Section 112.

<sup>68</sup> Guidelines for Examination of Patent Applications Under the 35 USC Section 112, “Written Description” Requirement, 66 Fed. Reg. 1099 (Jan. 5 2001) (bb. p. 98)

<sup>69</sup> *Ibid* at 1105.

<sup>70</sup> *Ibid*.

<sup>71</sup> This raising of the patentability bar in the context of the written description requirement does not, however, by any means counter the effect on the public domain of the Federal Circuit’s having virtually eliminated the non-obviousness bar with respect to DNA. The virtual elimination of the non-obviousness bar allows a vast proliferation of patents on relatively trivial inventions that are nonetheless essential for future research. By contrast, the raising of the written description bar typically serves merely to narrow the scope of the claims that can be made for some of these inventions. Even with narrow claims, the patent owner still exerts an inefficient level of control over future research.

sequence introduced into said mammal or an ancestor of said mammal, at an embryonic stage.”<sup>72</sup> This invention was disclosed to art and a claim for patent was made by the President and Fellows of Harvard College in the USA. The genetically modified mouse with a predisposition for developing cancer was intended for use in tests.<sup>73</sup>

Applications along the same lines were made in many countries: Australia, Canada, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, the Netherlands, Portugal, Spain, Sweden, and the United Kingdom.

As earlier mentioned, the U.S. Supreme Court in *Chakrabarty* accepted that “anything under the sun that is made by man” is patentable.<sup>74</sup> It can be readily assumed that inventions made beyond the sun would also be considered patentable under the provision of the U.S. Code which reads as “any invention (...) title.” When making the decision, the Court emphasized particularly the need to broadly construe Section 101 of Title 35 of the U.S. Code. In conclusion, the Court found that the claimed bacterium “plainly qualified as statutory subject matter.” Another notable point is that the Court refused to consider moral and policy arguments against granting patents for living matter.<sup>75</sup> The Court also stated that these moral and policy arguments presented issues beyond the Court’s capabilities and as such were more suitable for consideration through the legislation process.

The outcome of the decision made in *Chakrabarty* has influenced other decisions rendered in similar situations. Particularly, it opened the door to patenting the Onco-mouse in the United States.

Although no objections were proposed by the commissioners, the patenting of the Onco-mouse in the US took nearly four years. The first application was filed on June 22, 1984 and the patent was granted on April 12, 1988.<sup>76</sup>

### **The Onco Mouse in Europe**

The patent application for the Onco-mouse in the EPO became such a lengthy procedure that it has been called a “saga.”<sup>77</sup> After the filing in the US, the inventors also applied for a European Patent from the European Patent Office on June 24, 1985. This was the first-ever application to the EPO involving an animal.

Criticism of the patent procedure focused on the question of whether an animal as such could be patented at all.<sup>78</sup> More specific concerns were voiced about the potential for making commercial profit from engineered

72 Emir Aly Crown Mohammed, “Cat in the Hat, a Mouse in the House - Comparative Perceptives on the Harvard Mouse,” *IPJ*, V.18, (2004-2005), p. 170.

73 <http://www.epo.org/topics/issues/biotechnology.html>.

74 Mohammed, supra note 72, at 172.

75 Matthias Kamber, Coming out of the Maze: Canada Grants the Harvard Mouse, 35 *George Washington International Law Review* 764 (2003).

76 Patent number 4,736,866. See Mohammed, supra note 72, at 171.

77 Grubb, supra note 39, at 276; Bentley and Shermann, supra note 31, at 441.

78 <http://www.epo.org/topics/issues/biotechnology.html>



laboratory animals, with a number of groups proclaiming their opposition to laboratory testing on animals in general.<sup>79</sup>

The application was refused on July 14, 1989 on the grounds that the basic requirements of Art. 53(b) and 83 of the EPC were not met, because an animal variety was contrary to Art. 53(b).<sup>80</sup>

The exclusions from patentable inventions in Article 53(b) read as “plant or animal varieties or essentially biological processes for the production of plants or animal; this provision does not apply to microbiological processes or products thereof.”

