Patentability and Scope of Protection for DNA Sequence-Related Inventions from the Perspective of the United States of America and Europe

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Abstract: Since the mapping of the human genome and the technical innovations in the field of biotechnology, patent law has gone through great controversies. Protection is required for an investor to make an investment but how broad should the given protection be? Whether the invention is a micro-organism capable of dissolving crude oil, or the gene of a soya plant, the genetic engineering required for their production entails vast amounts of capital. The policy in that respect is tailored by legislative acts and judicial decisions, ensuring a fair balance between the interests of patent right holders and third parties. However, the policy differs from jurisdiction to jurisdiction, thus creating inconsistencies with regards to the given protection to the same invention, and as a result this could deter innovation and promote stagnation.

The most active actors shaping the patent policy on an international level are the patent offices of the United States of America, Japan and the European Patent Organization. These three patent offices have set up a cooperation programme in order to promote and improve efficiency with regards to their patent policies on a global scale. However, recent judicial developments have shown that the policy in respect to the field of biotechnology differs between the patent regimes of the United States of America and the two-layer system of the European Patent Organisation/ the European Union.

Keywords: Patent; DNA Biotechnology; Patentability Requirements; Scope of Protection; US Patent Regime; European Patent Regime

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A. Introduction

1 The debate regarding patents for biological material has intensified in the past forty years, resulting in high publicity and wide media coverage in the field of biotechnology.[1] The term *biotechnology*, for the purposes of this Research Paper, should be understood to mean "any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use."[2] Moreover, biotechnology is not a newly developed concept, but it is one of the first sciences developed by mankind.[3] The high publicity and media coverage mentioned above is a new feature for the field, and has resulted in a wide public awareness of experimentation and testing carried on living organisms in the name of technological development and medical progress.

2 Furthermore, this technological development and medical progress has been facilitated through patent systems. The "primary purpose of the patent system is to provide incentives for the disclosure of valuable inventions that might otherwise be kept secret. [The society] offers a bargain: a limited period of statutory exclusivity for the claimed invention in exchange for full disclosure of the invention."[4]

3 Additionally, without the negative monopoly rights for industrial exploitation provided by a patent, the majority of investors would hardly devote any resources if there is no guarantee that their investment would be secured in the end. This being said, then the research and development within heavy capital-intensive fields such as the one of biotechnology, would become stagnant if there was no adequate protection.

4 Thus, these *ownership* rights sparked the debate forty years ago concerning patents upon biological material. The debate was concentrated around the questions of whether or not "life" could be owned or whether these negative monopoly rights could amount to a modern form of slavery.[5] In that regard, "many advocates have ... declared deoxyribonucleic acid [hereinafter "DNA"] to be common to the global human heritage."[6] However, currently it is widely accepted that biological patents are vital for the development of modern medicine and bioresearch, leading to the debate's development. "The debate today has seen a shift in focus, from questioning the possibility to patent ... DNA-related inventions ... [to questioning] the strength of the patents and the type of protection those inventions receive."[7]

5 The purpose of this descriptive Research Paper is to examine the patentability and scope of protection for DNA sequence-related inventions from the perspectives of the United States of America and Europe. Moreover, it should be noted that the "DNA is considered to be a chemical substance, and consequently, the basic patent law principles applicable to chemical inventions will equally be applicable to DNA inventions."[8]

6 In Part B of this Research Paper, the author will examine the bio-patent policy from an international perspective. This will be followed by a discussion in Part C on the patent systems of both the United States and Europe, with an emphasis upon their respective jurisprudences concerning the patenting of DNA material.

7 Afterwards, this Research Paper will turn in Part D to an examination of certain specific issues related to the patentability of DNA sequences. First, it will be considered whether innovations in the field of biotechnology could be categorized as inventions, or non-patentable discoveries. This will be followed by a discussion on the criterion of *novelty* in respect to DNA sequence innovations. Afterwards, it will be considered whether the DNA sequence patents could fulfil the criterion for *inventive step/non-obviousness*. At the end of Part D, an examination on the *industrial applicability/utility* for DNA sequence inventions will be offered.

8 In Part E of this Research Paper, the author will turn to the issue of the scope of protection for DNA sequence-related patents and will elaborate upon the four main types of patents: product based patents, process based patents, use based patents and purpose-based patents.

9 In Part F of this Research Paper, the author will present a conclusion in light of the analysis that has been given.

B. Introductory remarks of the bio-patent policy from an international perspective

10 The validity and scope of a patent depends on the jurisdiction that grants it. This means that a patent granted by the United States Patent and Trademark Office (hereinafter "USPTO"), is applicable only within the jurisdiction of the United States. This could have a negative impact upon the decision of an inventor to disclose his or her invention if protection is not provided in other jurisdictions as well.

11 Organisations such as the European Patent Office (hereinafter "EPO") or the World Intellectual Property Organisation (hereinafter "WIPO") give a solution to this problem, through the administration of the European Patent Convention[9] (hereinafter "EPC") and the Patent Cooperation Treaty[10], respectively.

12 They provide the possibility to an inventor to apply for multiple patents within the jurisdictions of their respective Member States using a single application form. It should be noted that these organisations do not grant a single patent with unitary effect, but rather a bundle of domestic patents for which the inventor has applied.

13 There has been a discussion[11] for many years about the creation of a unitary patent for the European Union similar to the truly regional patent of the African Intellectual Property Organization (hereinafter "OAPI").[12] The negotiations in that regard culminated with the adoption of two Regulations through enhanced cooperation,[13] and the adoption of an Agreement on a Unified Patent Court (hereinafter "the Agreement").[14] The ambition behind these pivotal steps is to make the internal market of the European Union more competitive on the global technology scale.

14 It is interesting to note that, "as things now stand, an applicant seeking patent protection throughout the entire territory of the [European Union] ... will ... have to obtain a combination of a European patent with unitary effect and national and/or European patents. This is so because Spain and Italy do not participate in the enhanced cooperation in the area of the creation of unitary patent protection and, therefore, a unitary patent will at best cover the territories of only 25, but not all, EU Member States."[15]

15 The above-mentioned Regulations will be applicable either on the 1st of January 2014 or the date of entry into force of the Agreement, whichever is the later.[16] Moreover, the Agreement enters into force either on the 1st of January 2014 or four months after the thirteenth state has ratified it, and among those thirteen Member States it is required that France, Germany and the United Kingdom are present. [17]

16 "Globally, the EPO, USPTO, and Japanese Patent Office [hereinafter "JPO"] are the most influential actors in [the] international patent policy, and regularly meet in trilateral discussions."[18] Furthermore, intellectual property law is being enforced and applied primarily at the national level. This means that an international framework should outline this level in order to avoid discrepancies within the many national patent regimes. In that regard, WIPO plays a vital role for the administration of various intellectual property Unions and international agreements related to intellectual property law. [19]

17 The Agreement on the Trade-Related Aspects of Intellectual Property Rights (hereinafter "TRIPS"),[20] is an agreement that was adopted under the auspices of the World Trade Organisation (hereinafter "WTO"). TRIPS incorporates within itself many of the provisions covered by the Conventions administered by WIPO. Moreover, it primarily provides that the Members of the WTO are obliged to follow a minimum standard of protection for intellectual property rights.

