A Tale of Two Mice: Insights on the Divergent Treatment of Patent-Eligible Subject Matter in the United States and the European Union

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"The focus of this case is a very small animal, namely a mouse – to use a poet's description, a 'Wee, sleekit, cowrin, tim'rous beastie' (R. Burns, 'To a Mouse' 1785). In all other respects however, this case is not small."[1]

I. Introduction: Same Mouse, Two Outcomes

In early 1983, Philip Leder and Timothy Stewart, Harvard scientists, used a fine glass needle to carefully inject known cancer genes into a mouse embryo.[2] This process led to the development of the oncomouse.[3] The genetic modification imparted to the oncomouse made the mice predisposed to cancer development and ensured the mouse would pass the gene on to future generations.[4] The oncomouse became the first animal to be patented in the United States.[5] The oncomouse has also come to epitomize the differences between the approaches to patent-eligible subject matter in the United States and the European Union.

The oncomouse patent faced little opposition in the United States and the patent was granted less than four years after the application was filed.[6] At the time the oncomouse patent application was filed in the United States, the U.S. took an approach to patent eligible subject matter that embraced everything under the sun made by man.[7] This approach led to a surge in biotechnology patents, including the oncomouse, and the explosion of biotechnology innovation and investment in the United States.[8]

In the European Union, however, the oncomouse faced a nineteen year battle before the patent was held to be valid.[9] This struggle to patent the oncomouse in the E.U. can be traced back to the patent eligibility standards in place at the time the application was filed with the European Patent Office (EPO). At the time, the European Union took a restrictive approach to patent eligibility and patenting biotech inventions was extremely difficult.[10] Recognizing the problem, the E.U. passed a biotechnology directive to allow for a broader scope of patent eligible subject matter in the field of biotechnology.[11] This directive eventually allowed the oncomouse patent to be granted and held valid by the EPO Boards of Appeal.[12]

After the European Union broadened their patent eligibility standards to be more

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1 Case T 0315/03 - 3.3.8, OJ EPO 2004, The President and Fellows of Harvard College, Reasons, ¶ 1.1 at 58 (EPO Technical Board of Appeal, 2004).

2 *OncoMouse*, SMITHSONIAN: THE NATIONAL MUSEUM OF AMERICAN HISTORY, http://americanhistory.si.edu/collections/search/object/nmah_1449806 (last visited Dec. 15, 2018).

3 *Id.*

4 *Id.*

5 *Id.*; *See also* U.S. Pat. No. 4,736,866 (issued Apr. 12, 1988).

6 *See Id.* (showing a filing date of Jun. 22, 1984 and an issuance date of Apr. 12, 1988).

7 *See* Diamond v. Chakrabarty, 447 U.S. 303 (1980); *See also infra* Section II(c).

8 Kevin Madigan & Adam Mossof, *Turning Gold into Lead: How Patent Eligibility Doctrine is Undermining U.S. Leadership in Innovation*, 24 GEO. MASON L. REV. 939, 943–44 (2017).

9 *See infra* Section III(d).

10 *Id.*

11 *Id.*

12 *Id.*

in line with the United States, the U.S. changed course and adopted a more restrictive view of patent eligible subject matter.[13] This change in patent eligibility standards led to the U.S. and E.U., once again, taking divergent approaches to what inventions constitute patent-eligible subject matter.

Sections II and III of this Note trace the historical development of the patent eligibility standards in the United States and the European Union. Section IV of this Note details how the U.S. and E.U. approaches to patent eligibility have switched over the years as exemplified in the treatment of the BRCA patents in the United States and the European Union. Finally, Section V of this Note outlines the consequences of the current divergent treatment of patent-eligible subject matter, as well as why and how the standards should be harmonized

II. The Development of Patent-Eligibility Standards in the United States

A. The Statutory Framework for Patent Eligibility

Patent eligibility standards in the United States are primarily based on case law.[14] The statutory framework for patent eligibility that underlies the case law is 35 U.S.C. § 101.[15] This statutory provision defines patentability by outlining what subject matter is patent eligible. 35 U.S.C. § 101 provides that "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor False"[16] While 35 U.S.C. § 101 defines patent-eligible subject matter broadly, courts have imposed more stringent restrictions on patent-eligible subject matter, creating judicial exceptions to patent-eligibility. These exceptions include laws of nature, natural phenomena, mental steps, and mathematical algorithms.[17] Consequently, in the United States, patent eligibility is primarily defined by case law.[18] Despite the importance of case law in analyzing patent eligibility and the courts' creation of judicial exceptions, courts have long struggled with determining what is a patent-eligible invention and what is an unpatentable principle.[19] Consequently, the United States Supreme Court has adopted two conflicting approaches to analyzing patent-eligibility.

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13 *See infra* Section II(e).

14 Timo Minssen & Robert M. Schwartz, *Separating sheep from goats: a European view on the patent eligibility of biomedical diagnostic methods*, 3 J. L. & Biosciences 365, 367 (2016).

15 35 U.S.C. § 101 (2012).

16 35 U.S.C. § 101 (2012).

