Biotechnology Directive: A Major Step in Biotechnology Patent Law in Europe

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Abstract

Biotechnology has become a new crucial technology of increasing economic growth. Nowadays, biotechnology has been widely applied in the fields of agriculture, pharmaceutical industry, medicine, energy, and environment protection. With the development of new processes in biotechnology, new adjustments are needed from established patent rules. Thus the Directive was drafted by the Commission to meet the demands of biotechnology industry. The Biotechnology Directive had successively treated the patentability of gene-related inventions, the exceptions to patent and moral issues. In addition, the Directive generally achieved the goal of harmonization of patent laws among the member states. To some extent, the Directive simplified the uncertainty of the patent law which is benefit to increase the research investment and development funds, but the remaining issue limiting its wide acceptance have been discussed in this chapter.

Keywords

Biotechnology directive · Bioeconomy · Patent laws · Stem cells · Plant varieties · Animal varieties · European Union

8.1 Introduction

Biotechnology has become a new crucial technology of increasing economic growth. Nowadays, biotechnology has been widely applied in the fields of agriculture, pharmaceutical industry, medicine, energy, and environment protection. In 2003, US biotech companies employed approximately 200,000 people and

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generated USD 39.2 billion in revenues.[1] The rapid development of biotechnology is also reflected in the increasing of applications of biotechnology patent. According to the European Commission report, in the past 10 years, biotechnology patent at the United States Patent and Trademark Office and the European Patent Office have increased by 13–15% per year on average, compared with the 5% annual growth rates for all patents.[2]

There are three main sectors of biotechnology market: the United States, Europe, and Japan. The European Union, which identifies the importance of biotechnology to its future economic development, is committed to becoming a more competitive participant in this bright prospect market.[3] Inevitably, the patent regulations have received unprecedented challenges and struggled to adjust the system to this new technology.

One of the earliest important patent documents in Europe is the 1973 version of the European Patent Convention (EPC). It is a multilateral treaty which provides a complete system of patent protection for contracted nations. This system guarantees a European patent has an equal influence to a national patent.[4] Then in 1994, the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) entered into effect. This agreement is consist of a detailed series of minimum international legislative and regulatory standards.[5] As Daniel Gervais evaluated in his book, TRIPS was one of "most significant milestones in the development of intellectual property in the twentieth century."[6]

With the development of new technology especially biotechnology, new adjustments are needed from established patent rules. Thus the Directive was drafted by the Commission to meet the demands of biotechnology industry. There are two basic rationales behind the Biotechnology Directive.

One rationale was a lag of Europe compared with other economic areas.[7] Among three main areas of the United States, Europe, and Japan, they all believe that patent system can increase investment activity and enable a patented technology to be

[1] Hilderth M, Resilience: Americas Biotechnology Report 2003, Emst & Young, July 2003

[2] Commission of the European Communities, Report from the Commission to the European Parliament and Council, "An Assessment of the Implications for Basic Genetic Engineering Research of Failure to Publish, or Late Publication of, Papers on Subjects which could be Patentable as Required under Art.16(b) of Directive 98/44/EC on the legal Protection of Biotechnological Inventions" 7(Brussels 2002)

[3] Communication on Promoting the competitive environment for the industrial activities based on biotechnology within the Community SEC(91) 629 final

[4] Braendli P, 'The future of the European patent system' (1995) International Review of Intellectual Property and Competition Law

[5] Sommer T, 'Patenting the animal kingdom? From cross-breeding to genetic make-up and biomedical research' (2008) International Review of Intellectual Property and Competition Law

[6] Gervals D, The TRIPS Agreement: *Drafting History and Analysis* (2nd edn London Sweet& Maxwell, London2003

[7] MacQueen H, Waelde C and Laurie G, Contemporary Intellectual Property (Oxford 2008, New York)

protected worldwide. Thus they all retain propatenting attitudes and improve their patent system to promote development of economy. The United States Patent Office preferred the equal treatment of biotechnology and other technologies.[8] This led to a liberal attitude of the United States toward patentability of biotechnological inventions. Consequently, if the US patent principles confer an advantage than European patent principles do, it puts pressures to Europe to reform the patent system.[9]Under this structure, the Directive adapted in 1998 aimed to clearly express the patentability of biotechnological inventions.