After the first refusal of the EPO branch Examining Board, the case was appealed to another body of the EPO, the Board of Appeals. The Board of Appeals criticized the Examining Board’s decision and, with their concluded decision on May 13 1992, the EPO granted European Patent No. 0 169 672 to the Harvard Onco mouse. This patent included many of the privileges and interests which were granted already in the earlier US patent issuance.<sup>81</sup> This created oppositions from a lot of political parties, NGOs, religious groups and individuals.

Opposing applications were made especially by green activists, animal rights and farming interest groups. The Opposition Division of the EPO had dealt with the case from on and within the influence of the new 1998 EU Directive on biotechnological inventions -- 98/44/EC had its final acceptance in July 2004, 19 years after the patent application was made. They stated that another criterion had to be taken into account. This key criterion found a balance between “suffering and substantial medical benefit” in Rule 23(d) of the EPC.

The Opposition Division has particularly taken into account Rule 23 (b) and (c), which provides for patents for “plants or animals” under conditions laid down in the Rule 23 (d). Rule 23(d) also excludes from patentability “processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal and also animals resulting from such processes.”<sup>82</sup>

The Opposition Division stated that another criterion has to be taken into account. This key criterion found a requirement for balance between “suffering and substantial medical benefit” in Rule 23(d). The Opposition Division stated that if there is suffering in accordance with EPC Rule 23(d), this suffering must be balanced by a substantial medical benefit.<sup>83</sup>

When stating the benefits provided by the invention, the Opposition Division emphasized two points. The first was that the date of the patent application would be taken into account for the assessment, not the date at which the assessment was actually made. This meant that later evidence

<sup>79</sup> *Ibid.*

<sup>80</sup> Grubb, *supra* note 39 at 276; Mouhhammed, *supra* note 72, at 173.

<sup>81</sup> <http://www.epo.org/topics/issues/biotechnology.html>

<sup>82</sup> For details of this procedural issue, see Grubb, *supra* note 39, at 276; Mohammed, *supra* note 72, at 177-179.

<sup>83</sup> Harvard/Oncomouse (2003) OJEP 473, 503 (Opposition Division).

from the application date would be invalid for the assessment.<sup>84</sup> Second, as an answer to the question – how is the benefit to be assessed? – the Opposition Division focused on the subjective view point of the inventor. According to the general principles of the law, this subjective view point should be “bona fide.” Thus the inventor’s *bona fide* belief would be decisive for the medical benefit which is essential for right to patent for biotechnological inventions.<sup>85</sup> In conclusion, according to the opposition, Division Rule 23d (d) was not a ban to the patentability.<sup>86</sup>

The opponents also argued that the Onco-mouse patent fell afoul of Article 53 (a) of the EPC. Regarding this argument, the Opposition Division said that Art. 53 (a) would only apply to exceptional cases. They also added that they had no intention of applying extreme positions. They meant that they would not take responsibility for possible abuses of the invention.<sup>87</sup> According to the Opposition Division, *ordre public* and morality issue had to be examined first since the laws and regulations are common and these laws and regulations are the best indicators of the values of the whole society -- what they consider to be right or wrong.

In the end, the Opposition Division issued a written decision early in 2003 which limited the granting of a patent to rodent species considered to be suitable animals for experiment.<sup>88</sup> Some parts of the content and major principles of this decision were given and discussed above. An appeal was also filed in May 2003, and a final decision was rendered by the EPO Board of Appeals in July 2004. In this decision, mice were designated instead of rodents. Finally, after 19 years the first Onco mouse application was filed to the EPO, it was granted a patent.

This final decision cannot be further appealed at the EPO level. However, an application against the present patent of the Onco-mouse will be given to obtain an invalidity decision from a court at the national level.

## VI) FOUR APPLICATIONS OF DNA SEQUENCES IN RELATION TO PATENT CLAIMS:

### 1) Research Tool Patents and Experimental Use

#### a) Research Tools

The concept “research tool” covers the full range of resources that scientists use in their laboratories that have no immediate therapeutic or diagnostic value.<sup>89</sup> The term research tool as used in biotechnology can be defined in various ways. For example, one broad meaning was proposed by Walsh, *et al.* as “any impute into the process of discovering a drug or any other medical therapy or method of diagnosing a disease.”<sup>90</sup> Another