18 With regards to the patentability of DNA inventions, TRIPS is *silent*. Its Member States are not obliged explicitly to grant protection for DNA-related inventions. However, Article 27(3)(b) of TRIPS does not refer to DNA sequence inventions as an *exception* to patentability. Accordingly, it gives the Member States a wide margin of discretion with regards to the patentability of DNA in respect to the patentability criteria and excludability from patenting.[21]

19 A discussion concerning exactly this discretion will be provided within Part C of this Research Paper, namely in respect of the patent regimes of the United States and Europe. Before examining them separately in detail, it is required to be noted that the United States follows the doctrine of *first-to-invent* while in Europe the doctrine of *first-to-file* is the predominant one. The difference is that in the United States, the patent holder has to prove that he or she invented the DNA-related invention first in case of infringement proceedings, while in Europe all that matters in infringement proceedings is who filed the application first.

20 On a more recent note, the patent system in the United States will change from *first-to-invent* to *first-inventor-to-file* in 2013.[22]

C. Bio-patents from the perspectives of the United States and the European patent regimes

I. The jurisprudence in the United States with regards to Biotechnology

21 Under the Constitution of the United States of America, the Congress has the power "to promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries."[23]

22 The USPTO, mentioned above, is a federal administrative body established by the U.S. Patent Act, with the task of administering the U.S. patent system.[24] Under the U.S. Patent Act, there are four requirements with equal legal value, which an invention needs to fulfil in order to be granted a patent.[25] These requirements are: the invention must be of a patentable subject matter,[26] it must be novel,[27] it must have to have utility,[28] and it must be non-obvious.[29]

23 With regards to biotechnology, the patent regime of the United States could be said to be fairly liberal. *The debate* that was discussed in the introductory part of this Research Paper goes far beyond the question of whether or not "life" itself could or should be patented in the United States. As Chief Justice Burger noted, the relevant distinction in the field of biotechnology should be "not between living and inanimate things, but between products of nature, whether living or not, and human-made inventions."[30]

24 In the case of *Funk Bros Seed Co. v. Kalo Inoculant Co.*,[31] the Supreme Court of the United States developed the *product of nature* doctrine. This doctrine is used to define the patentable subject-matter for an invention in the field of biotechnology. The Supreme Court held that the "manifestations of laws of nature, [are] free to all men and reserved exclusively to none. He who discovers an unknown phenomenon of

nature has no claim to a monopoly."[32] The substance of this doctrine is that a product of nature cannot be patentable since it fails to satisfy the criterion of novelty. Examples of such *products of nature* include the laws of physics, mathematical equations and all non-isolated, non-purified living matter.[33]

25 Moreover, the case of *Diamond v. Chakrabarty*[34] marked the beginning of a new era for the U.S. patent system. The case concerned the challenging of a decision to grant a patent for a human-engineered bacterium of the Pseudomonas genus, which was able to break down crude oil and thus help treat and control oil spills.

26 The USPTO agreed that this was a *novel* invention; however it rejected granting the patent on two grounds: (1) the micro-organism was a *products of nature* and (2) the invention was not of patentable subject-matter. Mr. Chakrabarty appealed this decision and the Board of Patent Appeals and Interferences affirmed the USPTO's conclusion on the second ground. The Board of Patent Appeals relied on "the legislative history of the 1930 Plant Patent Act, in which [the] Congress extended patent protection to certain asexually reproduced plants, [and] the Board concluded that § 101 was not intended to cover living things such as these laboratory created micro-organisms."[35]

27 Mr Chakrabarty then appealed to the Court of Customs and Patent Appeals (hereinafter "CCPA"), which reversed the decision of the Board of Appeals. In the case of *In re Bergy*[36] the CCPA had concluded that "the fact that micro-organisms are alive is without legal significance for purposes of the patent law"[37], and it took this judgement into consideration while deliberating upon the *Chakrabarty* case.

28 In March 1980, the matter was brought before the attention of the United States Supreme Court. "Essentially, the Court held that the bacterium was altered to a sufficient extent to qualify as an invention,"[38] and thus the mutated organism fulfilled the criterion of *novelty* and was not a *product of nature*. The Supreme Court affirmed the judgement given by the CCPA on the 16th of June 1980, and on the 31st of March 1981 the USPTO issued the contested Patent.[39]

29 Since the Supreme Court rendered this judgement, "the patent office has been granting patents over genes, animals, plants and other products of biotechnology."[40] According to statistics made by the OECD in 2002, "one study estimates that the total number of DNA patents granted by the USPTO to date is somewhere around 10 000."[41] And according to the World Survey of Genomics Research, in 2001 alone the USPTO granted over 5 000 DNA patents.[42] "In a more recent article (2005), Kyle Jenson and Fiona Murray[43] identified 4,270 US patents containing claims on human DNA sequences."[44] According to research conducted by Eric J. Rogers, the USPTO granted more than 40 000 DNA-related patents until 2011, since the *Chakrabarty* case.[45]

30 *The debate* discussed in the introductory section of this Research Paper culminated in the resent case of *Association for Molecular Pathology v. United States Patent & Trademark Office and Myriad Genetics, Inc.*[46] The case had great potential in blocking the patentability of DNA-related inventions in the United States. "The high profile litigation brought the topic of DNA patenting into the spotlight, prompting several organizations, both domestically[47] and abroad,[48] to publish reports with policy recommendations[49]."[50]

31 This case concerned the patentability of two particular breast cancer genes (BRCA1, BRCA2) and certain methods for testing the genetic material. Moreover, the particular issues before the Court concerned 15 claims from 7 patents.[51]

32 Furthermore, research made by Myriad Genetics, Inc. showed that women with mutations in the above-mentioned genes were significantly susceptible to develop breast cancer. "Using positional cloning techniques, the inventors found that mutations in the BRCA genes correlate with a significantly increased risk of ovarian and breast cancer."[52] According to statistics presented by the National Cancer Institute,[53] the average American woman has 12.29% to develop breast cancer in her life. However, the statistics conducted by Myriad Genetics suggest that women with mutation in the BRCA genes are with 50-80% higher risk of developing breast cancer, and a 20-50% chance of developing ovarian cancer.[54]

33 "This may seem like a boon for medical research, a breakthrough in humanity's endeavour to conquer cancer."[55] However, the costs of testing the genetic material protected by the contested patent made it impossible for the insurance policies of some patients to cover the amount of the test.[56] Additionally, the defendant in the case had employed an aggressive strategy with respect to the contested patent. The strategy prohibited others from making the test of the genetic material, thus ensuring that if patients wished to make a second test due to fear of human mistake, they had to do it at Myriad Genetics laboratories again. Additionally, the patent put an estoppel upon the research and development in the field concerning the BRCA genes due to the fact that researchers and medical organisations feared potential infringement litigations.[57]

34 During the proceedings at first instance the District Court ruled that even if isolated and purified, the DNA-related inventions were still a product of nature. "It was the first time any federal court found DNA patents to be invalid for ineligible subject matter."[58] The plaintiff to the case also raised arguments with

respect the *constitutionality* of the patentability of DNA compounds.[59]

35 However, the United States Court of Appeals for the Federal Circuit squashed the judgement of the District Court, "holding that isolated and purified DNA molecules and certain DNA-related methods are indeed patentable subject matter."[60] The Appeals Court looked at three different types of patents, namely: (1) absolute product patents, (2) purpose bound patents for the purposes of analysing and comparing natural DNA sequences and mutated DNA sequences, and (3) purpose bound patents covering more than analysing and comparing between natural DNA sequences and mutated DNA sequences.