The other was the nonuniformity of member states. Despite the harmonization of substantive patent law in the contracting states, the interpretation and application of these laws are disagreeable.[10]Such as case Genentech v Wellcome Foundation, the EPO and UK courts have different standards of obvious.[11] In order to reinforce the research capability and promote economy in the whole Europe, the uncertainty of patent law in member states should be avoided. The Directive held the promise of harmonizing the rule of biotechnological patent throughout the EU. All member states have the obligation to transpose or implement in their national law. However, before July 2000, only six member states amend their national law to in line with the Directive. According to the second report of the Commission (2005), 21 member states had apprised the Commission of their instruments implementing the Directive.[12]

Originally, the first draft of Directive 1988 was rejected by the European Parliament. The main reason was that the Commission lacked considerations from ethical dimension. Some animal welfare groups and religious groups strongly protested against the drafted Directive and suggested that ethical considerations should be added.[13]After 10 years, the Directive 98/44 was finally adapted. However, a problem of potential conflict between legal systems arose. Because the EPC which is the rules of an intergovernmental treaty belongs to a non-EC instrument, the European Union (EU) has no jurisdiction over the EPC. For the purpose of releasing this discrepancy, in 1999 the Administrative Council of the European Patent Office decided to make some changes to the rules in the implementing regulations for adjusting the EPC to the Directive. Moreover, Rule 23b(1) EPC provides that: "Directive 98/44/EC of 6 July 1998 on the legal protection of biotechnological

[8] Morneault M, 'Stem Cell Research and Human Cloning: Where Do We Draw The Line?' (2005) New Eng.L.Rev.523

[9] Drahos P, 'Biotechnology patents, markets and morality' (1999) European Intellectual Property Review

[10] Braendli P, 'The future of the European patent system' (1995) International Review of Intellectual Property and Competition Law

[11] *Genentech Inc.* v *Wellcome Foundation Ltd* (1989) 8 RPC 147; (1988) 15 IPR 423

[12] Report from the Commission to the Council and the European Parliament, development and implications of patent law in the field of biotechnology and genetic engineering, at 2

[13] Sommer T, 'Patenting the animal kingdom? From cross-breeding to genetic make-up and biomedical research' (2008) International Review of Intellectual Property and Competition Law

inventions shall be used as a supplementary means of interpretation."[14] These countermeasures basically bridged the gap between the EU Biotechnology Directive and the EPC.

8.2 Discovery or Invention

In tradition patent system, the distinction between discovery and invention is explicit and unambiguous. As Kolle defined, "discovery is the unearthing of causes, properties or phenomena already existing in nature; invention is the application of such knowledge to the satisfaction of social needs,"[15] However, with the development of gene technology, the difference became vague and problematic.

In case Genentech v Wellcome Foundation, the House of Lords held that disclosing the structure of DNA belong to discovery which is excluded by the subject matter of patent.[16]According to Article 52(2)(a) EPC, discoveries which are not considered as inventions seem not to be patentable. As a result of lacking of patent protection, investments of human and nonhuman resource were reduced to some extent. Many people indicated that many efforts need to be thrown in order to obtain the DNA. As Crespi pointed out, "the inventor has not simply discovered or confirmed the existence of a gene but has been the first to characterize it, to define it chemically, and to make it available in a way that serves some useful purpose."[17] In case Relaxin, the Opposition Division held that the claims related to DNA sequence of a natural substance were classified as invention instead of discovery.[18]

The Directive settled the debate and affirmed the patentability of gene-related applications. Article 3(2) stipulated 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." Furthermore, the Article added that "An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element."

Conclusively, due to the adaption of Directive, the patenting of a gene-related biological product was no longer the obstacle to gene technology research and development but the driving force to this area.[19]

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[14] Aerts R J, 'Biotechnological patents in Europe-functions of recombination DNA and expressed protein and satisfaction of the industrial applicability requirement' (2008) International Review of Intellectual Property and Competition Law

[15] Kolle, 'For the evolution of this in the EPC' (1974) 5 I.I.C. 140 at 147–148; *IBM/Document retrieval* [1990]

[16] *Genentech Inc.* v *Wellcome Foundation Ltd* (1989) 8 RPC 147; (1988) 15 IPR 423

[17] Crespi, 'Patents on Genes: Can the Issues be Clarified?' (2000) 5(3) Bio-Science Law Review 199–204, at 199/200

[18] Icos Corporation/Seven transmembrane receptor [2002] OJEPO 293.307

[19] Sena G, 'Directive on Biotechnological Inventions: patentability of discoveries' (1999) International Review of Intellectual Property and Competition Law

8.3 Protection of Gene-Related Inventions

The dispute about the validity of gene-related patent mainly focuses on three general criteria – novelty, inventive step, and industrial application. The significant influence of Biotechnology Directive was embodied in the industrial application step.

8.3.1 Novelty

A dilemma exists in patenting genes. From one hand, it should be categorized as discovery because of its natural property. On the other hand, the novelty exam is designed according to the availability of genes.[20] The adaption of the Biotechnology Directive relieved this tension and confirmed the patentability of gene-related inventions under certain requirements.