84 Mohammed, *supra* note 72, at 179; Bentley and Shermann, *supra* note 31, at 441-442.

85 See *Ibid.*

86 Bentley and Shermann, *supra* note 31, at 442. .

87 Harvard/ Oncomouse, 2003 OJEPO, at 503.

88 T 315/03 (EPO)

89 Australia Law Reform Commission; 1 file:///C:/:/DOCUME~1/DO2ADD~1/DRB/LOCALS~1/Temp/R2PATWN2.htm.

90 J.P. Walsh, A. Arora and W.M.Cohen, “Effects of Research Tool Patents and Licensing on Biomedical Innovation” in *Patents in the Knowledge Based Economy* (Cohen and Merrill ed., Na.Ac.Press, Washington D.C.,2003),p.287.

definition was given as “the full range of tools that scientists use in the laboratory.”<sup>91</sup> Research tools may cover a gene, a protein, a process or a procedure. Some particular examples are polymerase chain reactions, cell lines, monoclonal antibodies, reagents, animal models, growth factors, combinatorial chemistry and DNA libraries, chemical markers, genomics databases, microarrays, assays, transgenic mice, embryonic stem cells, and any cell receptor or any enzyme.<sup>92</sup>

Any research tool in the above list is important to the drug industry for the process of drug discovery and for human health; each may be used severally or in combination with others. Normally all these are patentable if they meet the criteria in the country in which a patent is requested. The main question here to be answered is what exemptions to patent infringement might apply to typical uses of these types of research tools.

### **Recommendation of the Nuffield Council**

In the opinion of the Nuffield Council, patents on DNA sequences used as research tools should be granted restrictively. The Nuffield Council encourages the use of the Utility Guidelines for DNA sequences established by the USPTO and applied by the EPO. The Council advises the USPTO, EPO and JPO to observe how the Guidelines work in practice, aiming at a more clear expression of the inventor’s contribution. The Guidelines should be changed if this goal is not achieved.<sup>93</sup>

The Nuffield Council points out one particular type of research tool – ESTs – in case rights are granted to include all DNA sequences that consist of EST being the original patents’ subject, the applicant should not get the patent.<sup>94</sup>

They recommended to that national patent offices that “[t]he EPO and the World Intellectual Property Organization (WIPO) [should] limit patent claims for ESTs strictly to their specified uses to avoid dependency on subsequent patents which have overlapping DNA sequences. We further recommend that WIPO and the EC (39) closely monitor the development of EST patents worldwide.”

### **b) Experimental use**

A great deal of development takes place in the science of biotechnology every day. Experimentation to further general understanding must continue in this rapidly advancing area. In order to provide this, it is important to keep certain areas free of patent constraints, which are expressed through the experimental use exemption.

Many national laws on patenting traditionally allow such an exemption for the non-commercial activities of researchers, particularly in a university or government laboratory.

<sup>91</sup> NIH Guidelines, <http://ott.od.nih.gov/textonly/rtguide%5Ffinal.html>.

<sup>92</sup> Fiona Bor, Exemptions to Patents Infringement Applied to Biotechnology Research Tools (2006) E.I.P.R., 6.

<sup>93</sup> *Ibid.*, at 59, 60.

<sup>94</sup> *Ibid.*, at 58.

### **i) Europe**

The present European Law allows exceptions for experimental uses while private, non-commercial uses are also allowed.<sup>95</sup> For example, a scientist working alone without any financial support can claim a right to free use of a patented research tool. This is only possible where no physical material has to be obtained from the patentee or licensee.<sup>96</sup> According to a decision of the German Supreme Court, the experimental use exception covers clinical trials on human patients, where it is necessary to discover other medical applications or to provide more information on effects of treatment. In the event that any clinical test is being undertaken in a hospital with a separate purpose to improve the health of the patients, it can also be applied.<sup>97</sup>

Recent developments in EPC countries show that the experimental use exception may also be applied to commercial research. However, a distinction must be drawn between the work, which is undertaken only for improving or modifying the invention, and other kinds of activities that would be totally contrary to the purpose of patent system.