17 Michael Risch, *Everything Is Patentable*, 75 TENN. L. REV. 591, 596 (2008) (citing multiple sources).

18 Minssen & Schwartz, *supra* note 14, at 367.

19 Jeffrey A. Lefstin, *Inventive Application: A History*, 67 FLA. L. REV. 565, 566 (2015).

B. A Search for Inventiveness

The inventive concept approach to analyzing patent eligibility is exemplified in two Supreme Court cases, *Funk Brothers Seed Co. v. Kalo Co.*[20] and *Parker v. Flook*.[21] This approach begins with analyzing each individual element of a claim to determine if the element contains an abstract idea, natural phenomena, or law of nature.[22] If any element of the claim is found to contain one of these judicial exceptions, the court then determines if any other elements of the claim convey an inventive concept.[23]

In *Funk Bros.* the Court analyzed claims directed to a bacterial inoculant comprised of a variety of different bacteria that had been individually isolated and recombined.[24] This inoculant was able to infect various types of leguminous plants and fix nitrogen to promote the plants' growth.[25] While *Funk Brothers* was decided prior to the enactment of the modern patent statute, the Court's analysis appears to be clearly directed to patent eligibility.[26] The Court found the claims were unpatentable because "their qualities are the work of nature."[27] Because these qualities are the work of nature, they are "part of the storehouse of knowledge of all men.[28] They are manifestations of laws of nature, free to all men and reserved exclusively to none."[29] The Court failed to find an inventive concept in the claims, noting that the claimed combination of bacteria did not result in any species of bacteria acquiring a different use and each species maintained its original function.[30] The Court's analysis suggests that the concepts of non-obviousness, or "inventiveness," and patent eligible subject matter are connected and considered jointly. The intermingling of non-obviousness and patent eligibility is not unexpected as these patentability requirements were included in the same statutory section until four years after *Funk Brothers* was decided.[31]

After the *Funk Brothers* decision, the United States pharmaceutical industry became alarmed at *Funk Brothers* apparent requirement of an inventive application as a condition of patentability.[32] This requirement departed from the historical

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20 333 U.S. 127 (1948).
21 437 U.S. 584 (1978).
22 *Id.* at 598 (explaining that laws of nature, physical phenomena, and abstract ideas are not patent eligible subject matter).
23 *Funk Bros.*, 333 U.S. at 130.
24 *Id.* at 129–30 (articulating that strains of each species of root-nodule bacteria that do not exert mutually inhibitive behavior could be isolated and mixed).
25 *Id.*
26 Michael A. Sanzo, *Patent Eligibility in Biotechnology: A Look Under the Hood*, 45 AIPLA Q. J. 1, 5 (2017)
27 *Funk Bros.*, 333 U.S. at 130.
28 *Id*.
29 *Id.*
30 *Id.* at 131.
31 Sanzo, *Patent Eligibility*, *supra* note 26, at 3.
32 Lefstin, *supra* note 19, at 632.

standard of patent eligibility.[33] The pharmaceutical industry raised this concern in the hearings preceding the enactment of the 1952 Patent Act.[34] The industry urged Congress to clarify that newly discovered laws of nature remained patentable if they were embodied in new and useful applications.[35] It appears that Congress heeded the warning of the pharmaceutical industry and eliminated the inventive application required by *Funk Brothers*.[36] The elimination of the inventive application is supported by the statutory language of 35 U.S.C. §§ 100 and 101. Section 101 separated the requirements of patent eligibility and utility from those of novelty and non-obviousness, which were moved to § 102 and § 103, respectively.[37] In section 100, Congress defined "invention" as an "invention or discovery."[38] Additionally, the term "process" was defined as a "process, art, or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material."[39] These definitions suggest that Congress intended to overrule *Funk Brothers* in the Patent Act of 1952.[40]

Thirty years after the *Funk Brothers* decision and after the apparent overruling of the decision in the Patent Act of 1952, the Supreme Court again relied on the *Funk Brothers'* inventive concept approach to patent eligibility in its decision in *Flook*.[41] The claims challenged in *Flook* were directed to a method for updating alarm limits.[42] The Court analyzed each element of the claim and found the only novel feature of the method was a mathematical formula.[43] Next the Court considered whether the other elements of the claim, or the application of the formula, was sufficient to make the claims patent-eligible.[44] The Court found that the novelty of the mathematical formula does not contribute to whether the claims are patent eligible, rather the process itself must be new and useful.[45] Therefore, the Court only analyzed the elements of the claim that did not contain the mathematical formula and found the claims invalid because they contained no patentable invention (*i.e.*, they lacked an inventiveness).[46]

The inventive concept approach to patent eligibility involves analyzing each individual element of a claim and not the claim in its entirety.[47] Any element in the claim that is found to be directed to a judicial exception is not taken into account when evaluating the inventiveness of the claim.[48]

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33 *Id*. at 631-32.
34 *Id.* at 632.
35 *Id.* (citing *Patent Law Codification and Revision: Hearings on H.R. 3760 Before Subcomm. No. 3 of the Comm. on the Judiciary H.R.*, 82nd Cong. 116–18 (1951) (statement of I. J. Fellner, Manager, Patent Department, Dr. Salsbury's Laboratories).
36 Lefstin, *supra* note 19, at 634.
37 *See* 35 U.S.C. §§ 101–103 (2012).
38 35 U.S.C. § 100(a) (2012).
39 35 U.S.C. § 100(b) (2012).
40 Lefstin, *supra* note 19, at 634.
41 Parker v. Flook, 437 U.S. 584, 585 (1978).
42 *Id*. at 585.
43 *Id*.
44 *Id*. at 593-94.
45 *Id.* at 591.
46 *Flook*, supra note 21, at 594.
47 Sanzo, *supra* note 26, at 2.
48 *Id*. at 3.