Furthermore, according to Recital 22 of the Directive, "the granting of a patent for inventions which concern such sequences or partial sequences should be subject to the same criteria of patentability as in all other areas of technology: novelty, inventive step, and industrial application." The exam for novelty mainly rests on the prior art documents and availability to the public. Because the examination involves the individual case, it is difficult to draw a unified standard of novelty. From the previous cases, it is basically definite that isolated DNA natural counterpart cannot influence its novelty in Europe.[21] In the circumstance of the structural identity between the application and the known DNA sequence, the applicant can seek to use a patent as long as it provides a new function.[22]

Another notable issue is that novelty and inventive step are different from each other. In investigating novelty, items of prior art should be left separate. Besides, examination of inventive step only happen after novelty is met.[23]

8.3.2 Inventive Step

The request that the invention must not be "obvious to the person skilled in the art" should be satisfied in tests of inventive step. Three main factors can be distinguished during examination. First, the degree of proximity to the prior art and "near

[20] Zekos G I, 'Nanotechnology and biotechnology patents' (2006) Journal of Law & Information Technology

[21] Amanda Warren-Jones, 'Patenting DNA: a lot of controversy over a little intangibility' (2004) Medical Law Review.

[22] Oser A, 'Patenting (partial) gene sequence taking particular account of the EST issue' (1999) International Review of Intellectual Property and Competition Law

[23] Howlett M J and Christie A F, 'An analysis of the approach of the European, Japanese and United States Patent Offices to patenting partial DNA sequences (ESTs)' (2003) Review of Intellectual Property and Competition Law

anticipations" should be considered.[24] As Lindley stated, the inventive step is not "a mere analogy, or on the mere application of a principle"; instead it calls for "some ingenuity to overcome a practical difficulty in the adaptation or application."[25] Second, many situations of appeal addressed to the argument that it is "obvious to try."[26]But before finding a new technology from known techniques, almost all researches begin with simple trial-and-error methods.[27]So the requirement of inventive step needs something to mark out the line between the claimed research and the known research.[28]Also if the notional research group is in a strong expectation that there is no commercial reason to do it, taking the step could be inventive. Third, if the invention is the reason of commercial success, this achievement should be considered in the test of inventive.[29]

During the course of the Human Genome Project, the problem that "once sequencing methodology became routine no patent protection should attach" had arisen.[30] EPO held that the homologous DNA sequence was no inventiveness.[31]

8.3.3 Industrial Application

The industrial applicability requirement is the most controversial in patentability of gene-related invention. Article 52(1) EPC said that the patentable invention is "susceptible of industrial application." The Article further specified that "an invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture." Rule 27(1)(f) EPC explained that description shall "indicate explicitly, when it is not obvious from the description or nature of the invention, the way in which the invention is capable of exploitation in industry." A borderline seemed to be made to distinct between qualified and unqualified.

Nevertheless, many problems were still unsettled. For an instance pointed out by Amanda Jones, "the problem with gaining protection to probes has been to ensure that the claim is drafted to an actual use, rather than attaching a convenient use to a desirable invention of no more real value than simple knowledge."[32]

The effectiveness of Biotechnology Directive changed it. Article 5(3) of the Directive enlarges the standard of industrial applicability by providing that "the

[24] *Seller's Application* [1980] R.P.C. 103

[25] Lindley L J, Mutoh's application [1984] R.P.C. 85

[26] Paterson, *The European Patent System* (2nd ed, 2001) para 12-42a

[27] Brugger v Medicaid [1996] R.P.C. 635 at 661

[28] *Pharmacia v Merck* [2002] R.P.C. 775, paras 123–124

[29] *Martin v Millwood* [1956] R.P.C. 125 at 139

[30] The Nuffield Council's objection to protecting probes, op.cit.n. 8 at para.3.22

[31] Jones A W, 'Patenting DNA: a lot of controversy over a little intangibility' (2004) Medical Law Review

[32] Jones A W, 'Patenting DNA: a lot of controversy over a little intangibility' (2004) Medical Law Review

industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application." Recitals 23 and 24 of the Directive further state "(23) Whereas a mere DNA sequence without indication of a function does not contain any technical information and is therefore not a patentable invention; (24) Whereas, in order to comply with the industrial application criterion, it is necessary in cases where a sequence or partial sequence of a gene 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."

The Directive makes clear that the teaching of a mere reproduction of genetic information is excluded from patentability. However, the teaching of a function of a gene which is to some extent industrially applicable is a patentable invention.[33] Article 5(3) of the Directive has specific requirement on disclosure. The problem is what knowledge is actually needed and the degree of satisfaction of industrial application requirement.