36 (1) With respect to the absolute product patent, Judge Lourie and Judge Moore concurred that if a DNA molecule is isolated, it is patentable subject-matter "because the covalent bonds at the ends of a DNA molecule, when isolated, must be broken, making the molecule a 'distinct chemical entity' that is by definition 'markedly different' from any DNA molecules existing in nature."[61]

37 (2) With respect to the purpose-bound patents for the purposes of analysing and comparing natural DNA sequences and mutated DNA sequences, the Court held that it was not patentable subject-matter. This was due to the fact that *abstract mental processes*, which are involved in the analysis and comparison, would ensure that the scope of protection was too broad.[62]

38 (3) With respect to and purpose-bound patents covering more than analysing and comparing natural DNA sequences and mutated DNA sequences, the Court held that it was patentable subject matter. This was so because the additional step that goes beyond mere analysis and comparison could lead to "potentially valuable inventive methods."[63]

39 It is interesting to note that in the end of 2012 the United States Supreme Court expressed its willingness to adjudicate upon the case of *Myriad*.[64] It is expected that the Court will reach a decision on the matter in 2013.

40 On a more recent note, in 2012 the United States Supreme Court ruled upon the case of *Mayo Collaborative Services v. Prometheus Laboratories, Inc*.[65] The case concerned two patents for the use of thiopurine drugs in the treatment of autoimmune diseases, such as Crohn's disease and ulcerative colitis.[66] "Stated generally, the patents claim methods of: (a) administering a thiopurine drug to a patient, and (b) determining the levels of the drug or the drug's metabolites in red blood cells in [a] patient. The measured metabolite levels are then compared to known metabolite levels. If the measured metabolite levels in the patient are outside the known range, then the physician should increase or decrease the level of drug to be administered so as to reduce toxicity and enhance treatment efficacy."[67]

41 "Prometheus is the sole and exclusive licensee of the patents at issue. Mayo purchased and used medical diagnostic tests from Prometheus that embody the methods described in the patents. Mayo later developed and marketed its own diagnostic test, resulting in Prometheus bringing an action for patent infringement against Mayo."[68]

42 Throughout the proceedings, the District Court found that the two contested patents were of unpatentable subject matter because they dealt with natural law - "namely the correlation between thiopurine metabolite levels and the toxicity and efficacy of thiopurine drug dosages."[69] However, in 2009 the Court of Appeals for the Federal Circuit reversed the District Court's judgement and used the "machine-or-transformation test"[70] to determine that the claims of Prometheus were patentable.

43 In the case of *Bilski v. Kappos* in 2010, the majority of Justices in the United States Supreme Court agreed that "the 'machine-or-transformation' test should not serve as the exclusive test for determining whether a claimed method [is] patent-eligible or not."[71] For that reason the Supreme Court in the case of *Mayo v. Prometheus* vacated the decision of the Federal Circuit and ordered a rehearing of the appeal.

44 The Court of Appeals for the Federal Circuit again held that the claims were patent eligible and Judge Lourie stated that the they were "drawn not to a law of nature, but to a particular application of naturally occurring correlations, and accordingly do not pre-empt all uses of the recited metabolite levels and drug efficacy or toxicity."[72]

45 The Supreme Court again granted *a writ of certiorari* and disagreed with the Court of Appeals for the Federal Circuit in its decision. The Supreme Court considered that the claims set forward were directed only towards *laws of nature* and consequently were unpatentable. "The Court reviewed its precedents in order to explain that phenomena of nature and abstract concepts could not be patented because the 'monopolization of these basic tools through the grant of a patent might tend to impede innovation more than it would tend to promote it.'[73]"[74] However all inventions at some point use and apply natural laws, thus "a process is not unpatentable simply because it contains a law of nature or a mathematical algorithm"[75] and "an application of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection."[76]

46 In its analysis, the Supreme Court stated that the claims at hand dealt with natural law, thus it was

necessary to observe whether "the patent claims add *enough* to their statements of the correlations to allow the processes they describe to qualify as patent-eligible processes that *apply* natural laws."[77] The Supreme Court identified and deliberated upon three steps that the claims added in addition to the natural law – namely: (1) an *administering step*, (2) a *determining step*, (3) and a *wherein* step.[78]

47 (1) The *administering step* "referred simply to the relevant audience of the invention, namely, physicians who treat patients with certain diseases with thiopurine drugs."[79] In any event, the "prohibition against patenting abstract ideas 'cannot be circumvented by attempting to limit the use of the formula to a particular technological environment.'"[80]"[81]

48 (2) The *determining step* basically refers to *any* act of measurement of the metabolite level into the blood of a patient, performed by physicians. Moreover, it was even stated in the patent applications that the methods for determination of the metabolite level in the blood were well known in the art.[82] "Thus, this step tells doctors to engage in well-understood, routine, conventional activity previously engaged in by scientists who work in the field."[83]

49 (3) The *wherein step* "simply tells a doctor about the relevant natural laws, at most adding a suggestion that he should take those laws into account when treating his patient."[84] "According to Justice Breyer, an unpatentable law of nature does not become patentable merely by advising individuals to use the law."[85]

50 To summarize the above-mentioned observations, the Supreme Court considered that the claims were informative to the relevant audience, the additional steps were conventional and routine, and "when viewed as a whole, add[ed] nothing significant beyond the sum of their parts taken separately."[86] For those reasons the Supreme Court concluded that, "the steps are not sufficient to transform unpatentable natural correlations into patentable applications of those regularities."[87]

51 Additionally, the Supreme Court deliberated upon the case at hand in light of existing precedents dealing with the issue of patent eligibility of processes that embodied the equivalent of natural laws - namely the cases of *Diehr*[88] and *Flook*[89]. "The Court concluded that the claims at issue in [*Prometheus*] present a case for patentability that is weaker than the claim in *Diehr* and no stronger than the claim in *Flook*, emphasizing that the steps and wherein clauses of *Prometheus'* claims 'add nothing specific to the laws of nature other than what is well-understood, routine, conventional activity, previously engaged in by those in the field.'"[90]"[91]

52 Throughout the course of the proceedings, the U.S. Government raised an argument that "virtually any step beyond a statement of a law of nature itself should transform an unpatentable law of nature into a potentially patentable application sufficient to satisfy §101's demands."[92] Under this argument, other requirements like *novelty* and *non-obviousness* would have a more significant impact during patent examination. However, the Supreme Court decided that this approach was not consistent with prior law, and would make the *natural law* exception to patentability virtually hollow.[93]

53 The Supreme Court also responded to concerns that a decision against *Prometheus* could discourage diagnostic research.[94] "Justice Breyer observed that other interested parties had asserted that patents claiming the body's natural responses to illness and medical treatment should not be granted because they might limit physician access to critical scientific data. In view of these competing views, the Court was reluctant to depart from precedent denying patents on natural laws."[95]

54 The case of *Mayo v. Prometheus* represents the willingness of the otherwise *fairly liberal* patent regime of the United States to draw a clear line between what is patentable and what is not, by elegantly defining the *law of nature* exception.

II. The jurisprudence in Europe with regards to Biotechnology

55 "The European patent system displays a disciplined yet inclusive regime of according patent rights to biotechnology and its numerous progenies."[96] The two primary sources that are relevant for the patentability of biotechnology within Europe are the EPC,[97] and the Biotechnology Directive 98/44/EC[98] (hereinafter "the Biotech Directive"). The scope of application of the EPC coverers all of its signatory and extension states,[99] while the Biotech Directive is applicable only within the European Union.[100]

56 The Biotech Directive was adopted in July 1998 and it was supposed to be implemented by the 30th of July 2000; though it was done so in March 2006 after the Grand Duchy of Luxembourg became the last Member State to implement it.[101] However, on 19th of October 1998, the Dutch Government brought an annulment action before the European Court of Justice with respect to the Biotech Directive and the claim was rejected.[102]

57 Furthermore, in 1999, through a decision of the Administrative Council, a new "Chapter IV" was inserted into Part II of the Implementing Regulations of the EPC entitled "Biotechnological Inventions". It contained four rules that are in accordance with

the Biotech Directive.[103] This amendment to the Implementing Regulations serves as a supplementary interpretation of the patentability of biotechnology within the EPC, which gives additional clarification by providing clear exceptions.[104]

58 The EPC has a fourfold cumulative criterion for determining whether an invention is patentable-namely, the requirements of patentable subject matter[105], novelty,[106] inventive step,[107] and industrial application.[108] "These four criteria were reaffirmed in [the Biotech Directive]. In fact, for the purposes of ensuring compatibility between the EPC and the bio-patents, [the Biotech Directive] categorically under Article 3.2 specifies that biological material, after considerable human processing and intervention, cannot be precluded from the ambit of patent protection simply because its initial existence was inherent in nature."[109]

59 A clear distinction between the European and the U.S. patent regimes is the *public order and morality* exception from patentability. Under Article 53(a) of the EPC, any invention that is against the public order or morality is barred from gaining patent protection, while in the U.S. there is no such exception.