C. Everything Under the Sun Made by Man

A short two years after deciding *Flook*, the Supreme Court changed course and took a different approach in analyzing patent-eligibility in *Diamond v. Chakrabarty*.[49] The claims in *Chakrabarty* are directed to a human-made, genetically engineered bacterium capable of breaking down crude oil.[50] No naturally occurring bacterium is able to break down crude oil.[51]

The Court began its analysis in *Chakrabarty* with a statutory construction of 35 U.S.C. § 101, an approach that was not taken two years earlier in *Flook*. The Court determined that "Congress plainly contemplated that the patent laws would be given wide scope" and "include anything under the sun that is made by man."[52] The Court went on to acknowledge, however, that § 101 has limits and that "a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not have patented his celebrated $E = mc^2$; nor could Newton have patented the law of gravity."[53]

After analyzing the statutory language, the Court analyzed the claims of the *Chakrabarty* patent.[54] The Court again diverged from the approach laid out in *Funk Brothers* and *Flook* and analyzed the claims as a whole rather than the individual elements of the claims. Based on this whole-claim analysis the Court held that the claims "plainly qualif[y] as patentable subject matter" because they were directed to a non-naturally occurring manufacture or composition of matter.[55] The level of human intervention in the claims, the markedly different characteristics of the claimed bacteria from any found in nature, and the significant utility of the claimed bacteria factored heavily in the Court's decision.[56]

A year after the *Chakrabarty* decision, the Court used the same approach to patent eligibility to decide *Diamond v. Diehr*.[57] The *Diehr* claims are directed to a process for curing synthetic rubber, which employs a mathematical equation.[58] Despite the inclusion of the equation, the Court held that the claims were patent-eligible because they were not directed solely to the equation but rather claimed the equation in combination with the other steps in the process.[59] In holding the claims patent-eligible, the Court emphasized the importance of analyzing claims as a whole and not analyzing individual elements of the claim.[60] This whole-claim analysis is particularly important with process claims "because a new combination of steps in a

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49 447 U.S. 303 (1980).
50 *Id.*
51 *Id.* at 305.
52 *Id.* at 307–09.
53 *Id.* at 309.
54 *Chakrabarty*, 447 U.S. at 309.
55 *Id.*
56 *Id.* at 310.
57 450 U.S. 175 (1981).
58 *Id.* at 160.
59 *Id.* at 187.
60 *Id.* at 188.

process may be patentable even though all the constituents of the combination are well known and in common use before the combination was made."[61]

The whole-claim, everything under the sun made by man approach to patent eligibility appears to directly contradict the inventive concept approach taken by the Court in *Funk Brothers* and *Chakrabarty*. The Court, however, has maintained that these cases are not inconsistent and has attempted to distinguish the cases based on factual differences.[62] The difference in outcomes between the outcomes in *Funk Brothers/Flook* and *Chakrabarty/Diehr*, however, appear to be based on the approach to the analysis and not factual differences. If *Funk Brothers* and *Flook* were analyzed with the approach in *Charkabarty* and *Diehr*, the claims would likely have been found patent eligible.[63]

D. The Tale of the American Mouse

The *Chakrabarty* decisions was an implicit statement from the United States Supreme Court that biotechnology inventions, still an emerging and controversial filed in the 1980s, should be promoted and protected.[64] While other countries were hesitating to grant protection to innovations in biotechnology, by holding the *Chakrabarty* claims were patent-eligible, the United States Supreme Court recognized that results of biotechnology research may be directed to patent eligible subject matter.[65] The *Chakrabarty* decision has been cited as a driving force behind revolutionary advancements in biotechnology and medical treatment.[66] The *Chakrabarty* decision paved the way for Harvard College to secure the patent on the oncomouse.[67] The oncomouse patent in the United States was issued less than four years after the initial filing date of the application.[68] The United States early embrace of securing patent rights for biotechnology inventions led the U.S. to become "the birthplace of the biotech revolution."[69]

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61 *Id.*
62 *Diehr* 450 U.S. at 186; *Chakrabarty*, 447 U.S. at 310.
63 *See* Sanzo, *supra* note 26, at 5.
64 Madigan & Mossof, *supra* note 8, at 943–44.
65 *Id.*; Diamond v. Chakrabarty, 447 U.S. 303 (1980).
66 Madigan & Mossof, *supra* note 8, at 943.
67 U.S. Patent No. 4,736,866 (issued Apr. 12, 1988).
68 *See* U.S. Patent No. 4,736,866 (showing a filing date of Jun. 22, 1984 and an issuance date of Apr. 12, 1988).
69 Madigan & Mossof, *supra* note 8, at 944.