Although there have been few cases relating to experimental use, an exception for patent infringement regarding the statutory provisions of English law, particularly Section 60 (5), (a) (c), of the UK Patent Act, provides a rare example:

*Smith Kline and French laboratories Ltd. v. Evans Medical*

This case is about the private purposes exemption. The court in this case decided that private exemption exists only when he/she is carrying out an act for his/her own use. The court put a two-stage test involving:

- 1) To determine whether an act is private or public and
- 2) To determine whether the act has or has not been carried out for commercial purposes.

An act will only be exempt when these two stages have been passed.<sup>98</sup>

### **ii) The United States**

Section 271 of the US Patent Code (35 USC) states that “whosoever without authority makes, offers to sell, or sells any patented invention (...) infringes the patent.” However, until recently, the US courts have applied a common law experimental use defense, although the US courts have also taken into account certain circumstances which restrict the application of this rule. In addition to this common law experimental defense, there is a statutory experimental use defense under section 271(1) (e) of the Patent Code, but this latter one is no longer relevant.

A direct outcome of this decision is that the private purpose exemption

<sup>95</sup> Cornish and Llewelyn, supra note 3, at 842

<sup>96</sup> Ibid, at 842.

<sup>97</sup> Klinische Versuche I and II (1997) R.P.C. p. 623: (1998) R.P.C. p. 423.

<sup>98</sup> Bor, supra, note 92, at 6.

is mainly related to an individual who carried out scientific experiments at home with no commercial objective in mind. This does not cover any act carried out by a company; therefore there is no direct relevance to this kind of exemption for companies which are dealing with biotechnological research.<sup>99</sup>

An act undertaken for experimental purposes relating to the subject matter of the invention would also be exempt from patenting. This view supports the idea that patent law exists to stimulate the advancement of science and should not be used to inhibit it. Namely, the advancement of science has priority over the enforcement of patent rights.<sup>100</sup> This principle of exemption was adopted by the community patent convention (Art. 31 b of CPC) and has been transposed into the patent laws of various European countries.

When applying the experimental purposes exemption to biotechnological research, one difficulty is whether the exemption covers trials carried out in order to secure patent protection. The heart of the problem is whether such trials are considered to be “experiments” or not. According to a decision of a court in the *Monsanto* case,<sup>101</sup> an act cannot be considered “experimental” when the essential goal of the trial is merely to verify existing knowledge. However, it is applied to “research that is directed to generating new information about the invention itself to find out how it works, or to improve on it.”<sup>102</sup>

## 2) Diagnostic Tools

Patent protection through a diagnostic tools basis can be provided in the case of the association of a gene and a disease. From this perspective, the major issue is to identify mutations by making a comparison between the appearance of a patient’s gene sequence and a normal one. It is sufficient to be able to identify a mutation in a gene in order to fulfill the utility requirement and receive patent protection.

A broad scope exists for a patent on diagnostic tools. In most cases, the patents include the mutated, normal DNA sequence and the protein for which the sequence codes. The patent covers both the patented tool and all future screenings that could identify the mutation. Since the patents also cover proteins, it is not possible to develop alternative tests that screen for these specific proteins without a license. Thus, the original patent plays a great role for future research on diagnostic tools. All of them will be dependent on the original patent.

### Point of view of the Nuffield Council on Diagnostic Testing

The Nuffield Council advises to apply the requirement for the granting of product patents, especially the criterion of inventiveness, very strictly to applications for patents that provide the owner with rights over DNA

<sup>99</sup> Ibid.

<sup>100</sup> Ibid.

<sup>101</sup> *Monsanto v Stauffer* (1985) R.P.C. 515, CA

<sup>102</sup> See Bor, *supra* note 92, at 7..

sequences for use in diagnostic testing.<sup>103</sup> According to the Nuffield Council, the EPO, the JPO and the USPTO should find a way to achieve this. The goal of this recommendation is to provide product patents concerning DNA sequences used for diagnostic testing with an exceptional character. The USPTO and the US Government should consider changing their patent regulations.<sup>104</sup>

The Nuffield Council points out that use patents are an effective means of rewarding the inventor and encouraging others to develop alternative tests.<sup>105</sup>