Basically, under the new rule, the standard of industrial application has a more general purport but only a repeat of general criteria which mainly contain the description of the function, use, or purpose of a claimed product.[34] In a recent case Eli Lilly, the appellant applied to invalidate a patent of gene sequence for the reason of lacking of industrial application. This is the first time for the high court to make decision on the patentability of human genes. The Chancery Division revoked the patent and held that "whatever the merit of the discovery of Neutrokine-a, the specification contains no more than speculation about how it might be useful. It does not teach the person skilled in the art how to solve any technical problem."[35] This decision means that a large quantity of similar achievements of Human Genome Science is precluded by patent. As Irvine commented, partner of M&C, "You can't just leave it to clinical research carried out at a later date to get the technical contribution to the art necessary to have a valid patent."[36] Edward Nodder, another partner of Bristow evaluated that "this decision is very important for the UK and European pharmaceutical industry. Biotech products are an increasing source of revenue and patent protection is vital to safeguard the huge investments made by the industry in this area. The judgment provides strong guidance on what the threshold should be for a valid patent in this field of technology which had previously received relatively little judicial consideration."[37]

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[33] Aerts R J, 'Biotechnological patents in Europe-functions of recombinant DNA and expressed protein and satisfaction of the industrial applicability requirement' (2008) International Review of Intellectual Property and Competition Law

[34] Aerts R J, 'Biotechnological patents in Europe-functions of recombinant DNA and expressed protein and satisfaction of the industrial applicability requirement' (2008) International Review of Intellectual Property and Competition Law

[35] Eli Lilly and Co v Human Genome Sciences Inc., [2008] EWHC 2511(Pat)

[36] First High Court Ruling on Gene Patens, LexisNexis UK legal New Analysis

[37] Press releases, Bristows, 31 July 2008 http://www.brietows.com/?pid=48&level=2&nid=97

8.4 Exception of Patentability

Before the Directive, the general prohibition of patentability is Article 53(b) of EPC. In order to incorporate the EPC into the national law, the European Parliament and the Council accepted the Directive on July 6, 1998. As a result of the Biotechnology Directive, many provisions were amended, and the national patent law was basically uniformed with the EU.[38]

8.4.1 Plant Varieties

The International Convention for the Protection of New Varieties of Plants (UPOV) established in 1961 grants property right in new plant varieties. According to a ban on dual protection given by a sui generis plant breeder's right and patent, plant varieties should be excluded from patentability. For this purpose, the Article 53(b) of EPC precluded plant varieties from patentability.[39]

The following question is how to define plant variety in Article 53(b). In case Plant Genetic Systems,[40] the Board of Appeal specifically stated that "plant variety is characterized by at least one single transmissible characteristic distinguishing it from other plant grouping and which is sufficiently homogeneous and stable in its relevant characteristics." The Board of Appeal broadly explained the exception and held that claim rights over the plant varieties were not patentable.

This decision was overturned in Article 4(2) of the Biotechnology Directive. Article 4(2) further states that "Inventions which concern plants or animals shall be patentable if the technical feasibility is not confined to a particular plant or animal variety." This means if a claim covers two or more varieties, it should be patentable. In order to clarify, Recital 31 of the Directive provides that "Whereas a plant grouping which is characterized by a particular gene (and not its whole genome) is not covered by the protection of new varieties and is therefore not excluded from patentability even if it comprises new varieties of plants."

The principle was reconfirmed in case Novartis.[41] The Enlarged Board of Appeal mentioned that "a claim wherein specific plant varieties are not individually claimed is not excluded from patentability under Article 53(b), even though it may embrace plant varieties."[42] Following to this decision, the Administrative Council of the EPO issued the Implementing Regulations on June 16, 1999. In this document, the rule 23c (b) further states that an invention related to plant varieties should be patentable "if the technical feasibility is not confined to a particular plant or animal variety." In

[38] Schertenleib D, 'The patentability and protection of living organisms in European Union' (2004) European Intellectual Property Review

[39] Bently L & Sherman B, *Intellectual Property Law* (2nd edn Oxford, Oxford 2004) 426

[40] *Plant Genetic System/Glutamine synthetase inhibitors*, T356/93 (1993) 24 llC 618; [1995] EPOR 357; [1995] OJEPO 545 (TBA)

[41] *Novartis/Transgenic plant* G1/98 [1999] EPOR 123, 137 (TBA)

[42] *Novartis/Transgenic plant* G1/98 [2000] EPOR 303, 319 (EBA)

general, this new regulations end to the debate of patentability of genetically modified plant. However, the continuing problems highlighted by the challenge to the Directive still remain unsolved.[43]

8.4.2 Animal Varieties

Unlike plant varieties which are specifically protected by a sui generis system, there is no equivalent regime to protect animal varieties. Originally, Article 53(b) of EPC explicitly precluded animal varieties from patentability.[44] However, this became controversial with the development of biotechnology.

In OncoMouse case,[45] the Board of Appeal stated that Article 53(b) should be narrowly explained and not contained animals in general. The TBA therefore used "species" as a borderline of animal varieties in Article 53(b). Because OncoMouse was not a new species, the exception did not apply. However, the Examining Division said that "animal variety either meant a species or a subunit of a species." As a result, the subject matter of this patent was irrelevant with an animal variety and the exclusion of Article 53(b). However, after the adaption of the Directive, the Opposition Division redefined the meaning of animal variety.