E. Two-Stepping Back to the Inventive Concept

For three decades after the *Chakrabarty* decision the Supreme Court did not address eligible subject matter. The Court developed a renewed interest in patent eligibility in 2010 and issued four opinions on the subject within four years.[70] This series of decisions culminated in the adoption of the *Alice/Mayo* two-step approach to analyzing patent-eligible subject matter. The *Alice/Mayo* two-step moved away from the whole claim, everything under the sun made by man approach embraced in *Chakrabarty* and *Diehr* and towards the inventive concept approach exemplified by *Funk Brothers* and *Flook*.[71]

1. Laying the Framework for the Two-Step

In 2012, the Supreme Court decided *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*,[72] which laid the framework for the development of the *Alice/Mayo* two-step. Two patents were being challenged in the *Mayo* case. Both patents were directed to the use of thiopurine drugs in the treatment of autoimmune disorders.[73] The claims contained three steps: (1) administering the drug; (2) determining the amount of the drug in a patient's blood sample; and (3) a "wherein" step that correlates the drug level with a need to increase or decrease the amount of drug administered to the patient.[74]

The Court first found that the patents "set forth laws of nature—namely, relationships between concentrations of certain metabolites in the blood and the likelihood that a dosage of thiopurine drug will prove ineffective or cause harm."[75] The Court then looked to see if the claims "do significantly more than simply describe the natural relations."[76] These two steps laid the foundation for the *Mayo/Alice* two-step test for patent eligibility. The Court found that the claims do not add significantly more to the law of nature: "[T]he claims inform a relevant audience about certain laws of nature; any additional steps consist of well-understood, routine, conventional activity already engaged in by the scientific communityFalse"[77] The Court also stated that "simply appending conventional steps, specified at a high level of generality, to laws of nature, natural phenomena, and abstract ideas cannot make those laws, phenomena, and ideas patentable."[78]

The Court's analysis was driven by a concern of preemption. According to the Court, while granting patents for the discovery of new laws of nature may encourage

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[70] Bilski v. Kappos, 561 U.S. 593 (2010); Mayo Collaborative Services v. Prometheus Laboratories, Inc., 566 U.S. 66 (2012); Ass'n for Molecular Pathology v. Myriad Genetics Inc., 569 U.S. 576; Alice Corp. Pty. Ltd. v. CLS Bank Int'l, 573 U.S. 208 (2014).

[71] *See infra* Section II(b).

[72] 566 U.S. 66 (2012).

[73] *Id.* at 73.

[74] *Id.* at 74–75.

[75] *Id.* at 77.

[76] *Id.*

[77] *Id.* at 79–80.

[78] *Id.* at 82.

discover, "there is a danger that the grant of patents that tie up their use will inhibit future innovation premised upon them" and "otherwise foreclose[] more future invention than the underlying discovery could reasonably justify."[79]

2. Applying Mayo *to Genetic Information*

A year after the *Mayo* decision, the Supreme Court again addressed patent eligibility in *Association for Molecular Pathology v. Myriad Genetics, Inc*..[80] Myriad discovered the sequence and location of the BRCA1 and BRCA2 genes.[81] Mutations in BRCA1 and BRCA2 are associated with an increased risk for developing breast and ovarian cancer.[82] Myriad was able to develop medical tests for detecting mutations in a patient's BRCA1 and BRCA2 genes and assessing a patient's risk for developing breast or ovarian cancer.[83] Based on these discoveries, Myriad obtained a number of patents.[84] Nine composition claims from three of these patents were challenged in *Myriad*.[85] These claims were directed to genomic DNA (gDNA) and complementary DNA (cDNA) sequences of the BRCA1 and BRCA2 genes.[86]

The District Court granted summary judgment to the petitioners reasoning that the claims were invalid under 35 U.S.C. § 101 because they covered products of nature.[87] The Court of Appeals for the Federal Circuit reversed the District Court's decision.[88] The Supreme Court granted the petition for certiorari, vacated the Federal Circuit's decision and remanded the case back to the Federal Circuit for further consideration in light of the holding in *Mayo*.[89] On remand, the Federal circuit again held both the gDNA and cDNA composition claims valid under 35 U.S.C. § 101.[90]

The Supreme Court again granted the petition for certiorari.[91] The judgment of the Federal Circuit was affirmed in part and reversed in part.[92] The Court held that claims directed to gDNA are not patent eligible under 35 U.S.C. § 101. The Court did hold, however, that cDNA is patent eligible.

