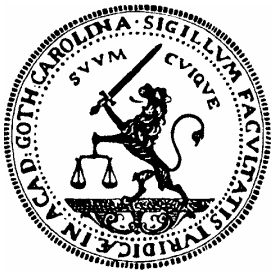

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Unpatentable Exceptions to the EPC. The rationale and understanding of Article 53(b) – A historical analysis.

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Contents

Summary

This thesis investigates Article 53(b) of the European Patent Convention and has at its core, the reasoning for this Article. It establishes and explains the ideological beginnings of these exceptions to patenting.

By focusing primarily on the two landmark cases on the Article, I have tried to draw out where the reasoning for this exclusion has come from and where the exclusion may potentially lead.

My method is not to determine what a patentable invention is or to try to explain 'Ordre Public' or ethical or public policy concerns. It is to break Article 53(b) down through analysis and clarification.

Firstly and most importantly, I separated it into Plant and Animal, then through this, examining where the law and cases have taken us, to help understand the rationale behind the Article. As stated in my delimitations, my material will be strictly limited to the Article, although to find a progressive history I may have to examine other documents to fully understand the historical value.

The thesis explains why the transgenic properties of animals and plants are so important to patents, breaking this down further into the specifics of Article 53(b) and explains how or why the patents were granted or not.

In doing this, I also highlighted potential problems and tried to find solutions or ways that the Article could be improved.

Not only is the variety aspect of Article 53(b) examined and explained, but the patenting of biological processes aspect is also broken down and explained in relation to why microbiology is accepted and how this would affect macrobiology.

The ethical implications are touched upon, but not examined in great depth, since this is in no way a theological paper. The legal and explanatory sides are critically analysed.

Preface

First and foremost, I would like to thank my sister, Maria-Antonella, for constantly encouraging me to research and assisting me in every possible way to get my work completed. Without ‘Nella’ back home to take care of everything, I would be truly lost.

A special thanks to my best friend Michele, all of the running around you do for me is appreciated and has helped me significantly this year.

Thanks to my Professors and Lecturers, especially Hans Henrik Lidgard, Henrik Norinder and Xavier Groussot, for guidance and help throughout the year.

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Abbreviations

EBA	Enlarged Board of Appeal
EPC	European Patent Convention
EPO	European Patent Office
EU	European Union
TBA	Technical Board of Appeal
SC	Strasbourg Convention
US	United States
USPTO	US Patent and Trademark Office
U.S.C.	United States Code

1 Introduction

1.1 Purpose

Originally, my idea was to break down the ‘Ordre Public’ criteria and follow through the legislation to get a general overview. Further research into this led to the ambiguity that it would be able to be addressed well, since the topic was so broad and the sources plentiful.

To really limit myself and to try to steer my research into one solid direction, the purpose of this thesis is to focus on the rationale behind Article 53(b).

This will be achieved by trying to discover the original intent behind it, and follow this with a historical analysis of the case law to put the Article into perspective.

In doing this, I hope to highlight strengths and weaknesses in the Article and potentially make suggestions as to if it needs clarification.

My thesis will also prove to be a fact-finding mission, as there is not a lot of history to the Article documented and in understanding the cases, I shall present the progressive importance in modern day society.

1.2 Delimitation

The lack of comparative legislation to Article 53(b) in US law will not allow a full comparative EU/US analysis as originally planned, but instead will add to the progressive understanding of the Article in the EU, and also display how landmark cases have been affected from the US.

I shall try to focus solely on the Article and supporting documentation from the EPC, without progressing to the Directive 98/44/EC on the legal protection of biotechnological inventions, since the EPC provides the legal framework for the granting of European patents.

My main delimitation is to avoid Article 53(a), as this is a wide topic that covers ordre public and morality on all levels and as stated in my purpose, the research would almost have been limitless.

1.3 Method and Material

My method is not to determine what a patentable invention is or to try to explain ‘Ordre Public’ or ethical or public policy concerns.

It is to break down the through analysis and clarification, Article 53(b). Firstly, into Plant and Animal, then through this see where the law and cases have taken us, to help understand the rationale behind the Article. As stated in my delimitations, my material will be strictly limited to the Article, although to find a progressive history I may have to examine other documents to fully understand the historical value.

2 Background to the European Patent Convention

Seeking patent protection in numerous European countries also faced the inventor with multiple barriers; whether it be multiple legal systems, language barriers or costs and time constraints.

To help make this process so much easier and to ease the burdens faced by an applicant, some European countries joined together under a treaty known as the European Patent Convention (EPC)[1] under which the European Patent Office (EPO) was created. The EPC was established in order to strengthen co-operation between European states regarding the protection of patentable inventions.[2]

For EPC member states, the EPO acts as a central searching and examining authority for patent applications that qualify under certain standard rules, and provides a legal framework[3] for the granting of European patents for patent applications, via a single, harmonized procedure before the EPO. A single patent application in one language[4] can be filed at the EPO at Munich.

The EPC also sets forth the framework for how the EPO is to operate by determining what constitutes a patentable invention and the process of obtaining and maintaining a European patent.

The process works whereby once a patent is granted and taking into account translations and payment of fees, the effect of a European patent in any country in which it is in force is the same as that of a national patent issued in that country.