A substantive advance was brought by the Directive. Article 4(2) explains that "inventions which concern animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety." That is to say, as long as invention does not limit to a specific animal variety, it can be patentable.

The subsequent cases move forward this principle. In amended case OncoMouse, the Opposition Division noted that "living matter and in particular plants and animals could be patentable."[46] Meanwhile, the Division emphasized that the exclusion confined to the varieties which should not contain the animals in general.

8.4.3 Essential Biological Process

Historically, biological processes of breeding plant and animal are unpatentable, because they belong to natural phenomena. Under Article 53(b) of EPC, European patents shall not be granted in respect of "essentially biological processes for the production of plants or animals."

The subsequent question was the degree of technical intervention to satisfy non-essential biological process. The Technical Board of Appeal didn't give clear answer to this question. The board noted that there were three possible approaches: (a) In the first approach, if any part of process invention is biological, it is excluded from

[43] Llewelyn M, 'The patentability of biological material: continuing contradiction and confusion' (2000) European Intellectual Property Review.

[44] Bently L & Sherman B, *Intellectual Property Law* (2nd edn Oxford, Oxford 2004) 424

[45] *Harvard/Onco-Mouse* [1990] EPOR 501

[46] *Harvard/Onco-mouse* [2003] OJEPO 473, 499

patentability[47]; (b)The second way requires that the decision considers the overall degree of human intervention in the process, which was given in case Lubrizol.[48] TBA held that quality rather than quantity of human intervention was significant. The criterion was "on the basis of the essence of the invention taking into account the totality of human intervention and its impact on the result achieved"[49]; (c) Under the last option, if any technical element exist, the invention is patentable. This method is reflected in the case Novartis[50] and reconfirmed in the Biotechnology Directive. Article 2(2) states that "a process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection."

However, The Technical Board of Appeal takes the view that Article 2(2) is somewhat self-contradictory, because crossing and selection which are classified as entirely natural phenomena would not happen without human intervention.[51] In the recent case Broccoli, two questions have been referred to the EBA: (1) "whether a nonmicrobiological process for the production of plants which contained the steps of crossing and selecting plants escaped the exclusion of Article 53(b) merely because it contained, as a further step or as part of any of the steps of crossing and selection, an additional feature of a technical nature"; (2) "if not, what were the relevant criteria for distinguishing nonmicrobiological plant production processes excluded from patent protection under Article 53(b) from nonexcluded ones?"[52] These questions refer to the explanation of the scope of exception from patentability. The case is pending, and the correct approach for interpretation is still to be determined.

According to Article 53(b), which stipulates that the exception of this provision does not apply to "microbiological processes or the products thereof," microbiological process and microorganism could be patentable. In case Plant Genetic Systems,[53] the Board of Appeal defined "microbiological process" as a process "in which microorganisms or their parts are used to make or to modify products or where new microorganisms are developed for specific uses." Simultaneously, the Board clarified the meaning of "microorganism" which should be "generally unicellular organisms with dimensions beneath the limits of vision which can be propagated and manipulated in a laboratory." However, the problem is whether the products which are genetically modified varieties from microbiological process could be patentable. This issue was discussed in case Plant Genetic Systems.[54] The Board of Appeal rejected the patent of genetically modified plant. The reason is that

[47] *Hospital/Contraceptive methods*, T820/94 [1995] EPOR 446

[48] *Lubrizol/Hybrid plant*, T320/I87 [1990] OJEPO 71.

[49] *Plant Genetic Systems/Glutamine synthetase inhibitors*, T356/93 [1995] EPOR 357.

[50] *Novartis/Transgenic plant*, T1054/96 [1999] EPOR 123,135(TBA).

[51] Sommer T, 'Patenting the animal kingdom? From cross-breeding to genetic make-up and biomedical research' (2008) International Review of Intellectual Property and Competition Law

[52] *Plant Bioscience/Broccoli*, T83/05 [2008] EPOR 14

[53] *Plant Genetics Systems/Glutamine synthetase inhibitors* [1995] OJEPO 545 (Board of Appeal)

[54] *Plant Genetics Systems/Glutamine synthetase inhibitors* [1995] OJEPO 545 (Board of Appeal)

"technical processes including a microbiological step may not simply be equated with microbiological processes." Because the process as a whole could not be viewed as microbiological, the resulting product would belong to the scope of exception. The problem was not distinctly and clearly answered in this case.

This was changed due to the implementation of the Biotechnology Directive. First, Article 2 of the Directive provides the definition of microbiological process as "any process involving or performed upon or resulting in microbiological material." Literally, in comparison with the concept given by the Board of Appeal, it was extended. Secondly, Article 4(3) of the Directive added the qualification "technical process" to Article 53(b) of EPC. Obviously, the scope of patentable subject matter expands into genetically manipulated process or the product of such a process.[55]Consequentially, the impact of the exclusion will be minimized. Thirdly, Article 4 (3) of the Directive expressly noted that the exception paragraph "shall be without prejudice to the patentability of inventions which concern a microbiological or other technical process or a product obtained by means of such a process." Therefore, this provision solves the problem as to the patentability of plant varieties of microbiological or technical process. The Directive clearly said that plant or animal varieties shall not be patentable only because they are the result of microbiological or technical process.