60 The EPO Board of Appeals in the case of *Plant Cells/ Plant Genetic Systems*[110] has defined the notions of *Public Order* and *Morality*. According to the Board of Appeals, public order "covers the protection of public security and the physical integrity of individuals as part of society"[111] while it also encompasses the protection of the environment. Moreover, the concept of morality has been defined as "... related to the belief that some behaviour [is] right and acceptable whereas other behaviour [is] wrong, this belief being founded on the totality of the accepted norms which [are] deeply rooted in a particular culture. For the purposes of the EPC, the culture in question [is] defined as the culture inherent in [the] European society and civilisation. Accordingly, inventions the exploitation of which [is] not in conformity with the conventionally accepted standards of conduct pertaining to this culture [are] to be excluded from patentability as being contrary to morality."[112]

61 The Decisions in *Hormone Relaxin*[113] and *Harvard Onco-mouse*[114] provide clear examples of the willingness of the European patent regime to grant patents to biotechnological inventions. Additionally, those decisions illustrate how the EPO deals with situations in which, the subject-matter concerned could be viewed initially as contrary to public order and morality.

62 The *Hormone Relaxin* case limited the *product of nature* doctrine. It involved a DNA-sequence patent for the process of the creation of one specific protein. However, it was contested that the process of isolation lacked inventive step. EPO held that the subject matter in this case was more than a mere discovery; thus it involved inventive step because the protein had to be isolated from its surroundings and a process had to be developed to obtain it.[115] The controversy surrounding this case was the fact that it dealt with human tissue, in particular the DNA of pregnant women. However, "once extracted and treated, [the DNA] was characterised, not as 'life', but as substance carrying genetic information which can be used to produce proteins that are medically useful. The patent grant was therefore maintained."[116]

63 The *Harvard/Onco-mouse* case involved a genetically modified organism - a non-human mammal, in particular a mouse, which had an oncogene that made it highly susceptible to the growth of breast cancer cells, making it a useful subject for Onco-research. This organism was engineered at Harvard Medical School in the laboratory of Dr. Philip Lader and Dr. Timothy A. Stewart. At first, the scope of the controversial patent was for a method of producing transgenic non-human mammals, but through the course of proceedings, the scope was narrowed to a method of producing transgenic rodents containing an additional cancer gene.[117]

64 Harvard College applied for patent protection for the abovementioned method before The Examination Division of the European Patent Office, which deliberated and later rejected the application. The grounds for rejection were that the organism was a non-patentable invention, its subject-matter was *an animal variety* and that patent law was not the right legislative tool for regulating issues related to genetic engineering.[118]

65 "On appeal, the Technical Board of Appeals held that the Examining Division had misconstrued the exclusion, which being an exception to patentability, ought to be construed narrowly.[119] Importantly, the Board of Appeal said that Article 53 (b) [EPC] did not exclude animals *in general*"[120] from patentability. Moreover, there were compelling reasons to deliberate, upon the implications for patentability stemming from Article 53 (a) EPC.[121] Furthermore, the Technical Board of Appeals considered that the genetic engineering of animals was problematic in several respects, namely that it caused suffering towards the test subjects and the possibilities of exposing the outside environment to those test subjects.[122] It was considered that this could lead to unforeseeable and irrevocable repercussions.

66 For the abovementioned reasons, the Technical Board of Appeals construed a *balancing test*: "The decision as to whether or not Article 53(a) EPC is a bar to patenting the present invention would seem to depend mainly 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. It is the task of the department of first instance to consider these matters in the context of its resumed examination of the case."[123]

67 The case was remitted to the Examination Division, which identified three interests that needed to be taken into account while deliberating upon the case at hand in light of the above-mentioned balancing test. Those three interests were, firstly the interest of humankind to remedy widespread and dangerous diseases; secondly the protection of the environment from the uncontrolled dissemination of unwanted genes; and thirdly the avoidance of cruelty to animals.[124]

68 "The Examination Division concluded that upon balancing the various considerations, the Oncomouse invention was of great benefit to mankind, would limit the number of animals used for cancer research ... and that the risk of escape was minimal."[125] Moreover, "of the advantages of the invention, the animals were considered highly useful in a form of experimentation indispensable to medical research. It was the importance of this consideration which justified the patent grant."[126]

69 On a more recent note, the European Court of Justice sat in Grand Chamber in 2010 over a case with tremendous impact upon the patentability of DNA-related inventions in Europe. The case of *Monsanto Technology LLC v. Cefetra BV and Others*[127] concerned a European Patent granted in 1996 for a DNA sequence that was inserted into a Soya bean plant,[128] making it resilient and non-sensitive to commonly used herbicide.[129]

70 The factual situation of the case is as follows: the Argentinian company Monsanto owned the above-mentioned European Patent but did not have a patent in Argentina. Three European companies, Cefetra, Vopak and Toepfler, imported soya meal into the internal market of the European Union, containing the protected DNA sequence within their products. Monsanto brought infringement proceedings before a Dutch Court, which later referred four questions to the European Court of Justice.

71 The first question concerned the interpretation of Article 9 of the Biotech Directive. The Dutch Court essentially asked whether Article 9 confers patent protection rights, even if the protected DNA sequence stopped performing its designated function but could resume performing it, if it is inserted into the cells of a living organism.[130] Thus, the question was principally whether Article 9 of the Biotech Directive provides for an absolute product protection.[131]

72 The European Court of Justice stated "that the protection provided for in Article 9 of the Directive is not available when the genetic information has ceased to perform the function it performed."[132] Moreover, the Court completely rejected the argument of Monsanto concerning the absolute product protection,[133] stating that through textual interpretation of Article 9, the protection it provides is closely linked and conditional to, the functionality of the DNA sequence concerned.[134]

73 The second question raised by the Dutch Court essentially concerned the scope of the Directive.[135] In particular whether Article 9 effects an exhaustive harmonisation of the protection it confers, precluding national legislation, which grants absolute product protection.

74 The European Court of Justice analysed the recitals of the Directive, concluding that the legislature's intention was to ensure an equal level of protection for patents in all Member States.[136] Leading to the conclusion that "the Directive effects an exhaustive harmonisation in the European Union, with the result that it precludes national legislation offering absolute protection to a sequence of DNA as such, regardless of whether it performs the specific function for which it was patented."[137]

75 The third question raised by the Dutch Court essentially referred to the temporal scope of the Directive.[138] In particular whether the Directive's scope extends to patents granted prior to its adoption.