### 3) Gene Therapy

It is possible that different mutations can cause the same disease within a single gene. Research efforts have been recently aimed at repairing or removing the mutated sequence and change it with a normal one.<sup>106</sup> This makes us able to cure illnesses including Alzheimer's disease and spinal cord injuries. Granting patent protection for gene therapy does not constitute a problem and will not confine future researches. Since some kinds of gene therapy are considered unexceptionable for ethical reasons, attention is concentrated on the "somatic cell gene therapy which affects only non-reproductive cells."<sup>107</sup>

In Europe, since the gene therapy methods are considered medical treatment, they are not patentable, but the vectors and constructs used may be so. On the other hand, "ex vivo" process steps will be patentable as being the last step of administering the transformed cells to the patient is not claimed. In the USA, all steps of the process are patentable.<sup>108</sup>

#### Point of view of the Nuffield Council

The Council suggests widely denying patent protection for the use of the relevant DNA sequences in gene replacement therapy by regarding it as obvious and therefore rejecting the inventive step. The main issue of patent protection should be the development of secure and effective methods of appropriate gene delivery, rather than providing simply the definition of the sequence used in therapy.<sup>109</sup>

### 4) Therapeutic Proteins

These proteins are made artificially and used as pharmaceuticals. The therapeutic nature of the proteins has been known for a long time. According to the prior knowledge, it was only possible to produce proteins from humans and animals with the use of tissue. It has been possible only from the mid-1980s to produce them on a large scale using an artificial method. Then companies started to patent the genes that

<sup>103</sup> Nuffield Council on Bioethics, *The ethics of patenting DNA - a discussion paper* (2002) at 53 (hereinafter "Nuffield Council").

<sup>104</sup> *Ibid* at 53.

<sup>105</sup> *Ibid* at 54.

<sup>106</sup> *Ibid* at 61.

<sup>107</sup> Grubb, *supra* note 39, at 267

<sup>108</sup> *Ibid* at 268

<sup>109</sup> Nuffield Council, at 62 and 64.

code for therapeutic proteins. The patents cover both the specific DNA sequences and structures of the proteins.<sup>110</sup> It seems that a large group of companies are interested in these products. In contrast with other gene patents, protein patents may easily be patented, since they provide a protein that is new and inventive. But it is important that they are only granted a relatively narrow scope and that there really is a practicable use. Namely, a significant utility takes place before the patents are issued.

### **Proposal of the Nuffield Council**

It is generally recommended by the Nuffield Council to grant patents for DNA sequences applied to the development of new medicines based on therapeutic proteins. However, the claims should be defined narrowly, in order to keep the protection range low. This should lead to the protection only of the protein and not to the whole DNA sequence.<sup>111</sup>

### **VII) CONCLUSION**

Historically, patent systems have been developed to encourage invention and innovation.<sup>112</sup> A patent system motivates the creation of useful inventions, including the investment required to develop and commercialize them; society's recognition of individuals who disclose their inventions and patents enables the systematic registration of a wide range of discoveries. Without any doubt we need a patent system. Even though patent systems and their implementation result in massive problems, it's believed that it is necessary to keep them.

The selected cases represent distinct and important decisions of biotech patents, namely DNA sequences and whole living organisms. The Onco-mouse patent litigated throughout its lifetime. The main issue was driven by public concern. This case raised new questions concerning patentability and led to landmark decisions. Today it is accepted that DNA sequences and proteins are patentable if its function is known. However in Europe there are strict conditions on patenting higher organisms.

The application for the patent on the Onco-mouse 20 years ago has created a new field and there will be new challenges for patent protection in the future due to the rapid development of biotechnological research.

Patents on biotechnological inventions have created monopolies especially within public health. Biotechnological patents on the one hand are giving massive rights to the patent owners; on the other hand, patents create monopolies in inventions that have been aimed at the public interest. As a result, these very conflicting situations give rise to a dilemma.

Although it is obvious that the current legal instruments are not suitable for the protection of biotechnology, governments worldwide rely on old and inappropriate structures for the protection of genetic inventions. Today there is no distinction between inventions and discoveries; the

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<sup>110</sup> Ibid at 62-63.

<sup>111</sup> Ibid at 64.

<sup>112</sup> Lutz, *supra* note 1, at 207.



inventive step is basically irrelevant and the utility requirement is largely unessential. Regarding their purpose, well-suited corrections and additions will contribute to new innovations being made and help to distribute these to people worldwide.