8.5 Morality Issues

It seems to be easy to conclude that patent has a closer connection with economy than morality. Historically, the morality provision existed for a long time but was rarely used. Until recently, the development of Biotechnology raised many ethical issues. The morality objection became one of the strongest forces by the Greens, animal rights campaigners, and others to reject the Biotechnological patent.

In Article 53(a) of the European Patent Convention 1973, it states that European patents shall not be granted to "inventions the commercial exploitation of which would be contrary to 'ordre public' or morality; such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States". However, neither the definition of "ordre public" nor the benchmark of morality was provided by this provision.

As Gitter notes, "morality is an exceedingly complex standard to implement as a criterion of patentability."[56] In dealing with the increasing applications of biotechnology patent, the European Patent Office had established two standards: one is "abhorrence" standard, and the other is "unacceptability" standard. Respectively, there are two methodologies relevant to the moral standard: the "balancing exercise"

[55] Bostyn S J R, 'The patentability of genetic information carrier' (1999) Intellectual Property Quarterly

[56] Donna M Gitter, 'Led Astray by the Moral Compass: Incorporating Morality into European Union Biotechnology Patent Law' (2001) 19 *Berkeley Journal of International Law* 1, 21

approach followed "unacceptability" standard; the "rebuttable presumption" approach followed "abhorrence" standard. According to Amanda Warren Jones, this distinction is significant because "under the 'balancing exercise' all of the issues considered form part of the reason why the invention is patentable or not: whereas the 'rebuttable presumption' approach identifies a single issue upon which the decision rests."[57]

The first instance of adapting "abhorrence" standard is Lubrizol[58] case. The Opposition Division held that "an invention will be excluded from patent protection only where the public in general would regard the invention as so abhorrent that the grant of a patent would be inconceivable." In reference to the benefit, the invention of hybrid transgenic plant might bring to the solution of food crisis, it should be excluded from Article 53(a) of EPC.

The second case Relaxin[59] further confirmed the "abhorrence" standard. In this case, the European Patent Office stated that DNA was not life, and the use of pregnancy had not offended human dignity. "An overwhelming consensus" which the invention was abhorrent would be required to fall within the scope of immorality under Article 53(a). Thus, the Division rejected the oppositions of the Green Party. This decision accorded with the general principle that the exceptions to patentability should be constructed narrowly.[60]

Compared with the "abhorrence" standard, the "unacceptability" standard is stricter and higher. The approach which adheres to this standard is called the utilitarian approach. As Shawn H.E. Harmon said, "this approach weighs risks/harms against benefits such as individual financial reward, economic development, and scientific advancement which may promote better healthcare and greater health."[61]

This approach was first used in OncoMouse case.[62] The Technical Appeal Board mainly put the emphasis "on a careful weighing up of the suffering of animals and possible risks to the environment on the one hand and the invention's usefulness to mankind on the other." After balancing animal suffering, environment risks, and usefulness to mankind, the decision was made.[63] The benefit to cancer research outweighed other aspects, the patent would be maintained.

The formalistic treatment of the morality criterion in OncoMouse case was referred to but not fully spread in case Plant Genetic Systems. In this case, the Technical Appeal Board applied the utilitarian analysis through weighing benefit

[57] Jones A W, 'Finding a common morality codex for biotech- a question of substance' (2008) International Review of Intellectual Property and Competition Law

[58] *Lubrizol/Hybrid plants*, T320/87 [1990] EPOR 173

[59] *Howard Florey/Relaxin*, T74/91 [1995] EPOR 541

[60] Crespi R S, 'The human embryo and patent law-a major challenge ahead' (2006) European Intellectual Property Review

[61] Harmaon S H E, 'From engagement to reengagement: the expression of moral values in European patent proceedings, past and future' (2006) European Law Review

[62] *HARVARD/Onco-mouse,*T19/90, 1990, O.J. EPO 12/1990, 476, and 1992 O.J. EPO 110/1992, 588

[63] *Harvard/Transgenic animal* (T-315/03) [2005] E.P.O.R. 31 at 10.5–10.8 [161]--[164]

against disadvantage. However, the Opposition Division in the same case stated that "its function has to be seen as a measure to ensure that patents would not be granted for inventions which would universally be regarded as outrageous."[64] Furthermore, the Opposition Division indicated that the possibility of genetically modified plants disturbing the ecological balance "has no bearing on whether a patent is granted or not."[65] This represented the uncertainty in relation to the morality assessment.