Questions of infringement for a granted European patent are left to the national law in each individual member country in which protection is sought. The EPC is primarily concerned with the granting of European patents and, therefore, with their validity, but not with their enforcement.[5] In interpreting the scope of the European patent, the EPC instructs member countries that;

"The extent of protection conferred by a European patent or a European patent application shall be determined by the terms of the claims. Nevertheless, the description and drawings shall be used to interpret the

[1] The European Patent Convention, also known as the Convention on the Grant of European Patents, was signed in Munich on Oct. 5, 1973 and entered into force in Oct. 7, 1977.
[2] Leith, P. Perspectives on Intellectual Property Volume 3. 1998. p. ix(9)
[3] Article 2(1) EPC
[4] Article 14 EPC
[5] Supra fn 2 at p. x(10)

claims."[6]

Other requirements the EPC imposes on its member countries provide that:

• the European patent has a term of 20 years from the filing date (with the possibility of extension in cases of national emergency or to compensate for marketing delay caused by the need for obtaining approval from a governmental entity),

• Process patents confer protection on products directly obtained by the process, and

• the collection of compensation for use of the invention after the application is published, but before the patent is granted, must be provided for in circumstances where liability under national law for infringement of a national patent would exist (provided that, if required by the member country, a translation of the claims pending in the application were filed in the national patent office of the country where such collection is pursued).

[6] Id at Art 69(1) Extent of Protection

2.1 Patentability of Living Matter

Genetic engineering has given humans the power to manipulate living matter since its discovery in the 1970's, and one of the main concerns is questioning the legitimacy of patenting living matter.

"You cannot invent nature", was how one French lawyer put it in a highly critical commentary on the judgment given by the Supreme Court of the United States on 16th June 1980 in Diamond v Chakrabarty.[7]

2.1.1 Diamond v Chakrabarty

A bacterium was developed (derived from the Pseudomonas genus) capable of breaking down crude oil, which was proposed to use in treating oil spills. A patent examiner turned down the request for a patent, because the law dictated that living things were not patentable.[8]

The Supreme Court overturned this decision and held that a new organism had been created and there was human interference with nature that created something new and that living organisms were patentable matter.

"A live, human-made micro-organism is patentable subject matter under 101.[9] Respondent's micro-organism constitutes a "manufacture" or "composition of matter" within that statute".[10]

The practice of granting patents on living matter goes much further than 1980. It predates the emergence of genetic engineering and was endorsed in the early 1960's.[11]

That the first known patent of a living organism was granted in Finland in 1843 and Louis Pasteur[12] received a patent from US Patent Office for isolated yeast (free from organic germs or disease) as early as in 1873.[13]

[7] Diamond v. Chakrabarty, (1980) 447 U.S. 303
[8] 35 U.S.C. 101
[9] Id.
[10] Supra fn 7 at para. 308-318
[11] First by the UPOV Convention (1961) and subsequently by the Strasbourg Convention (1963)
[12] US Patent 141,072
[13] Westerlund, L. Biotech Patents, Equivalency and Exclusions. 2001 p. 1

3 Article 53(b)

3.1 What is Article 53(b) and what should it protect?

3.1.1 Exceptions to Patentability

Article 53 of the EPC states that;

European patents shall not be granted in respect of:

(a) inventions the publication or exploitation of which would be contrary to "ordre public" or morality, provided that the exploitation shall not be deemed so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States;

(b) Plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes or the products thereof.

3.1.2 History and Purpose

The first sentence of Article 53(b) excludes from protection two kinds of biologically related material and biotech processes.

The roots of biotechnology patents stem all the way back to 1883 when the Paris Convention[14] expanded the contents of intellectual property to include 'biological inventions'.[15]

This Article seems to have a direct relation to Article 2(b) of the Strasbourg Convention[16] (SC) and one could say that it actually rests on it legally.

[14] The Paris Convention for the Protection of Industrial Property signed on 20th March 1883
[15] Id. at Article 1(3)
[16] The Convention on the Unification of Certain Points of Substantive Law on Patents for Invention. Signed by Member States of the Council of Europe on the 27th November 1963. This Convention establishes patentability criteria and it intended to harmonize substantive patent law but not procedural law.

Article 2(b) had gained considerable importance as the biotech field has progressed and as it does not bind states to offer patents on animal or plant varieties, it effectually makes possible the exclusion in the EPC.[17]

After much research, the purpose of 'excluding specific biological matter' from patentability can be assumed, but overall is obscure. The legislations purpose is not explicitly stated, although one can infer many reasons behind this, mainly public policy based and as the preamble states, it is to "strengthen cooperation between European States with respect to the protection of inventions".

Present justification leans towards more of a commercial perspective and reflects the current view of the patent system as based upon the legal policy in society and economic life. The interference in biological life has far-reaching consequences that can be perceived as good or bad, depending on the field of technology it comes from. [18]

[17] Westerlund, L. Biotech Patents, Equivalency and Exclusions. 2001 p. 319
[18] Id. p. 320

3.1.3 Essentially Biological

Like the exclusion of plant and animal varieties (which will be assessed later on in this paper), Article 53(b) exclusion of essentially biological processes from patentability originates from Article 2 of the Strasbourg Convention.[19] Essentially biological processes referred only to the normal or traditional, breeding activities of plants and animals.[20]

Humans are now able to change the genetic material of plants and animals by manipulating the natural, or "essentially biological" processes. The term "essentially biological" which appears in the prohibition of plants or animals produced by an "essentially biological process", is defined as consisting of entirely natural phenomena, such as crossing or selection.[21]

This narrow definition of "essentially biological" makes it possible for patenting genetically modified plants or animals since genetic modification is not a process consisting of "entirely natural phenomena".