In its analysis of the gDNA composition claims, the Court cited to *Funk Brothers*.[93] The Court compared Myriad's gDNA claims to the ineligible claims in *Funk Brothers*. According to the Court, Myriad's claims, just like those in *Funk Brothers*, "fell squarely within the law of nature exception."[94] The gDNA claimed

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79 *Id.* at 86.
80 569 U.S. 576.
81 *Id.* at 582.
82 *Id.*
83 *Id.* at 583.
84 *Id.* at 583.
85 *Id.*
86 *Id.*
87 *Id.* at 586 (citing Ass'n for Molecular Pathology v. USPTO, 702 F. Supp. 2d 181, 220–37 (S.D.N.Y. 2010)).
88 Ass'n for Molecular Pathology v. USPTO, 653 F.3d 1329 (Fed. Cir. 2011).
89 Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 566 U.S. 902 (2012).
90 Ass'n for Molecular Pathology v. USPTO, 689 F.3d 1303 (Fed. Cir. 2012).
91 Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 568 U.S. 1045 (2012).
92 Ass'n for Molecular Pathology v. Myriad Genetics, Inc. 569 U.S. 576, 596 (2013). // Previously cited
93 *Id.* at 591 (citing Funk Bro's Seed Co. v. Kalo Inoculant Co., 333 U.S. 127 (1948)).
94 *Id.* at 591.

was identical to that found in nature and did not, according to the Court, create a new composition of matter.[95]

cDNA, however, "does not present the same obstacles to patentability as naturally occurring, isolated DNA segments."[96] The Court held cDNA patent eligible because it is different from the naturally occurring gDNA sequence and is a new composition created by man. Consequently, cDNA is not a product of nature and is, therefore, patent eligible under 35 U.S.C. § 101.[97]

While there were no method patents before the Court in *Myriad*, the Court noted in dicta, that the case did not "involve patents on new *applications* of knowledge about the BRCA1 and BRCA2 genes" and "as the first party with knowledge of the [BRCA1 and BRCA2] sequences, Myriad was in an excellent position to claim applications of that knowledge. Many of its unchallenged claims are limited to such applications."[98]

3. Doubling Down on the Two-Step

Despite the patent community's frustration with the *Mayo* decision,[99] the Supreme Court doubled down on this two-step approach to patent eligibility in *Alice Corp. Pty. Ltd v. CLS Bank International*.[100] The Court affirmed that the two-step approach established in *Mayo* was the appropriate test for all claims directed toward laws of nature, natural phenomena, and abstract ideas:

> First, we determine whether the claims at issue are directed to one of those patent-ineligible concepts. If so, we then ask, '[w]hat else is there in the claims before us?' . . . We have described step two of this analysis as a search for an 'inventive concept'—*i.e.*, an element or combination of elements that is 'sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself.[101]

The Supreme Court's search for an inventive concept is reminiscent of the approach the Court took in deciding *Funk Brothers* and *Flook*.[102] Additionally, searching for an inventive concept in elements or a combination of elements in the claims also results in a claim analysis focused on individual elements as opposed to the claim as a whole. The *Alice/Mayo* two-step has thus swung the analysis of patent eligibility back to the approach taken in *Funk Brothers* and *Flook* and away from the *Chakrabarty* approach that bolstered biotechnology innovation.

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95 *Id.*

96 *Id.* at 594.

97 *Id.* at 595.

98 *Id.* at 596 (quoting Ass'n for Molecular Pathology v. USPTO, 689 F.3d 1303, 1349 (Fed. Cir. 2012)).

99 *See e.g.* Gene Quinn, *Killing Industry: The Supreme Court Blows Mayo v. Prometheus*, IPWATCHDOG (March 20, 2012) (discussing how the Court's decision in *Mayo* failed to take basic patent law principles into account and discussing why the decision was wrongly decided).

100 537 U.S 208 (2014).

101 *Id.* at 217 (internal citations omitted).

102 *See supra* Section II(b).

Despite the frustration the two-step approach has generated in the patent community,[103] the Supreme Court has denied multiple petitions for certiorari challenging the *Alice/Mayo* two-step.[104] Consequently, it appears the Supreme Court believes the two-step is the appropriate test for patent eligibility. Members of the patent bar have begun to call for an amendment to 35 U.S.C. § 101 to overrule the *Alice/Mayo* two-step test.[105] However, any change to the current standard for patent eligibility in the United States does not appear likely in the near future. Consequently, patent eligibility in the U.S. will continue to be decided based on application of the current case law, the *Alice/Mayo* two-step.

III. The Development of Patent-Eligibility Standards in the European Union

Unlike the United States, patent eligibility in the European Union is primarily governed by statutory law and not case law.[106] The primary statutory provisions governing patent eligibility in the EU are Articles 52 and 53 of the European Patent Convention (EPC).[107] EPC Article 52, which details patentable inventions, states:

> (1)European patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application.
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> (2)The following in particular shall not be regarded as inventions within the meaning of paragraph 1:
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> (a)discoveries, scientific theories and mathematical methods;
>
> (b)aesthetic creations;
>
> (c)schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers;
>
> (d)presentations of information.
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> (3)Paragraph 2 shall exclude the patentability of the subject-

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[103] *See e.g.* Gene Quinn, *The Top 3 Reasons the U.S. Patent System in Decline*, IPWATCHDOG (April 26, 2017) http://www.ipwatchdog.com/2017/04/26/top-3-reasons-u-s-patent-system-decline/id=82571/ (stating that in 2017, the United States fell to a tenth place tie with Hungary in the U.S. Chamber of Commerce world rankings for patent protection and listing uncertainty in patent eligibility as a significant contributing factor to the decline in the strength of the U.S. patent system); Gene Quinn, Mayo v. Prometheus*: A Lawless Decision By An Omnipotent Court Wreaking Havoc On Patents*, IPWATCHDOG (Jan. 23, 2017) http://www.ipwatchdog.com/2017/01/23/mayo-v-prometheus-lawless-decision-wreaking-havoc-patents/id=77438/.