76 The European Court of Justice held that, "Article 9 of the Directive precludes the holder of a patent issued prior to the adoption of that directive from relying on the absolute protection for the patented product accorded to it under the national legislation then applicable."[139]

77 The fourth question raised by the Dutch Court essentially asked whether Articles 27 and 30 TRIPS[140] affected the interpretation of Article 9 of the Biotech Directive.[141]

78 The European Court of Justice affirmed that the provisions under the TRIPS Agreement did not have direct effect,[142] and held that the given interpretation of Article 9 of the Biotech Directive did not run counter to the obligation imposed by TRIPS[143] and "that Articles 27 and 30 of the TRIPS Agreement do not affect the interpretation given of Article 9 of the Directive."[144]

D. Analysis of specific issues relating to patenting DNA sequences

I. Invention or Discovery?

79 Before analysing this topic, the terms of *discovery* and *invention* must be defined. A "*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."[145] One of the issues with regards to *the debate* described in the introductory section of this Research Paper was that a living organism could be only discovered and not invented. The rationale behind this is that there must be a distinction between patentable inventions and unpatentable discoveries. In the field of biotechnology, and in particular DNA sequence research, however, sometimes this distinction is not that clear.

80 The approach taken by the EPO is different from the one taken by the USPTO in respect to the distinction of *invention* and *discovery*. The United States Code does not make an explicit distinction between the two. However, in practice, natural phenomena are excluded from patentability.[146] Moreover, the recent developments in the case of *Prometheus*,[147] in which the United States Supreme Court clarified the *law of nature* exception of patentability, actually blurred the distinction between *discoveries* and *inventions* in the United States. However, under the EPC, the question of *invention* versus *discovery* is explicitly answered. Discoveries are of unpatentable subject matter, thus they have a detrimental effect upon a patent applicant.

81 Moreover, the Biotech Directive also refers to both *unpatentable discoveries*,[148] and *patentable inventions*.[149] In the case of DNA sequence-related inventions, the claimed patents are not naturally occurring phenomena. This is so because with patenting in the field of biotechnology, the rights that are asserted are not over DNA sequences that occur naturally, but rather for DNA sequences that have been isolated and purified. The rationale behind this is that "although these DNA sequences do in fact match the sequences of our genes, they are only patented in the context of molecules which have been artificially created by cloning and are isolated from the human body."[150]

82 The notion of *isolation* was clarified by a joint statement made by EPO, USPTO and JPO in 1988 stating that, "purified natural products are not regarded under any of the three laws as products of nature or discoveries because they do not in fact exist in nature in an isolated form. Rather, they are regarded for patent purposes as biologically active substances or chemical compounds and eligible for patenting on the same basis as other chemical compounds."[151] "Although this statement was made before the question of patenting genes came into the forefront of [*the debate* discussed in the introductory section of this Research Paper], it is consistent with the positive approach taken by these three Patent Offices on the subject of gene patents."[152]

II. Novelty with regards to DNA sequences-related inventions

83 This patentability requirement refers to the fact that an invention must not be known to the world before the patent application was lodged. With regards to the patent regimes of the United States and Europe, the major difference in this respect is that in the United States, there is a *grace period* of one year and in Europe there is no such thing.

84 With respect to DNA sequence related-inventions, for example, the human genome or the human DNA are already existent in nature and thus cannot be patented. However, an isolated sequence that is the result of a technical process is patentable.[153]

85 Moreover, the existence of a DNA sequence in a DNA library is not destructive for the element of *novelty*, given the fact that this sequence was not freely available to the public.[154] Furthermore, "it is established patent practise to acknowledge novelty for a natural substance that has been isolated for the first time and which had no previously recognised existence."[155]

86 For the sake of an academic argument, let's consider that a DNA sequence existent in nature, even if isolated, cannot be patented due to a lack of novelty.[156] Yet, the process that creates an identical DNA sequence that is already in existence in nature is patentable *per se*. Pursuant to the general principles of patent law, in conjunction with Article 64(2) EPC, lead to the conclusion that the protection provided to a process by a patent extends to the product stemming from that process.[157] This is so because "individual [DNA sequences] in their natural state are not directly accessible and additional work is required to isolate them."[158]

87 If the novelty of an isolated DNA sequence that is of patentable subject-matter has been proven, then an examination of the inventive step/non-obviousness and the industrial application/utility is required to be made for a patent to be granted.

III. The inventive step/non-obviousness and DNA sequence-related inventions

88 This patentability requirement refers to the fact that an invention must not be obvious to a person proficient in the state of the art. "When considering whether an invention is obvious, [the respectful authority] views the invention through the eyes of a notional interpreter equipped with the attributes, skills, background knowledge, and qualifications relevant to the field in which they work."[159] The qualification, skills, knowledge, *et cetera*, of the person proficient in the state of the art are dependent upon the technical field within which the invention belongs. However, for the sake of clarity this *artificial* person is not held to the standard of a Nobel Prize Laureate level of skilfulness, but should be sufficiently proficient in the concerned state of art.[160]

89 As already stated in the introductory section of this Research Paper, the DNA sequence is simply a chemical compound and as such, the patent law principles applicable to the field of chemistry are applicable to DNA sequences as such. For that reason, the principle that the preparation of a chemical compound given that it is not new in structure is considered to be non-inventive, and applies *mutatis mutandis* to the field of DNA sequence patenting.

90 The competent authorities in Europe and the United States differ in their application of the *inventive step/non-obviousness* requirement. In the United States, following the judgement of *In re Deuel*, a DNA sequence is *prima facie* non-obvious if it is structurally different from one already existent in nature.[161] Moreover the amount or methodology of work put into the characterisation of the DNA sequence is irrelevant for the purposes of this patentability requirement.[162] Furthermore, "many have argued that technological advances in DNA sequencing now mean that the process of isolating a gene can no longer be regarded as inventive,"[163] but so far the patent policy in the United States does not take those considerations into account.

91 The patent regime of the United States has a low threshold with respect to the *non-obviousness* requirement. Even if the nature and function of a DNA sequences has been established through the usage of trivial means, such as with *in silico* techniques,[164] this does not preclude the eligibility of the DNA sequence under the requirement of *non-obviousness*.[165]

92 The approach followed by EPO, on the other hand is more restrictive. Structural non-obviousness is not sufficient enough, thus requiring an inventive method for isolation[166] or unexpected or surprising features of the end product.[167] Moreover, an isolated DNA sequence could lack inventive step if it is structurally related to a natural DNA sequence with a known function.[168]

IV. Industrial applicability/utility of DNA sequences-related inventions

93 This patentability requirement refers to the fact that an invention must be capable of being applied in any field of industry. It is considered that *Industrial Application* and *Utility* are two concepts that are highly equivalent.[169]

94 However there are differences between the two notions that have been elaborated upon by the Standing Committee of the Law of Patents of WIPO in 2003.[170] An invention is considered to be *industrially applicable* "if it can be made or used in any kind of industry, including agriculture. [Moreover] the general understanding is that the term "industry" shall be interpreted in the broadest possible sense."[171] In respect to the field of biotechnology, Article 5.3 of the Biotech Directive states that, "the industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application."[172] Furthermore, with regards to DNA sequences, Recital 23 of the Biotech Directive states that, "a mere nucleic acid sequence without indication of a function does not contain any technical information and is therefore not a patentable invention."[173]

95 Under the patent regime of the United States of America, the main tool that the USPTO uses in order to examine an invention in light of this patentability requirement is the Utility Examination Guidelines.[174] Under those guidelines it is stated that an invention has to demonstrate a "specific, substantial and credible utility."[175] "The term *credible* is interpreted ... as meaning that the usefulness claimed for the invention must be theoretically possible, even though it may not have been demonstrated in the claims."[176]

96 Industrial applicability/utility, in particular, have a very specific feature in regards to the field of biotechnology. In respect to *the debate* discussed in the introductory section, it was argued that if this patentability requirement was not interpreted strictly, patents may be granted in a fairly liberal manner - meaning that a patent could be granted on biological products without a specific *use*, barring competitors within a field from taking research initiatives.[177] The rationale behind this notion is that, "the purpose of granting a patent is not to reserve an unexplored field of research for an applicant."[178]

97 "Even if a credible utility is stated in a patent, if further novel and non-obvious uses for a DNA

sequence are found, patent law provides that a [absolute] product patent on the sequence will extend to cover the new uses, despite their not being specified in the original patent."[179]

E. Scope of protection for DNA sequence patents

I. Introductory remarks

98 The scope of a given patent defines the exclusivity of the rights it confers. Moreover the "scope of protection can influence the viability of a specific line of research."[180] For this reason, the question of how broad or narrow the protection given by a patent should be is of primary importance.