According to Lubrizol,[22] whether or not a non-microbiological process was to be considered as "essentially biological" within the meaning of Article 53(b) had to be judged on the basis of the essence of the invention - taking into account the totality of human intervention and its impact on the result achieved.

The necessity for human intervention alone was not a sufficient criterion for its not being "essentially biological". Human interference might only mean that the process was not a "purely biological" process, without contributing anything beyond a trivial level. It was further not a matter simply of whether such intervention was of a quantitative or qualitative character.[23]

[19] Van de Graaf, Patent Law and Modern Biotechnology: A Comparative Study About the Requirements and the Scope of Protection 28 (1997) p. 103
[20] Id.
[21] European Patent Office, Implementing Regulations to the Convention on the Grant of European Patents, 1973. Rule 23b (http://www.european-patent-office.org/legal/epc/e/r23b.html)
[22] T320/87 LUBRIZOL/Hybrid plants. (1990) O.J. EPO 71
[23] Case Law of the Boards of Appeal of the European Patent Office, 5th Edition 2006, p. 43 (http://webserv.epo.org/projects/babylon/eponet.nsf/0/F7944E5E0AD5958DC12572BC004B2CB6/$File/clr_2006_en.pdf)

3.1.4 Macro and Microbiological

The last sentence of Article 53(b) indicates that microbiological processes and their direct products are distinguishable from essentially biological products. This exemption also derives from Article 2 of the SC.

The provision was in line with the distinction that was made at the time between macro and microbiology. At the time, the macrobiological processes and products were not in anyway considered technological, and thus were not within the reaches of patent law. This was in contrast to microbiological processes and their direct products, for which several patents had been granted in the nineteenth century.[24]

The term "microbiological process" only refers to processes that are "typically" microbiological. Products that are created or manipulated with the help of microorganisms, by a process that is entirely microbiological, are the products that "derive directly there from". Hence, they are patentable under EPC article 53(b).[25]

The TBA has determined that the term "microorganism" also encompasses multicellular material, such as plants, animals, plasmids, and viruses.[26]

(The term "microorganism" does not have a taxonomic meaning, but instead refers to the size of the organisms, biology of microscopic forms).

[24] Straus, J. Biotechnological Inventions--Their Protection and Its Limitations, 1992(GRUR Int'l 256)
[25] Supra fn 19 p. 107
[26] T356/93 Plant Genetic Systems

4 Plant Varieties

4.1 History

The exclusion of "plant and animal varieties" from patentability is very specific in Article 53(b).

The term "variety" was not defined in the EPC. However, the legal history of Article 53(b) suggests that plant varieties were excluded from patent protection under the EPC mainly because an alternative form of protection was available under the International Convention for the Protection of New Varieties of Plants (UPOV Convention).[27]

In 1983, the Technical Board of Appeals (TBA) determined that the scope of subject matter excluded under Article 53(b) is that which is protectable under the UPOV Convention.[28]

In the CIBA[29] case, the term "plant varieties" was first defined as a multiplicity of plants which were largely the same in their characteristics and remained the same within specific tolerances after every propagation cycle.[30]

The claims for plant propagating material in the case were refused by the first instance because the subject matter was excluded under Article 53(b). However, the TBA concluded that only plants which are characterised by their genetically determined peculiarities are prohibited from patentability under the Article.[31]

The importance of this case is overshadowed by the fact that it mainly concerned plants treated in a specific way with chemical agents to make them resistant to herbicides, thus not constituting a genetic invention; therefore, the subject matter was not within the exclusion of Article 53(b).

It defined "plant varieties" as "a multiplicity of plants, which are largely the same in their characteristics and remain the same within specific tolerances

[27] The International Convention for the Protection of New Varieties of Plants, signed in Paris in 1961. The Convention entered into force in 1968. It was revised in Geneva in 1972, 1978 and 1991. The 1991 Act entered into force on April 24, 1998.
[28] T49/83 CIBA GEIGY/Propagating Material. (1984) O.J. EPO 1984.
[29] Id.
[30] Case Law of the Boards of Appeal of the European Patent Office, 5th Edition 2006, p. 42 (http://webserv.epo.org/projects/babylon/eponet.nsf/0/F7944E5E0AD5958DC12572BC004B2CB6/$File/clr_2006_en.pdf)
[31] Holtz, C. The Outer Limits of Patentability – Biotechnology, NIR 1996, Issue 1 p. 25

after every propagation or every propagation cycle" as reflected in the 1961 UPOV Convention.[32]

This definition would therefore cover "all cultivated varieties, clones, lines, strains and hybrids which can be grown in such a way that they are clearly distinguishable from other varieties, sufficiently homogeneous and stable in their essential characteristics".[33]

4.2 Lubrizol / Hybrid plants

In 1990, the EPO considered product-by-process claims to heterozygous hybrid plants.[34]

It decided that Article 53(b) only prohibited the patenting of plants in the genetically fixed form of a plant variety and did not apply to plants which did not meet the profile of a variety and which belonged to a classification unit taxonomically higher than that of a variety.[35]

4.3 Plant Genetic Systems

Also in 1990, the EPO issued a patent to Plant Genetics Systems[36] including claims to seeds, plants and plant cells that are herbicide-resistant by virtue of having a resistance gene integrated in the plant genome.