[104] *See, e.g.*, Gene Quinn, *Supreme Court Denies Cert. in* Sequenom v. Ariosa Diagnostics, IPWATCHDOG (June 27, 2016) http://www.ipwatchdog.com/2016/06/27/70409/id=70409/; Dennis Crouch, *Denied Certiorari on Section 101*, PATENTLYO (Oct. 2, 2017) https://patentlyo.com/patent/2017/10/denied-certiorari-section.html.

[105] *See e.g.*, Jeffrey A. Lefstin, Peter S. Menell, & David O. Taylor, *The Need for Legislative Reform: The Berkeley Section 101 Workshop*, PATENTLYO (Oct. 10, 2017) https://patentlyo.com/patent/2017/10/legislative-berkeley-workshop.html.

[106] *See e.g.* Minssen & Schwartz *supra* note 14, at 367; Jessica C. Lai, *Myriad Genetics and the BRCA Patents in Europe: The Implications of the U.S. Supreme Court Decision*, 5 UC Irvine L. Rev. 1041, 1044 (2015).

[107] Convention on the Grant of European Patents, Oct. 5, 1973, 13 I.LM 268,Arts. 52, 53 (as revised by the Act Revising the EPC 29 Nov. 2000) [hereinafter EPC].

matter or activities referred to therein only to the extent which a European patent application or European patent relates to such subject-matter or activities as such.[108]

EPC Article 53 outlines exceptions to patentability and states:

> European patents shall not be granted in respect of:
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> (a)inventions the commercial exploitation of which would be contrary to "ordre public" or morality; such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States;
>
> (b)plant or animal varieties or essentially biological processes for the production of plants or animals; this provision shall not apply to microbiological processes or the products thereof;
>
> (c)methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods.[109]

A. The European Patent Convention

The EPC is a multinational treaty which was implemented in 1978. The treaty allows for a patent application to be filed, examined for patentability under common standards, and granted by the European Patent Office (EPO).[110] The granted patent can then be brought into force as patents equivalent to those granted by the national patent office in any Contracting State.[111] The development of what is excluded from patentability in the EPC spanned more than half a century and involved the development of several international intellectual property laws and treaties.[112]

After the Second World War, the Council of Europe (CoE) was set up in 1949 after multiple proposals by, among others, Winston Churchill.[113] The CoE placed the creation of a European Patent Office on their agenda and began collection useful material on the creation of the EPO. A Committee of Experts was created in 1950 and

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[108] EPC Art. 52.

[109] EPC Art. 53.

[110] SIGRID STERCKX & JULIAN COCKBAIN, EXCLUSIONS FROM PATENABILITY: HOW FAR HAS THE EUROPEAN PATENT OFFICE ERODED BOUNDARIES? 17 (2012).

[111] *Id.*; As of Dec. 15, 2018, Contracting States include: Albania; Austria; Belgium; Bulgaria; Switzerland; Cyprus; Czech Republic; Germany; Denmark; Estonia; Spain; Finland; France; United Kingdom; Greece; Croatia; Hungary; Ireland; Iceland; Italy; Liechtenstein; Lithuania; Luxembourg; Latvia; Monaco; Republic of North Macedonia; Malta; Netherlands; Norway; Poland; Portugal; Romania; Serbia; Sweden; Slovenia; Slovakia; San Marino; and Turkey. *Member states of the European Patent Organisation*, EUROPEAN PATENT OFFICE, https://www.epo.org/about-us/foundation/member-states.html (Last visited Dec. 15, 2018).

[112] STERCKX & COCKBAIN, *supra* note 110, at 20.

[113] *Id.* at 21.

in 1953 the Committee sent a questionnaire to Member States asking what was excluded from patentability in those countries.[114]

Roger Gajac presented a study on the substantive points of patentability to the Committee of Experts in November 1955. This study became known as the 'Gajac study' and laid out the common features of possible exclusions from patentability.[115] The Gajac study laid the foundation and the rationale for most of the exclusions now found in Art. 52 and Art. 53 of the EPC.[116]

In regards to inventions and discoveries, the Gajac study stated, "as a general rule, a patent can only protect an invention (a creation) and not a discovery, that is the mere becoming aware of a pre-existing reality."[117] Furthermore, "[a] natural product or a natural phenomenon could no more be the object of patent protection than the revelation of a law of nature, even though a patentable technical indication may be based on a discovery."[118] Additionally, a discovery may be patentable if it "provide[s] an industrial activity with precise and constant character. . ." or "if it takes the form of a concrete technical instruction addressed at industry."[119]