In its report, The Nuffield Council on Bioethics recommended a rather restrictive approach for granting patents on DNA sequences. Patents on diagnostic tests should be sharply examined for the criterion of inventiveness, the granting of patents on research tools should be discouraged, patents on gene therapies should be thoroughly analyzed if they are not obvious and patents on therapeutic proteins should be narrowly defined. Patent offices and courts should feel encouraged to make use of the patent system in a more rational way as far as patents on DNA sequences are concerned.

The promises of biotechnology are great and must be allowed to develop within a fair, competitive and intellectual property framework, which can only be achieved through worldwide legislation and the establishment of a single appellate jurisdiction.<sup>113</sup> From my point of view, in order to achieve this goal, it would be necessary to combine the function of the major institutions like the USPTO, EPO and JPO and establish a common regulation.

The approach to biotechnological inventions in the United States is more generous than in Europe. Europeans tend to stick to the morality issues and for that reason the patent bar granting biotechnological inventions is very high. On the contrary, the United States is more liberal, which has a global impact on the world economy. USPTO and the Federal Circuit have badly rendered the decisions affecting the issues. Commentators talk about the financial motivations behind these decisions. Thus, many companies find the US an attractive place to invest since it is easy to obtain a patent there. The European countries are probably losing investment because they operate a more stringent system than the US. The attitudes of the European countries are criticized. In my view, the administrators of the European countries must go on to follow their own ways; it is not necessary to change the decisions since the countries in Europe have totally different cultures and backgrounds. It seems unlikely that the European approach will be changed in the near future.

One possible solution is for a related organization such as the WIPO to take control of biotechnological patenting. As a first step, the USPTO, EPO and JPO could come together for negotiations under WIPO's umbrella. In the long term, other countries need to be involved, and it might be possible to seek an agreement to construct a totally new system which deals with biotechnological patent issues. It is necessary to seek a wider attendance of countries in order to be effective for imposing new rules to these and other countries. Regarding the cultural, political, ethical, and social differences, it could be thought that these countries can make rules

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<sup>113</sup> Schertenleib, *The Patentability and Protection of DNA-Based Inventions*, (2003) E.I.P.R.

more effectively since a single system takes into account everyone's needs and requirements. However, it is necessary to adopt minimum standards for the countries starting with the US, the EU countries, and Japan. In fact, there are many other areas in which lists of minimum standards are already applied. These standards can be adopted through the WIPO. Since the WIPO procedures are not compulsory, it is unknown whether the system will work or not. In order to achieve this system, the sensitivities of society must be improved and the public must be enlightened on this issue. The primary initiatives may be taken by the voluntary groups including NGOs. The lobbying activities of the companies must be reduced and politicians should be convinced to take the issue seriously.

This article has detailed the differences between the American and European models. On the one hand, the European model takes an ethical approach, and on the other, the American model is liberal, where the thresholds are mostly very low to grant a patent. In my view, income must be obtained through industrial activities on biotechnology; in the meantime, ethical considerations are also taken into account. Patents could be granted for biological inventions in the present system, but this should not give rise to any monopoly for the patent holders.

The risk of cancer constitutes a great danger for the human beings at present. For instance, a lot of women are facing a risk of breast cancer, while the children have anemia or AIDS. Therefore, patients and the people in danger need inventions for a better treatment and a better/long life. These inventions are scientific in nature and are necessary for human beings to survive. Patenting is a part of this unique system and it cannot be approached without ethical considerations, no matter how much income it provides. A common set of criteria must be taken into account and applied when issuing a patent; thus a continuous process must be provided for these inventions.

Despite all political and ethical concerns, public debates and worldwide litigation, the importance of biotechnological research in general, and of patents in particular, is likely to further increase rather than decrease in the future. It is in the interest of most people to increase their life span, whatever the costs, search for new sources of nutrition for the constantly increasing population, but also for the curiosity and motivation of scientists to find inventions on one hand and high investments in this field on the other hand. This branch of technology is extremely lucrative but also makes IP protection necessary. Otherwise it may risk not achieving the very objectives it seeks to achieve, with the end result that the disease is cured, but the patient killed.<sup>114</sup>

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114 Lui, *supranote 1*, at 259