99 The fact that, within the field of biotechnology, a patent is granted for living matter possibly capable of reproduction is a clear example of how necessary it is to define the broadness or narrowness of the scope of protection.[181] If that living matter reproduces, the next generation could have the genetically modified genes of the previous one.[182] Thus, the controversial question that arises is should the scope of the protection be extended towards the offspring of a genetically modified organism as well?[183] "There has been considerable controversy in the literature on this subject, particularly for the cases of plants and animals. It suffices here to say that patent protection indeed extends to the further generation animals and plants if the genetic information is still present in the further generations and performs its function."[184]

II. Different types of Patents

100 There are four main types of patents, which have differentiating characteristics. These types of patents are absolute product patents, process based patents, use based patents and purpose bound patents.

101 The absolute product patent is a patent on the substance of an invention *per se* - the product derived. The rights granted to this type of patents cover all uses of the protected product. The term *product* in the field of DNA sequence patents is understood to mean "a chemical or biological entity, substance or composition[185] (as distinct from a device or electrical circuit)."[186]

102 The process based patent is a patent that grants certain rights upon a method, technique or process. The rights granted under this patent may also cover the product directly derived from it. However, if the same product is achieved through another method, technique or process any claims for infringement of the first process based patent cannot be raised.

103 The use based patent is a patent that grants rights upon the specific use of a product. "An exception [to the use based patent are the] first medical use patents. [The first medical use patents] are patents on products that are not novel in themselves, but for which no medical use has been previously described. This kind of patent exists only under European patent law. The claims cover manufacture of the known product for all medical uses."[187]

104 The purpose bound patent is a patent that grants rights upon a product for a specific purpose. The rights derived from this type of patent cannot protect the right holder of uses outside of the specified purpose.[188] "The purpose-bound protection is a product patent and should not be confused with the use patent, the use patent does not provide any protection over the product as such but only for the [specified] use ... whereas the purpose-bound product protection protects the actual product but [it] is limited to the disclosed purpose."[189]

105 From the four types of patents, the ones that could confer protection over the DNA sequences as such, are the absolute product patent and the purpose bound patent. For that reason, the author of this Research Paper will focus his analysis upon these two types of patents.

1. Absolute product patent

106 In the case of *Diamond v. Chakrabarty*, discussed above, the applicant tried[190] to register not only the process with which the contested bacterium was created, but also the particular use of the bacterium and the bacterium *per se*. "The fact is of interest here because the claim for using the bacterium was granted in just two years, whereas the claim on the bacterium *per se* [took] almost nine years to be granted."[191] This shows the reluctance of the otherwise liberal United States patent regime to grant negative monopoly rights for industrial exploitation over genetically modified products *per se*.

107 The notion of absolute product based patents in the field of biotechnology is relatively new. However, as already stated, DNA is considered to be a chemical compound and as such the principles governing the patenting in chemistry are applicable to it. One of the very first known absolute product based patents for a chemical invention has its origins in the United States of America shortly after the Second World War. On the 9th of May 1950 the USPTO granted an absolute product patent for the chemical of penicillin.[192]

108 As it was discussed in Part C of this Research Paper, the notion of an absolute product patent was put under judicial scrutiny recently in the cases of *Association for Molecular Pathology v. United States Patent & Trademark Office*[193] and *Monsanto Technology LLC v. Cefetra BV and Others.*[194] Both cases dealt with the issue concerning the scope of protection for patents granted in the field of biotechnology.

109 In the United States currently, absolute product based patents are permissible while in Europe the picture is much more complex. Under the case-law of EPO, "[i]t is generally accepted as a principle underlying the EPC that a patent which claims a physical entity *per se*, confers absolute protection upon such physical entity; that is, wherever it exists and whatever its context (and therefore for all uses of such physical entity, whether known or unknown)."[195]

110 However, according to the interpretation given by the European Court of Justice, the protection granted by Article 9 of the Biotech Directive is exhaustively harmonising within the European Union and cannot provide protection to DNA absolute product patents.

2. Purpose-bound patent

111 "The most suitable and most advocated alternative to the absolute product patent protection is the purpose-bound protection, which in contrast to the absolute product patent would extend no further than the use disclosed in the application."[196] The scope of this type of patent is confined within the *specified* use, thus other uses not listed or that fall outside of the disclosed purpose could be claimed by other applicants.

112 This type of patent has an interesting implication for the field because a single purified DNA sequence could be subject to protection for many right holders. Since the European Court of Justice has interpreted that the Biotech Directive does exhaustively harmonise the level of protection in all Member States to purpose bound patents, it would be interesting to observe the development of biotechnologies and bioresearch in Europe. This policy decision could either promote the research and development in the field of DNA related inventions, or it could simply deter it.

F. Conclusion

113 The patent regimes of the United States of America and Europe do not resemble much. The policy choices made in constructing those regimes seem fairly different, however, they reach the same conclusions. Namely, that an inventor should be rewarded for his or her invention and that there should be a threshold with respect to patenting living matter.

114 As discussed in this Research Paper, there are substantial differences with regards to the patentability requirements of DNA-related inventions. However they do not render the patent systems fundamentally different.

115 Moreover, as recent developments have shown, the patent regimes in the United States of America, and Europe[197] have chosen different policy paths. The United States allows protection for absolute product patents while in Europe this type of patent is prohibited in the field of DNA sequences.

116 It is interesting to note that the United States Supreme Court has decided to adjudicate upon the *Association for Molecular Pathology et al v. Myriad Genetics Inc et al* case and its Judgement is expected to be delivered in June 2013.[198] In my opinion, the United States Supreme Court will tailor a judgement that would be fairly similar to the decision of the European Court of Justice in the case of *Monsanto Technology LLC v. Cefetra BV and Others*. Thus, it will bring the patent regimes even closer.

117 The rationale behind the decision of the European Court of Justice is that the research and development in the field of biotechnology over a particular purified and isolated DNA sequence should not be restricted. Others should have the right to research and make academic contributions freely, without fear of patent infringement litigations.

118 However, on the other hand, biotechnology is a field that requires high amounts of investment. If an investor cannot fully secure his interest, he or she most probably will be precluded from disclosing an invention or will not invest in the first place. Thus instead of promoting research and development in the field, this policy could actually promote stagnation.

119 Will the United States Supreme Court rule on the issue of *purpose bound patents* versus *absolute product patents* in the same manner as the European Court of Justice did, or will it choose to follow another policy path? And which is the *right* policy to follow? Only time will answer those questions.