With respect to systems and methods, the Gajac study reported "[a]ll national practices agree on excluding monetary, insurance, accounting, calculation, education, publicity. . .as well as rules of games or methods of medical treatment, from the scope of application of the law."[120]

The study went on to address scientific principles and theories, finding "[a]ll the countries' practices are also in agreement that purely scientific doctrines, principles or theories are excluded from the scope of the application of the law, whereas their industrial applications are not."[121]

Finally, the Gajac study reported that "[i]n all countries. . .one finds a prohibition on patenting inventions that are contrary to 'ordre public' or morality."[122]

The Gajac study was followed a year later by a proposal by Eduard Reimer, the 'Reimer proposal' on behalf of the German experts. The Reimer proposal concisely stated what should not be patent eligible: "No invention should be patentable when it is simply a question of: (a) scientific principles and theories, (b)instructions to the human brain, such as accounting systems and rules of games, (c) the creation of aesthetic forms, (d) the bringing to light of a pre-existing fact (discovery)."[123] Furthermore, the proposal suggested that patents should be granted on inventions that are "capable of industrial application."[124]

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[114] *Id.*
[115] *Id.* at 21–22.
[116] *Id.* at 22 (author's translation from French).
[117] STERCKX & COCKBAIN, *supra* note 110, at 22.
[118] *Id.*
[119] *Id.*
[120] *Id.* at 23.
[121] *Id.*
[122] STERCKX & COCKBAIN, *supra* note 110, at 23.
[123] *Id.* at 24.
[124] *Id.*

After the Reimer proposal, there was a pause in the activity of the CoE.[125] In 1960, the EoC agreed to a preliminary draft of the Strasbourg Patent Convention (SPC), to harmonize substantive requirements for patentability.[126] While the CoE was drafting and agreeing to the preliminary draft of the SPC, another working group consisting of the heads of various examining patent offices had also been meeting to draft a convention, the Council of Europe Patent Convention (CEPC), for facilitating the filing of patent applications in different countries for the same invention..[127] Drafting of both the SPC and the CEPC continued in parallel for a number of years. Various drafts of both conventions were produced between 1960 and 1965 adjusting the original suggestions of the Gajac study and Reimer proposal.[128]

The final draft of the SPC was considered in October of 1963 and signed in November of 1963. Art. 2(a) of the SPC provided:

> The Contracting States shall not be bound to provide for the grant of patents in respect of
>
> (a)inventions the publication or exploitation of which would be contrary to 'ordre public' or morality, the mere prohibition of the exploitation of the invention not making it so contrary.
>
> (b)plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to micro-biological process or the products thereof.[129]

Drafting of the CEPC continued until January of 1965. Articles 9 and 10 of the final draft of the CEPC closely mirror Articles 52 and 53 of the EPC, respectively:

> Article 9
>
> (1)European patents shall be granted for inventions which are new, which involve an inventive step and which are susceptible to industrial application.
>
> (2)The following in particular shall not be regarded as inventions within the meaning of paragraph 1:
>
> (a)scientific knowledge and theories as such;
>
> (b)mere discovery of substance occurring in nature;
>
> (c)purely aesthetic creations;
>
> (d)financial or accounting systems, rules for playing games or other systems, insofar as they are of a purely abstract nature;

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[125] *Id.*
[126] *Id.* at 19, 30.
[127] STERCKX & COCKBAIN, *supra* note 110, at 30.
[128] *Id.* at 30–38.
[129] *Id.* at 37.

(e)methods of therapy, including diagnostic methods.

Article 10

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 to be so contrary merely because it is prohibited by laws or regulations 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 process or the products thereof.[130]

After the final drafts of the SPC and CEPC were completed, there was a pause on the development of a unified European patent law. Focus instead shifted to the development of international harmonization of patent law on a global scale.[131] Attention turned to creating the Paris Cooperation Treaty (PCT), a system where an applicant can file a single patent application that has the potential to become a national or regional application in any of the Contracting States.[132]

After the final draft of the PCT was approved in 1969, Europe's attention returned to unifying European patent law.[133] From May 1969 to June 1972 there were a series of Intergovernmental Conferences (IGCs) which were arranged by European countries working towards a common European patent system. This renewed push for a unified European patent system resulted in the drafting of the EPC. The EPC drew on portions of the CEPC, the SPC, and the PCT.[134] The EPC went through multiple rounds of revisions and the final draft was completed in 1972.[135] This draft was considered at the Munich Conference which was held in September and October of 1973. After a great deal of deliberation, the final draft of EPC 1973 was approved at the Munich Conference.[136] The EPC came into effect in July 1978 and the national laws of the Contracting States were brought into line with the EPC.[137]