Although the EPO initially granted the patent, Greenpeace opposed it. The Board then reviewed the patent, analyzing separately the following three categories:

(1) The plant cells and seeds,
(2) The process for producing the transgenic plant, and
(3) The transgenic plants.

The TBA reversed this decision in 1995 and held that the plant cells and seeds and the process for producing the transgenic plants were patentable. However, the court found the transgenic plant not patentable because it fell under the realm of "plant variety" according to Article 53(b).

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[32] Id. at para. 2
[33] Id.
[34] Lubrizol, Supra fn 22
[35] This decision was consistent with the grant of a patent to T19/90, OncoMouse/HARVARD. (1991) O.J. EPO, 589. On the grounds that "rodents" and "non-human mammals" have a higher taxonomic rank than "animal variety.
[36] T356/93 Plant Genetic Systems v. Greenpeace Ltd.

The provisions of Article 53(b) were interpreted as stating that plant varieties, if produced by a "microbiological process", are patent eligible.[37]

The Board then discussed the meaning of the terms "essentially biological process" and "microbiological process", finding that the term "microbiological processes" encompasses all recognized "technical activities in which direct use is made of microorganisms".

This definition was justified by saying that technical processes were not to be considered "microbiological processes" within the context of Article 53(b) simply because they included a microbiological step.[38]

It concluded that a process for producing plants was not "essentially biological" if it comprised "at least one essential technical step, which cannot be carried out without human intervention and which has a decisive impact on the final result".[39]

Based on these interpretations and conclusions, the Board held that while the claimed plant cells did not fall under the definition of a "plant variety", the descendant plants grown from the plant cells were not patent eligible because they were not produced by a microbiological process.

It decided that the term "plant variety" encompasses "any plant grouping within a single botanical taxon of the lowest-known rank which, irrespective of whether it would be eligible for protection under the UPOV Convention, is characterized by at least one single transmissible characteristic distinguishing it from other plant groupings and which is sufficiently homogeneous and stable in its relevant characteristics."[40]

It further stated that "a product claim which embraces within its subject matter 'plant varieties' as just defined ... is not patentable under Article 53(b)" and held that the claimed seeds and plants comply with the definition of plant variety since they are distinguishable, uniform and genetically stable. Therefore, they were excluded from patentability.

EPO policy made a U-turn with the Plant Genetic Systems decision in relation to Lubrizol. Plants 'per se' were no longer considered acceptable, whereas plant cells were determined to be patentable.

This viewpoint was reaffirmed in Novartis.

[37] Id. at 546
[38] Id. at 577
[39] Id. at 578
[40] Id.

4.4 Novartis II [41]

This case is the leading case in relation to the 'plant' aspect of Article 53(b) and I shall break down the case and explain what points are important, to try and help understand the rational behind the plant variety exception.

4.4.1 Plant Patentability exception within Article 53(b)

Although four questions were posed to the Enlarged Board of Appeal (EBA) in the case, only questions 2-4 were fully addressed.

Question 2 looked at to what extent are claims relating to plants patentable under Article 53(b).

In applying the "plant varieties" exception to patentability under Article 53(b) the EBA found that the Novartis application was not necessarily limited to plant varieties, it had to determine whether Article 53(b) should be broadly interpreted to cover claims to plants in general.

They had to distinguish between a "substantive approach" and a "literal approach". Under the substantive approach, a patent is granted with respect to plant varieties if a claim covers plant varieties. Under the literal approach, Article 53(b) is satisfied if the words "plant variety" do not appear in a claim.[42] The conclusion was that the wording of the claim was not decisive, it is the "substance of a claim that is decisive in assessing the subject-matter to which the claim is directed".[43]

The EBA determined that the method of the invention, i.e. modification by genetic transformation, did not necessarily result in a product that constituted a "plant variety". After reviewing various definitions of the phrase "plant variety" (including Article 1(vi) of the UPOV Convention and Rule 23(b) EPC[44]), the EBA concluded that the expression of characteristics of a plant variety that results from a given genotype, or combination of genotypes, is a reference to the entire constitution of a plant or set of genetic information.[45]

Therefore, the EBA concluded that the resulting products of the Novartis invention did not expressly or implicitly define a single variety, or a

[41] G01/98 Novartis/Transgenic plant (2000) EPO
[42] Id. at para. 3.1.2
[43] Id.
[44] Rule 23c EPC - Patentable biotechnological inventions (http://www.european-patent-office.org/legal/epc/e/r23c.html)
[45] Supra fn 41 at para. 3.1.6

multiplicity of varieties, which necessarily consists of several individual varieties.

It held that "In the absence of the identification of specific varieties in the product claims, the subject-matter of the claimed invention is neither limited nor even directed to a variety or varieties".[46]

In other words, product claims having subject matter which covers or embraces plant varieties, but which do not identify or individually claim specific plant varieties, are not claims to a plant variety or varieties within the meaning of Article 53(b).

4.4.2 Microbiological Processes

The second half-sentence of Article 53(b) provides that the exclusion of plant and animal varieties, and essentially biological processes for their production, does not apply to "microbiological processes or the products thereof".

The EBA had to determine whether the process Novartis claimed constituted a "microbiological process", and if so, whether plant varieties resulting from the microbiological process would be patentable as "products thereof" under Article 53(b).