An important change was made by the implementation of the Biotechnological Directive. Although the first proposal of the Directive was rejected by the European Parliament because it lacked ethical considerations, the 10-year revision added many public concerns about the morality of biotechnology inventions. Article 6(1) of the Directive said "Inventions shall be considered unpatentable where exploitation or publication would be contrary to public policy or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation." This reflected Article 53(a) of EPC. Significantly, Article 6(2) gives some direct examples of immoral inventions: "a. Processes for cloning human beings; b. Processes for modifying the germ line genetic identity of human beings; c. Uses of human embryos for industrial or commercial purposes; d. 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."

In the Directive, a series of definitions and interpretation was laid down to serve the aim "to provide an equal level of patent protection for biotechnological inventions in all the Member States."[66] Anomalously, the morality provision seemed not to be stricter. According to Amanda Warren-Jones, "there being a discernable intention in the Biotech Directive to leave the morality provision outside of this overarching aim at clarity."[67] He indicated that the list of unpatentable subject matter was nothing but a "general guideline." The individual nations can choose what moral standard being applied.[68]

One of exclusions in Article 6(2) is the use of human embryos for industrial or commercial purpose. However, the provisions do not provide a distinct explanation of "uses of human embryos." In case University of Edinburgh/Stem Cell Isolation, two interruptions of Rule 23d(c) EPC which was equal to Article 6(2) of the Directive were discussed: one is narrowly explained as "uses of human embryos as such"; the other is broadly explained as "uses of human embryos together with the

[64] Plant Genetic System/Glutamine synthetase inhibitors, T356/93 (1993) 24 llC 618; [1995] EPOR 357; [1995] OJEPO 545 (TBA)

[65] Plant Genetic System/Glutamine synthetase inhibitors, T356/93 (1993) 24 llC 618; [1995] EPOR 357; [1995] OJEPO 545 (TBA)

[66] The "Council's Reasons" for amending the Commission's 1992 version of the proposed Directive (1992 version, OJ EC C44, at 36 (16 February 1993); OJ EC C101, at 71 (9 April 1994)

[67] Jones A W, 'Finding a common morality codex for biotech- a question of substance' (2008) International Review of Intellectual Property and Competition Law

[68] Jones A W, 'Finding a common morality codex for biotech- a question of substance' (2008) International Review of Intellectual Property and Competition Law

cells being retrieved there from by destruction of the embryos, namely, human ES cells."[69] The Opposition Division stated that broadly interruption should be applied. The Division further explained that "if the patenting of a product is ethically unacceptable, it is hardly conceivable that the patenting of "uses" of this product can be judged differently."[70] But Claudio Germinario, a former EPO Appeal Board member, has an opposite view. He indicated that this decision was contrary to the previous findings of the Appeal Boards that the interruption of exclusions from patentability should be narrow.[71]It should be noted that the UK patent Office agrees the Germinario's opinion.[72]

The following case WARF seamlessly addressed to the problem of the correct approach to Rule 23(d)(c). The filed application did not direct to the method which involved the destruction of the human embryo. Instead, they claimed the product which was derived from those methods. The Enlarged Board of Appeal finally rejected the appeal on November 25, 2008. The decision clearly said that "Rule 28(c) EPC forbids the patenting of claims directed to products which at the filing date could be prepared exclusively by a method which necessarily involved the destruction of the human embryos from which the products are derived, even if the said method is not part of the claim."[73] This means the Europe Patent Office refused to permit any patent which involving the destruction of human embryos or their use for industrial or commercial purposes.

However, the controversy of patentability of human stem cell will be prolonged. As Dr. Paul Chapman pointed out, the decision leaves a backdoor to those applications which "out of necessity makes use of human embryos for industrial and commercial purpose, but does not necessarily involve the destruction of embryos,"[74] for instance, the common applications about using stem cell lines as starting material. Thus the uncertainty of law had not been fully clarified.

8.6 Conclusion

The Biotechnology Directive had successively treated the patentability of gene-related inventions, the exceptions to patent and moral issues. In addition, the Directive generally achieved the goal of harmonization of patent laws among the member states. To some extent, the Directive simplified the uncertainty of the patent law which is benefit to increase the research investment and development funds.

[69] Opposition Decision re EP 0695351, Edinburgh University. Not published in OJEPO

[70] *University of Edinburgh/Stem Cell Isolation (Edinburgh),* T-1079/03 EP 949131742 unreported, July 21, 2003, Opposition Division, at 22

[71] Claudio Germinario, "The Value of Life" (2004) Patent World 16–18.