■

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1 There is a vast amount of media coverage concerning the field of Biotechnology, e.g. Reuters, Scientists See Biotech Battle (The New York Times, 1987) http://www.nytimes.com/1987/06/23/business/scientists-see-biotech-battle.html?ref=biotechnology, accessed 6 February 2013; K. Schneider, Witnesses Clash on Animal

Patents (The New York Times, 1987) http://www.nytimes.com/1987/06/12/us/witnesses-clash-on-animal-patents.html?ref=biotechnology, accessed 6 February 2013; J. Tierney, Are Scientists Playing God? It Depends on Your Religion (The New York Times, 2007) http://www.nytimes.com/2007/11/20/science/20tier.html?pagewanted=all&_r=0, accessed 6 February 2013; J. Chatzimarkakis, Getting an appetite for biotechnology (BBC NEWS, 2009) http://news.bbc.co.uk/2/hi/science/nature/7905567.stm, accessed 6 February 2013.

2 Convention on Biological Diversity (adopted 22 May 1992, entered into force 29 December 1993) 1760 UNTS 79, Article 2.

3 For example, early civilizations such as the ones in Mesopotamia and Egypt understood and studied the importance of biotechnology in the fields of agriculture and animal husbandry; another example of early developments in biotechnology is the process of Ethanol fermentation; See W. Thieman and M. Palladino *Introduction to Biotechnology* (2nd edn, Benjamin Cummings, San Francisco 2004); J. Arnold, *Origin and History of Beer and Brewing: From Prehistoric Times to the Beginning of Brewing Science and Technology* (Alumni Association of the Wahl-Henius Institute of Fermentology, Chicago 1911).

4 D. Chisum, *Chisum on patents: a treatise on the law of patentability, validity, and infringement* (LEXIS pub, New York 1978) at 7-200.

5 See A. Gustafsson 'Patenting Human DNA Sequences Absolute Product Patents - A Reasonable Degree of Protection?' (LL.M. Thesis, University of Lund 2007).

6 V. Ling, 'Patently Ours? Constitutional Challengs to DNA Patents' (2012) 14 UPJCL 813, 848; See Universal Declaration on the Human Genome and Human Rights, UNGA Res 53/152 (10 Mar 1999) (adopted by unanimity); Parliamentary Assembly, 'Protection of the human genome by the Council of Europe' (Recommendation 1512, 2001) http://assembly.coe.int/Documents/AdoptedText/ta01/EREC1512.htm, accessed 5 February 2013; World Medical Association, 'World Medical Association Council Meeting' (press release, 2000) http://www.wma.net/en/40news/20archives/2000/2000_16/index.html, accessed 5 February 2013.

7 *Patenting Human DNA Sequences Absolute Product Patents - A Reasonable Degree of Protection?* (n 5) p. 5.

8 Directorate-General for Research and Innovation, European Commission, S. Bostyn 'Patenting DNA sequences (polynucleotides) and scope of protection in the European Union: an evaluation' (2004) KI-NA-21-122-EN-C p. 3.

9 Convention on the Grant of European Patents (European Patent Convention) (adopted 5 October 1973, entry into force 7 October 1977) 1065 UNTS 199 (EPC).

10 Patent Cooperation Treaty (adopted 19 June 1970, entered into force 24 January 1978) 1160 UNTS 231.

11 On 29th of June 2012, the Competitiveness Council of Ministers reached an agreement in relation to the adoption of a proposed Regulation for the creation of an EU-wide patent and the establishment of a Patent Court; See Academy of European Law, 'Speakers' Contributions - The Creation of Unitary Patent Protection in The European Union' Paris, 29-30 November 2012.

12 See World Health Organisation (Report of The Advisory Committee on Health Research), 'Genetics, genomics and the patenting of DNA: Review of potential implications for health in developing countries' (2005) LC/NLM classification: QU 33.1 p.15.

13 European Parliament and Council Regulation (EU) 1257/2012 of 17 December 2012, implementing enhanced cooperation in the area of the creation of unitary patent protection [2012] OJ L361 (Unitary Patent Regulation); Council Regulation (EU) 1260/2012 of 17 December 2012, implementing enhanced cooperation in the area of the creation of unitary patent protection with regards to the applicable translation arrangements [2012] OJ L361/89 (Translation Regulation).

14 Council of the European Union doc. 16351/12 of 11 January 2013, Agreement on a Unified Patent Court [2013].

15 Dr. M. Ficsor, 'Coexistence of National Patents, European Patents and Patents With Unitary Effect,' 'ERA Conference on the Creation of Unitary Patent Protection in the European Union,' Paris, 29-30 November 2012 p.11; See *Speakers' Contributions - The Creation of Unitary Patent Protection in The European Union* (n 9) p.19.

16 See *Unitary Patent Regulation* (n 13) Article 18; *Translation Regulation* (n 13) Article 7 (2).

17 See *Agreement on a Unified Patent Court* (n 14) Article 89.

18 *Genetics, genomics and the patenting of DNA: Review of potential implications for health in developing countries* (n 10) p. 15.

19 WIPO administers 25 treaties, three of those jointly with other international organizations; See World Intellectual Property Organization 'WIPO-Administered Treaties' http://www.wipo.int/treaties/en/index.jsp, accessed 3 February 2013.

20 Agreement of Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods (adopted 15 April 1994, entered into force 1 January 2005) 1869 UNTS 299 (TRIPS).

21 For example, in Brazil, an inventor cannot patent "the genome or germplasm of any natural living being, when found in nature or isolated therefrom, and natural biological processes," but he or she could patent a gene sequence. See Section 1, Article 10 IX of Industrial Property Law No. 9279/96; see *Genetics, genomics and the patenting of DNA: Review of potential implications for health in developing countries* (n 10) p. 76.

22 The "first-to-invent" patent system will be altered on 16th of March 2013, after the "Leahy-Smith America Invents Act" (H.R.1249 - America Invents Act to amend title 35, United States Code, to provide for patent reform), adopted under the Obama Administration. The new patent system will be "first-inventor-to-file" and is considered to bring the American patent regime close to the ones of Europe and Japan.

23 The Constitution of the United States, Article I, Section 8.

24 35 *USC* Part I.

25 35 *USC* Part II.

26 35 *USC* 101.

27 35 *USC* 102.

28 35 *USC* 101.

29 35 *USC* 103.

30 *Diamond v. Chakrabarty*, 447 U.S. 303, 313 (1980).

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

32 *Ibid* at 130.

33 See E. Gold, J. Carbone, 'Detailed legal analysis of gene patents, competition law and privacy law' in E. Gold, J. Carbone 'Myriad Genetics: In the eye of the policy storm' Appendix B (2010) 12 Genetics in Medicine 39, 70.

34 *Diamond v. Chakrabarty* (n 30).

35 Dr. P. Janicke, 'IP Survey – Patent Cases 2012' (2012), University of Houston Law Center.

36 *In re Bergy*, 563 F.2d 1031 (1977).

37 *Ibid.*

38 *Detailed legal analysis of gene patents, competition law and privacy law* (n 33).

39 USP 4,259,444, Microorganisms having multiple compatible degradative energy-generating plasmids and preparation thereof (Patent, 1981) http://patft.uspto.gov/netacgi/nph-Parser?Sect2=PTO1&Sect2=HITOFF&p=1&u=/netahtml/PTO/search-bool.html&r=1&f=G&l=50&d=PALL&RefSrch=yes&Query=PN/4259444, accessed 6 April 2013.

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41 Organisation for Economic and Cooperative Development, 'Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies' (OECD Publications, Paris 2002).

42 R. Singh, Dr. L. Walters, 'DNA Patent Database,' Kennedy Institute of Ethics (Georgetown University, Washington DC 2009).

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44 *Detailed legal analysis of gene patents, competition law and privacy law* (n 33).

45 E. Rogers, 'Can You Patent Genes? Yes and No' (2011) 93 JPTOS 19, 19.

46 *Association for Molecular Pathology v. Myriad Genetics*, 653 F.3d 1329, 1358 (2012).