They found that the term "microbiological processes" as used in the provision was synonymous with processes using microorganisms, and that microorganisms were "different from the parts of living beings used for the genetic modification of plants".[47]

The question to be decided when considering if a genetically engineered plant variety could also be considered a product of a microbiological process was whether or not the genetically engineered variety is closer to the original concept of a plant variety or closer to the original concept of a product of a microbiological process.

The conclusion was that the genetically engineered plant varieties of the invention bore no relation to what was originally meant by the product of a microbiological process, but that they were virtually indistinguishable from conventionally produced plant varieties. This led the EBA to the conclusion that genetically engineered varieties are covered by the prohibition in Article 53(b) even if they are considered the product of a microbiological process.

[46] Id.
[47] Id at 3.2

They claimed processes for the preparation of hybrid plants did not constitute an exception to patentability because they represented an essential modification of known biological and classical breeders' processes, and the efficiency and high yield associated with the product showed important technological character.

This appears to me be totally contrary to the provisions of Article 53(b), as if a microbiological process is used, why should it matter for the benefit of the microbiological processes exclusion to be available whether the product looks like a like a plant, or a liquid in other cases.

(In current practice however, cells and parts thereof, including plant cells, are themselves treated as microorganisms when determining the patentability of such microorganisms or products derived there from).[48]

The EBA determined that this broad definition of "microorganism" did not mean that genetically modified plants should be treated as "products of microbiological processes" within the meaning of Article 53(b). Since such an interpretation would disregard the purpose of Article 53(b) to exclude, as unpatentable, subject matter that is eligible for protection under the plant breeders' rights system.[49]

The EBA also reasoned that refusing to allow genetically modified plants to be treated as products of microbiological processes would not preclude inventors from adequate intellectual property protection. The EBA found that a plant variety resulting from genetic engineering could qualify for protection under the UPOV Convention just as equally as those resulting from traditional breeding techniques.

The EBA further found that a claim in which specific plant varieties are not claimed is not excluded from patentability under Article 53(b), even though it may embrace plant varieties. It argued that had it been the intention of the Convention to exclude plants from patent eligibility altogether the provision would have used the more general term "plant" instead of "plant varieties."[50]

It realized that a contrary view would have the logical consequence that "any genetic material for introduction into a plant would have to be excluded from patent protection."[51] It also noted that there are exceptions to the rule that an invention is not patentable because it covers an embodiment which does not fulfil the requirements for patentability.[52]

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[48] Guidelines for Examination, Part C, ch. IV, S 3.5 http://www.epo.org/patents/law/legal-texts/guidelines.html (The term 'micro-organism' includes bacteria and other generally unicellular organisms with dimensions beneath the limits of vision which can be propagated and manipulated in a laboratory…, including plasmids and viruses and unicellular fungi (including yeasts), algae, protozoa and, moreover, human, animal and plant cells).
[49] UPOV Convention
[50] Id. at para. 3.3.1
[51] Id. at para. 3.3.2
[52] Id. at para. 3.3.3

Finally, the EBA reiterated that the purpose of Article 53(b) was that European patents should not be granted for subject matter for which the grant of patents was excluded under the ban of dual protection in the UPOV Convention.[53]

Therefore, it concluded that inventions ineligible for protection under the plant breeders' rights system were intended to be patentable under the EPC if they met the all other requirements of patentability.[54]

The definition of plant variety follows a logical pattern that has its roots deep within patent law but has required a new and more precise 'biotech' angle applied to it.

It can be clearly analysed and summed up by the body of case law available, and its limitations are acceptable as it is a matter of clear interpretation of the law and judgements.

Article 53(b) also has a prohibition on patents for 'animal varieties' and essentially biological processes for the production of animals. The issue of animal varieties is far more complex.

[53] Id. at para. 3.6
[54] Id. at para. 3.7

5 Animal Varieties

5.1 History

The reason for excluding animal races from patentability is related to the controversy that arose during the preparatory discussions for the Strasbourg Convention (SC). The participating countries fiercely debated the ethical implications, resulting in the concerned signatories excluding animal races.[55]

Another reason animal races were excluded was the dominating view at the time that assumed that patent law was neither suited for, nor appropriately directed at, animal races. The rationale included the presupposed difficulties in disclosing the invention, the self-replicating capabilities of animals that complicate determining the content and scope of patents, and the lack of expertise on the part of various patent offices and courts.[56]

In my extensive research, I found it extremely difficult to find the historical background and various national policies to the animal variety exemption. Not only because there does not seem to be that much material out there on this particular area, but also that a lot of the information I was working with was also in other EU languages. – Maybe with more time my results would have been different, but since I am limited to one month to write this thesis, I must present an analytical historical progression of the EU and US post 1970's.

5.1.1 Ex Parte Allen

The US was once again at the forefront of biotechnology and the question of whether multi-cellular animals could be patented was examined in the 1980's. In Ex Parte Allen[57], the key issue was the patentability of "polyploid pacific coast oysters" that had an extra set of chromosomes.

This new, sterile oyster was edible all year round because it did not devote body weight to reproduction during the breeding season. The applicant sought to patent a method of inducing polyploidy in oysters as well as the resulting oysters as products-by-process.

[55] Straus. J. The Ethical, Legal and Economic Problems of Patent and Species Protection for Biotechnological Animal Breeding and Animal Production (1990) 39 (GRUR Int'l) 913
[56] Id.
[57] 2 U.S.P.Q.2d 1425 (Bd. Pat. App. & Inter. 1987).