[72] Crespi R S, 'The human embryo and patent law-a major challenge ahead' (2006) European Intellectual Property Review

[73] G-02/06 of the Enlarged Board of Appeal of the European Patent Office

[74] Chapman P, 'Rejection of controversial stem cell patent fails to fully clarify law' M&C (London 28 November 2008)

First, the Directive ended the debate of discoveries and invention and affirmed that gene-related invention is eligible to the subject of patent. Second, the Directive expanded the standard of industrial applicability which must be disclosed in the application and required the indication of a function and technical information of DNA sequence. Third, the Directive clearly indicated the allowance of the genetic modified plant and animal. Also the Directive provided explicit answer to the degree of technical intervention to satisfy nonessential biological process. The Directive gave negative answer to the patentability of plant or animal varieties merely due to they are the result of microbiological or technical process. Last, considering the diversity of moral standard among member states, the Directive listed the immoral inventions and gave the space to the divergence.

It is not exaggerate to say that the Biotechnology Directive is a milestone of biotechnology patent law in Europe. However, it was challenged by various grounds.

Some objections were from the government of member state. The Government of Netherlands, which was supported by Italy and Norway, challenged the lawfulness of the Biotechnology Directive. They mainly argued that "it is incorrectly based on Article 100a (now Article 95) of the Treaty; that it is contrary to the principle of subsidiary; that it infringes the principle of legal certainty; that it is incompatible with international obligations; that it breaches fundamental rights, and that the procedure for its adoption was incorrect."[75]

The annulment was rejected by the ECJ. First, the court used the patentability of plant varieties and that of the human body as the evidence that Article 100a was the correct rational basis of enacting the Directive. Second, the ECJ indicated the guideline was given to the Article 6. Therefore the Directive had not exacerbated the legal uncertainty. Third, the court said the Directive handled the biotechnological inventions which could not be acted by member state alone. Thus the Directive did not violate the principle of subsidiarity. Fourth, the ECJ held that no evidence could be provided to prove the patent protection of biotechnological invention limited the purposes of the CBD. Last, Article 5 and Article 6 are the guarantee of human dignity. Besides, "only inventions that combined natural and technical elements in a way that allowed an industrial application to be isolated were patentable."[76]

Some objections were from the scholars. For instance, Amanda Odell-West, from the University of Sheffield, suggested that Recital 42 exclusion within the Biotechnology Directive could be invoked. According to Recital 42 of the Directive, the exclusion of Article 6(3) "in any case does not affect inventions for therapeutic or diagnostic purposes which are applied to the human embryo and are useful to it."[77]However, this provision seems not always suitable for Preimplantation Genetic

[75] Broensword R and Beyleveld D, 'Is patent law part of the EC legal order? A critical commentary on the interpretation of Article 6(1) of Directive 98/44/EC in Case C-377/98' (2002) Intellectual Property Quarterly

[76] Netherlands v European Parliament (c-377/98) [2002] All E.R. (EC)97; [2001] E.C.R. I-7079; [2001] 3 C.M.L.R. 49; [2002] F.S.R.36; (2002) 68 B.M.L.R.1

[77] West A O, 'Preimplantation Genetic Diagnosis, the medical exclusion and the biotechnology directive' (2007) Medical Law International Vol 8 pp. 239–250

Diagnosis (PGD), which can detect many different types of inherited diseases in embryos generated by in vitro fertilization. He provided the following reasons: First, PGD is not always beneficial and useful to the embryo. It can be used to genetically discriminate and select between embryos. Second, when PGD is used in private clinics, it essentially belongs to "the commercial use." Third, because of low percentage of success, a large number of embryos are made then discarded.[78] So, Recital 42 of the Directive seems to lack consideration in this situation and should be amended.

Among these challenges, the majority of disputes are related to moral issue. However, the scientific advancement could make these debates meaningless. Taking an instance of stem cell, the ethical controversies are mainly about human embryo stem cells. But the recent news reported that an ordinary adult stem cell can achieve the same goal of embryo stem cell.[79] This major breakthrough was gotten by a San Francisco research and development company. They claimed that those cells "can match tissues in the heart, lung, liver, pancreas, blood vessels, brain, muscle, bone, and fat." Moreover, adult stem cells can "avoid some of the complications found with embryonic stem cells, such as a specific type of cancer." This great news not only ended the dispute surrounding the Directive but also helped ignite the ethical contention of the use of embryos in stem cell research.

In sum, the Biotechnology Directive undeniably exist some insufficiency and uncertainty within itself.[80, 81] However, we cannot neglect the contribution of the Directive because of its faults.

[78] West A O, 'Preimplantation Genetic Diagnosis, the medical exclusion and the biotechnology directive' (2007) Medical Law International Vol 8 pp. 239–250

[79] Unruh B, 'Scientific breakthrough! No embryonic stem cells needed' 22 August 2008 World net daily

[80] Singh HB, Keswani C, Singh SP (Eds.). Intellectual Property Issues in Microbiology (2019) Springer-Nature, Singapore. 425 pages, ISBN- 9789811374654

[81] Singh HB, Jha A, Keswani C (Eds.). Intellectual Property Issues in Biotechnology. (2016) CABI, Wallingford, UK. 304 pages, ISBN-13: 9781780646534