47 See S. Merrill and A. Mazza, *Reaping the Benefits of Genomic and Proteomic Research: Intellectual Property Rights, Innovation, and Public Health* (1st edn, National Academy Press, Washington, DC 2006).

48 See The Nuffield Council on Bioethics, 'The ethics of patenting DNA a discussion paper' (2002), London; Danish Council of Ethics, 'Patenting human genes and stem cells' (2004), Copenhagen.

49 See T. Caulfield, 'Evidence and Anecdotes: An Analysis of Human Gene Patenting Controversies' (2006) 24 Nature Biotechnology 1091; G. van Overwalle and E. van Zimmeren, 'Reshaping Belgian Patent Law: The Revision of the Research Exemption and the Introduction of a Compulsory License for Public Health' (2006) 64 Chizaiken Forum 42, 49; J. Warcoin, "Patent Tsunami' in the Field of Genetic Diagnostics: A Patent Practitioner's View' (2009) 331, 338 in G. van Overwalle, *Gene Patents and Collaborative Licensing Models Patent Pools, Clearinghouses, Open Source Models and Liability Regimes* (CUP, Cambridge 2009).

50 See, *Patently Ours? Constitutional Challenges to DNA Patents* (n 6) p. 823.

51 USP 5,747,282, 17Q-linked breast and ovarian cancer susceptibility gene (Patent, 1998) http://patft.uspto.gov/netacgi/nph-Parser?Sect2=PTO1&Sect2=HITOFF&p=1&u=/netahtml/PTO/search-bool.html&r=1&f=G&l=50&d=PALL&RefSrch=yes&Query=PN/5747282, accessed 6 February 2013;

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52 *Association for Molecular Pathology v. Myriad Genetics* (n 46) at 1339; *Patently Ours? Constitutional Challenges to DNA Patents* (n 6) p. 824.

53 N. Howlader, A. Noone, M. Krapcho, N. Neyman, R. Aminou, S. Altekruse, C. Kosary, J. Ruhl, Z. Tatalovich, H. Cho, A. Mariotto, M. Eisner, D. Lewis, H. Chen, E. Feuer, K. Cronin, 'SEER Cancer Statistics Review, 1975-2008,' (National Cancer Institute 2010) http://seer.cancer.gov/csr/1975_2008/results_merged/, accessed 6 February 2013; see *Association for Molecular Pathology v. Myriad Genetics* (n 46) at 1339; see, *Patently Ours? Constitutional Challenges to DNA Patents* (n 6) p. 814.

54 *Association for Molecular Pathology v. Myriad Genetics* (n 46) at 1339; see American Cancer Society, 'Breast Cancer' (description of the BRCA1 and BRCA2 genes as major reason for development of breast cancer) http://www.cancer.org/cancer/breastcancer/detailedguide/breast-cancer-risk-factors, accessed 6 February 2013; see, *Patently Ours? Constitutional Challenges to DNA Patents* (n 6) p. 815.

55 *Patently Ours? Constitutional Challenges to DNA Patents* (n 6) p. 815.

56 *Association for Molecular Pathology v. Myriad Genetics* (n 46) at 1340.

57 *Association for Molecular Pathology v. Myriad Genetics* (n 46) at 1341.

58 *Patently Ours? Constitutional Challenges to DNA Patents* (n 6) p. 828.

59 For detailed and structured analysis on the issue see *Patently Ours? Constitutional Challenges to DNA Patents* (n 6).

60 *Association for Molecular Pathology v. Myriad Genetics* (n 46) at 1351; *Patently Ours? Constitutional Challenges to DNA Patents* (n 6) p. 815.

61 *Association for Molecular Pathology v. Myriad Genetics* (n 46) at 1351; *Patently Ours? Constitutional Challenges to DNA Patents* (n 6) p. 827.

62 *Association for Molecular Pathology v. Myriad Genetics* (n 46) at 1355-1357.

63 *Association for Molecular Pathology v. Myriad Genetics* (n 46) at 1358; *Patently Ours? Constitutional Challenges to DNA Patents* (n 6) p. 826.

64 *Association for Molecular Pathology et al v. Myriad Genetics Inc. et al*, Docket No. 12-398, United States Supreme Court.

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67 J. Thomas, 'Mayo v. Prometheus: Implications for Patents, Biotechnology, and Personalized Medicine' (2012) 7-5700 CRS Report for Congress R42815.

68 P. Jackman and L. Brandes, 'Mayo Collaborative Services v. Prometheus Labs., Inc.: Medical diagnostic methods merely applying a law of nature are not eligible for patent protection' (Sterne, Kessler, Goldstein & Fox, MSBA Annual IP Law Update 2012) http://www.skgf.com/media/pnc/4/media.1734.pdf, accessed 25 February 2013.

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70 "The classic test of patent-eligibility of method claims is the *machine-or-transformation test*, which grants patent-eligibility to a process claim if it (1) is implemented with a particular machine specifically devised and adapted to carry out the process in a way that is not concededly conventional nor trivial; or else (2) transforms an article from one thing or state to another."; see R. Xu, 'From Prometheus to Myriad to Classen, What a Messy Subject Matter: A Review on Recent Life Science Method Patent Cases' (2013) 11 NJTIP 119, 138; *Bilski v. Kappos,* 561 U.S. ___ , 130 S. Ct. 3218 (2010).

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75 *Parker v. Flook*, 437 U. S. 591 (1978).

76 *Diamond v. Diehr*, 450 U.S. 175, 187 (1981).

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80 *Diamond v. Diehr* (n 76) at 191-192.

81 *Bilski v. Kappos* (n 70) at 14.

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86 See *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* (n 65) p. 11.

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164 Observing software simulations without actually performing the operation in question.

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183 *Patenting DNA sequences (polynucleotides) and scope of protection in the European Union: an evaluation* (n 8) p.108.

184 "For a detailed analysis of the issues relating to the patentability of genetically manipulated animals and plants and the scope of protection of such inventions, see, S. Bostyn, 'The Patentability of Genetic Information Carriers; The New E.U. Directive 98/44/EC on the Legal Protection

of Biotechnological Inventions' (1999) IPQ 13-26.; G 0001/98 *Transgenic plant*/NOVARTIS II (1999) EPOR 303.; See C-377/98 *Kingdom of the Netherlands v European Parliament and Council of the European Union* [2001] ECR I- 07079 paras. 42-49.; Opinion of Advocate General Jacobs in case C-377/98 *Kingdom of the Netherlands v European Parliament and Council of the European Union* [2001] ECR I- 07079, delivered on 14 June 2001 paras. 113-141"; *Patenting DNA sequences (polynucleotides) and scope of protection in the European Union: an evaluation* (n 8) p.108.

185 "The term composition of matter patent is sometimes used in the United States to refer to a patent on a chemical product. Confusingly, it has been used in relation to both individual substances and true compositions of two or more substances." See *The ethics of patenting DNA a discussion paper* (n 48) p. 25.

186 *The ethics of patenting DNA a discussion paper* (n 48) p. 24.

187 *The ethics of patenting DNA a discussion paper* (n 48) p. 25.

188 Specified in the patent application.

189 *Patenting Human DNA Sequences Absolute Product Patents - A Reasonable Degree of Protection?* (n 5) p.36; See S. Bostyn, 'Protection of biotechnological inventions in France and Germany after directive 98/44/EC,' 欧州知的財産ニュース (2005 年 5月号) available at http://www.jetro.go.jp/world/europe/ip/archive/pdf/news_009_1.pdf, accessed 8 February 2013.

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193 *Association for Molecular Pathology v. Myriad Genetics* (n 46).

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195 G0002/88 *Friction reducing additive*/MOBIL OIL III (1989) OJ EPO 93 at p. 15.

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