Following the reasoning in Chakrabaty[58], the United States Patent and Trademark Office (USPTO) concluded that such organisms were eligible for patenting. It found this particular type of pacific coast oyster to be obvious, however, and thus rejected the patent application. Nonetheless, the polyploid oyster paved the way for the patenting of other non-naturally occurring animals.

Shortly after the Allen decision, the USPTO issued a notice declaring that it would consider non-naturally occurring, non-human multicellular living organisms, including animals, to be patentable subject matter within the scope of the Patent Act. In 1988, for example, Philip Leder and Timothy Stewart were granted a patent on transgenic non-human mammals[59] that covered the so-called "Harvard OncoMouse," which was genetically engineered to be a model for the study of cancer.

5.2 Transgenic Animals

Animals are "transgenic" when DNA from other species is artificially introduced into their genome. This genetic manipulation raises a host of ethical issues that can be highly controversial.

Such issues are much wider than the questions relating to patentability. Governments, at any stage of research and development, may directly outlaw any technology deemed inherently unacceptable, but it is notable that some controversial new technologies only surface publicly when they reach the patent office.

There are various definitions for the term transgenic animal. The Federation of European Laboratory Animal Associations defines the term as "an animal in which there has been a deliberate modification of its genome, the genetic makeup of an organism responsible for inherited characteristics".[60]

These animals are developed primarily for specific economic traits.[61] However, they are also produced for potentially beneficial applications, such as medical research, enhanced food production, and the production of proteins or organs. The area that concerns Article 53(b) is transgenic animals produced as disease models (animals genetically manipulated to exhibit disease symptoms so that effective treatment can be studied).

This is the main issue at stake in the landmark case in the field for animals in relation to Article 53(b), OncoMouse.

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[58] Supra fn 7

[59] US Patent No. 4,736,866

[60] FELASA (Federation of European Laboratory Animal Science Associations) 1982, rev.1995. Transgenic Animals -- Derivation, Welfare, Use and Protection.

[61] For example, transgenic cattle were created to produce milk containing particular human proteins, which may help in the treatment of human emphysema.

5.3 OncoMouse

The OncoMouse patent was filed as one of the first patent applications on a transgenic animal in June 1985. The patent application entitled "Method for producing transgenic animals"[62] claimed it was a method for producing a transgenic mammalian animal having an introduced oncogene sequence,[63] as well as the transgenic animal itself.[64]

This makes the mice more prone to develop tumours at a much younger age than normal mice. They provide a model system for the study of cancer and they may be used as a sensitive test for determining the carcinogenicity of substances.

The application was first refused by the EPO on the grounds of Article 53(b), which prevents patenting of animal varieties, and of Article 83, because it could not be assumed that the only examples in the application, namely mice, could be extended to all other animals. The applicant successfully appealed this decision.

This was down to the Examining Divisions interpretation of the provision of Article 53(b) that "European patents shall not be granted in respect of… animal varieties" as referring not only to cases where a specifically designated variety was claimed, but also to cases where varieties were covered by a claim.

In determining the scope of Article 53(b), the TBA first addressed the different terminology found in the three official texts of the EPC, which are written in German, English, and French.

The English version of Article 53(b) excludes "animal varieties". The German version of Article 53(b) excludes "Tierarten". The French version excludes "races animals".

Within these different languages, the terms have differing scopes. The German term "Tierarten" (animal species) is broader than the English term "animal varieties" and the French term "races animals" (animal races).[65]

All three texts were equally acceptable under the EPC, so the TBA reasoned that there was a need to establish a common meaning as to the "extent that animals are excluded from patentability under Article 53(b)".[66]

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[62] European Patent Application No. 85 304 490.7 (filed June 24, 1985).
[63] Id. Claim 1
[64] Id. Claim 17
[65] T19/90 Harvard/OncoMouse (1990) EPO 501, 509-10
[66] Id. at 510

The TBA concluded that, “It was the task of the EPO to find a solution to the problem of the interpretation of Article 53(b) EPC with regard to the concept of ‘animal varieties’”. The interpretation of the Examining Division excluded not only certain groups of animals from patentability, but in reality all animals.[67]

Exceptions to patentability according to the TBA must be “narrowly construed”. They dismissed the possibility that the reference to certain categories of animals in Article 53(b), rather than to animals as such, was simply a mistake by the legislators, because nothing in the legislative history supported such an assumption.

The conclusion was drawn that the use of the terms, “animal varieties”, “races animals” and “Tierarten”, was a clear indication that Article 53(b) was not intended to cover animals as such.

Furthermore, the TBA noted that Article 53(b) also contained in the same first half-sentence of the provision, a reference to “animals” in general, with regard to “essentially biological processes”. Following this line of reasoning, because of its use of the different terms “animal varieties” and “animals”, the EPC legislator could not have meant “animals” in both cases.

Continuing its analysis of the meaning of the term “animal variety”, the Board concluded that the proper question to be answered by the Examining Division was whether or not the subject matter of the application constitutes an “animal variety” as that term is used in Article 53(b).

To aid the Examining Division in its decision, the TBA advanced a balancing test wherein the “interest of the inventors in this field in obtaining reasonable protection for their efforts” should be balanced with “society's interest in excluding certain categories of animals from patent protection”.[68]

The TBA found that the Examining Division was wrong in refusing the OncoMouse application on the grounds that Article 53(b) excludes the patenting of animals as such, and instructed them to re-examine the case.

[67] Id.
[68] Id. at 487

5.3.1 OncoMouse II[69]

The Examining Division had to then consider whether the term "animal variety" or its counterparts ("race animale" and "Tierart") covered the subject matter of the OncoMouse application, which was generically drafted to claim "mammals" and "rodents".

The Examining Division avoided specifically interpreting the scope of the term "animal varieties" by concluding that;

"Although the term 'animal variety' was not entirely clear, in particular in view of the differing wording in the three equally binding languages of the EPC, it nevertheless could be stated with certainty that rodents, or even mammals, constituted a taxonomic classification unit much higher than species ('Tierart'). An 'animal variety' or 'race animale' is a sub-unit of a species and therefore of even lower ranking than a species."[70]

Accordingly, the Examining Division found that the subject matter of the claims to animals 'per se' in the OncoMouse application were not covered by the three terms of Article 53(b) of the EPC.

Although the patent was granted, the validity of the patent was opposed and challenged. The main argument raised by opponents was to the patentability of animals under Article 53(b).

[69] Harvard/OncoMouse, (1991) EPO 525
[70] Id at 526

5.3.2 OncoMouse III[71]

In addressing the patentability of animals in accordance with Article 53(b), the Opposition Division first reviewed recent developments in the Implementing Rules of the EPC, as well as in relevant case law.

The Opposition Division first referred to Rule 23c(b)[72], which stipulates that inventions concerning plants and animals are patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety.

The referral contained several legal considerations with regard to Article 53(b).

Firstly, exceptions to patentability have to be construed narrowly.

Secondly, the appearance of "animals" (in general) and "animal varieties" in the same half-sentence of Article 53(b) is a clear indication that the legislator did not intend the term "animal varieties" to cover animals in general or that the legislator meant "animals" in both cases.

Lastly, if the subject matter of the claims is not covered by any of the three terms "animal variety", "race animale", or "Tierart", then Article 53(b) constitutes no bar to patentability.[73]

5.3.3 Novartis Applied

The Opposition Board also noted that the recent decision in Novartis II[74] relating to the patentability of plants under Article 53(b) had held that "a claim wherein specific plant varieties are not individually claimed is not excluded from patentability under Article 53(b) EPC even though it may embrace plant varieties".

In light of the case law, the Opposition Division concluded that "living matter" and in particular, plants and animals, are accessible to patent protection, and that it applies not only to process protection but also product protection. As has already been established for plants under Rule 23c(b)[75],

[71] T315/03 OncoMouse/Harvard, OJ EPO 10/2003 – Decisions of the Opposition Division, at 497, para. 8.1.1
[72] Rule 23c EPC - Patentable biotechnological inventions (http://www.european-patent-office.org/legal/epc/e/r23c.html)
[73] Id at para. 8.1.2
[74] Supra fn 41
[75] Rule 23c EPC - Patentable biotechnological inventions (http://www.european-patent-office.org/legal/epc/e/r23c.html)

if a grouping is characterized by a specific gene and not by its whole genome, then it is not excluded from patentability as a "variety".

In applying its conclusions to the OncoMouse patent, the Opposition Division noted that,

"There is no doubt that the invention as claimed is applicable to more than just varieties of mice… Therefore, the argument that the patent relates to particular mouse strains and therefore to animal varieties which are not patentable under Article 53(b) EPC must fail. The feasibility of the invention is not confined to a particular animal variety in the meaning of Rule 23c(b)".[76]

This final decision[77] followed the logic of previous decision and held that the principle adopted in Novartis II for plant varieties should be followed in the case of animals.

A patent may not be granted for a single animal variety, but can be granted even if varieties may fall within the scope of its claims. The Board noted that the widest definition of "animal variety" that can be given to the animal exclusion under Article 53(b) is "species".

Since mouse is a genus, which is a taxonomic category higher than "species", claims directed to transgenic mice were not considered to be excluded by Article 53(b).

[76] Id.
[77] T315/03 Supra fn 70

6 Questions raised

6.1 Why Plant Varieties and not Animal

There is an alternative means of protecting plant varieties under UPOV, but there is no means of analysing whether the legislators intended to also exclude transgenic plants from patentability because they can also theoretically get UPOV protection. If this was the true legislative intent, however, why was there not an adequate resolve applied to animal varieties.

There is no UPOV equivalent for animals; patents are the only possible way to protect intellectual property rights in transgenic animals.

6.2 Secondary Life Forms

A question that also needs to be addressed is whether the descendants of transgenic life forms should be protected to the same extent as the original transgenic life form. Breeding is much simpler and faster means of obtaining multiple copies of the patented product. If breeding the life form is not considered an infringement, then does that effectively make patent protection of a transgenic life form is essentially worthless.

6.3 Limits and Bounds

With the EPC 2000 coming into force in 13th December 2007, there is a need for better clarification of Article 53(b). The extent to which intellectual property protection will be given for transgenic life forms and specifically the extent to which the patentability exceptions under Article 53(b) will apply, needs to be fully addressed.

7 Further Analysis

7.1 Novartis Analysis

In Novartis, the EBA held that the exception to patentability in Article 53(b), 1st half sentence, applies to plant varieties irrespective of the way in which they were produced.

Therefore, plant varieties containing genes introduced into an ancestral plant by recombinant gene technology are excluded from patentability. The underlying reason for this is that the exclusion in Article 53(b) was made to serve the purpose of excluding from patentability subject matter which is eligible for protection under the plant breeders' rights system. It does not make any difference for the requirements under the UPOV Convention or under the Regulation on Plant Variety Rights, whether a variety is obtained by traditional breeding techniques or genetic engineering.

This meant that the term 'plant variety' was appropriate for defining the borderline between patent protection and plant breeders' rights protection irrespective of the origin of the variety.

The argument that the legislator of the EPC did not envisage the possibility of genetically modified plant varieties and for this reason could not have had the intention of excluding them from patentability could not be accepted - laws are not restricted in their application to situations known to the legislator.

7.1.1 Microbiological

Accordingly, the board interpreted the term “microbiological” as qualifying technical activities in which direct use was made of microorganisms.

These included not only traditional fermentation and biotransformation processes, but also the manipulation of microorganisms by genetic engineering. (All activities in which an integrated use is made of biochemical and microbiological techniques, including genetic and chemical engineering techniques, in order to exploit the capacities of microbes and cultured cells).

The board thus defined the concept of “microbiological processes” under Art. 53(b) as processes in which microorganisms are used to make or modify products or in which new microorganisms are developed for specific

uses.
The concept of “the products thereof” encompassed, in the board's view, products which were made or modified by microorganisms as well as new microorganisms as such.

Novartis also went on to say that processes of genetic engineering are not identical with microbiological processes. The term microbiological processes in Article 53(b) were used as being processes using microorganisms.

Whether a plant variety was the result of traditional breeding techniques, or whether genetic engineering was used to obtain a distinct plant grouping, did not matter. This meant that the term “plant variety” was appropriate for defining the borderline between patent protection and plant breeders' rights protection irrespective of the origin of the variety.

7.2 OncoMouse Analysis

In interpreting the term “animal varieties” the EBA in this decision emphasised the narrow interpretation to be given to the provisions of Article 53(b).

Bearing in mind that for animals - unlike plant varieties - no other industrial property right was available, the board decided that the exception to patentability under Article 53(b) applied to certain categories of animals but not to animals as such.

It thus constituted no bar to patentability for subject matter which was not covered by any of the terms “animal varieties”, “races animales” or “Tierarten”.

A clear distinction was made in the OncoMouse decision as the TBA acknowledged a distinction between animals and animal varieties, thus animals are not within the exclusion per se.

7.3 Legal Certainty

Due to the lack of a clear definition of the terms plant and animal varieties one might argue that there is also a lack of legal certainty in this field. Case law from the EPO clarifies the matter to some extent, however, it does not provide a clear definition.

When interpreting the case law it is important to remember that animals have no other industrial property rights protection unlike plant varieties, and therefore the scope of the animal varieties exclusion is narrower than that of plant varieties.

8 Concluding Remarks

In the EU, essentially biological processes and their products are not patentable, but an essentially biological process has to consist entirely of natural phenomena. With slight human intervention, they may be subject to patent law.

Both in the US and the EU, transgenic animals can fulfil the requirements for patentability. In the US, the decisions in Chakrabarty[78] and Ex parte Allen[79] show that animals that do not occur in nature could be patented.

In the EU, OncoMouse[80] shows that animals can fulfil the requirements for patentability.

Both in the US and the EU, the patent offices grant patents for the entire animals concerned, but the actual invention may be the insertion of one gene and expression thereof, to alter directly only a minor portion of the genome of the animals.

Biotechnologists seeking protection in Europe under a European patent for animal related inventions should not be apprehensive of the Article 53(b) prohibition on “animal varieties”.

The application of the “animal varieties” exception appears to be strictly limited to animal related inventions with subject matter claiming a specific animal variety. Even with the “animal varieties” exception to patentability under Article 53(b), the European patent still remains a viable option for biotechnologists with animal related inventions.

[78] Supra fn 7
[79] Supra fn 57
[80] Supra fn 70

8.1 Moral issues

The human rights aspect and ethical debate, although intended to not be part of this paper cannot be fully ignored. The cases (moreover OncoMouse) had balancing that had to be done under the public order clause lay between pain and suffering (that is inflicted on the mice) versus beneficial consequences for humanity.

Despite the fact that animals have always been used by man as a resource, the production of transgenic animals arouses strong feelings among the public.

This being, exclusion on public order grounds is rare, provided some benefit of the invention can be shown.[81] From a policy-making and a philosophical point of view, this situation is unsatisfactory: for policy-making because of the concept's weakness in the face of powerful commercial interests; for a philosopher because of the internally paradoxical nature of the utility argument.

Only the most extreme utilitarian would argue that the most minimal benefit is always sufficient to decide in favour of allowing patenting of the invention, not least because a utilitarian, like any other moral philosopher, has to believe that ethics is indeed something more than a fig leaf, and that moral considerations count.

By making it possible to mix genetic material from separate species, genetic engineering has given man the power to produce an endless range of plant and animal varieties, all tailor-made to suit his own needs.

Transgenic animals open up a number of possibilities:

(i) They can be used in medical research to study human disease patterns;

(ii) They can be used to synthesize chemical substances needed for human medicines, which can easily be obtained from their physiological fluids;

(iii) In agriculture, there is scope for rearing fast growing, high–weight animals yielding predetermined nutritional values or with in-built resistance to disease.

[81] Cornish, W. R., Llewelyn, M. & Adcock, M. Intellectual Property Rights and Genetics. Report prepared for the UK Department of Health, July 2003

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