In the years immediately following the implementation of the EPC, there were numerous amendments to the EPC Rules and discontent began to set in over the exclusions to patentability.[138] Soon after the EPC came into effect, it became apparent that the exclusions to patentability laid out in the EPC were hindering the granting of patents in certain industries, such as pharmaceuticals. In 1983 the European Commission noted that the current legal situation surrounding biotechnology in the EU suffered from several deficiencies. The Commission stated that there were discrepancies in the statute as well as a shortage of case law on the subject. Consequently, the Commission recommended that a proposal for a European

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130 *Id.* at 38.
131 *Id.* at 39.
132 STERCKX & COCKBAIN, *supra* note 110, at 39.
133 *Id.* at 39–40.
134 *Id.* at 40.
135 *Id.* at 40–47.
136 *Id.* at 47.
137 STERCKX & COCKBAIN, *supra* note 110, at 49S. .
138 *Id.*

approach to biotechnology patent rights should be worked out.[139] The Commission was also concerned that the European treatment of biotechnology was hindering its ability to compete with countries such as the United States with respect to biotechnology.[140] The Commission declared:

> [w]hereas the two leading nations in biotechnology, the United States of America and Japan, have been able continuously to adapt their patent protection according to the latest needs of the industry, science and consumers, the Member States, representing comparable potential of intellectual manpower and capital, are immobilized by a not yet completed and. . .in part outdated legal framework.[141]

The Commissions' proposal paved the way for the adoption of the European Biotechnology Directive (Biotech Directive).[142]

B. The European Biotechnology Directive

The purpose of the Biotech Directive was to ensure uniform application and interpretation of the law and, therefore, foster innovation in Europe.[143] This would allow Europe to compete with the United States, which had become the a leader in the field of biotechnology while Europe lost the "competitive and commercial edge in biotechnology."[144]

While the Commission first drew attention to the need for the Biotech Directive in 1983, the Directive was not passed until 1998.[145] The first draft of the Directive was proposed in 1988 and faced multiple drafting challenges during the ten year drafting process.[146] The first draft of the Directive attempted to clarify living matter could be patentable if it met the technical requirements of patentability. This first draft faced opposition, however, because it did not address issues of morality.[147]

The final form of the Directive is based on the EPC.[148] The Directive provides that a patent may not be issued if the commercial exploitation of the invention would violate ordre public or morality even if the other patentability requirements are

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139 *Id.*

140 Lai, *supra* note 106, at 1056.

141 Donna M. Gitter, *Led Astray by the Moral Compass: Incorporating Morality into European Union Biotechnology Patent Law*, 19 Berkeley J. Int'l L. 1, 9 (2001) (quoting Proposal for a Council Directive on the Legal Protection of Biotechnological Inventions, EUR. PARL. DOC. (COM 88 496 finally–Syn 159) 22 (1988)).

142 STERCKX & COCKBAIN, *supra* note 110, at 50–56.

143 Cynthia M. Ho, *Splicing Morality and Patent Law: Issues Arising from Mixing Mice and Men*, 2 WASH. U. J. L. & POL'Y 247, 275 (2000).

144 Lai, *supra* note 106, at 1056; Madigan & Mossof, *supra* note 8, at 944.

145 Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions, 1998 O.J. (L 213) 13, *available at* https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31998L0044:EN:HTML [hereinafter Directive].

146 Ho, *supra* note 143, at 276 n.136; Sterckx & Cockbain, *supra* note 110, at 49–56.

147 Ho, *supra* note 143, at 275.

148 *Id.* at 276.

met.[149] This language is similar to that found in Article 53 of the EPC.[150] The Directive, unlike the EPC, explicitly dictates what biotechnology subject matter violates ordre public or morality. There are four categories of subject matter outlined in the Directive which are per se violations of ordre public or morality and are consequently unpatentable.[151] The Directive provides:

> [T]he following, in particular, shall be considered unpatentable:
>
> (a) processes for cloning human beings;
>
> (b) processes for modifying the germ line genetic identity of human beings;
>
> (c) uses of human embryos for industrial or commercial purposes;
>
> (d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

This list, however, is not exhaustive. The examples are intended to provide some guidance to courts and patent offices.[152] In addition to the examples listed in article 6 of the Directive, the preamble states that "this list obviously cannot presume to be exhaustive."[153]

Outside of the ordre public or morality requirements in the Directive, which is not found in U.S. patent law, the remaining articles of the Directive moved in the direction of the contemporaneous case law in the United States.[154] At the time of the passage and implementation of the Directive, the most recent decisions on patent eligibility were *Chakrabarty*[155] and *Diehr*.[156] The Directive, therefore, was intended to embrace the everything under the sun made by man approach to patent-eligible subject matter that was being applied in the United States.

In regards to elements isolated from the human body, such as DNA, the Directive provides:

> Whereas, therefore, it should be made clear that an invention based on an element isolated from the human body or otherwise produced by means of a technical process, which is susceptible of industrial application, is not excluded from patentability, even where the structure of that element is identical to that of a natural element, given that the rights conferred by the patent do not extend to the

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149 *Id.*

150 *Compare* EPC, *supra* note 107, art. 53(a), at 27 *with* Directive, *supra* note 145, art. 6.

151 Ho, *supra* note 143, at 276.

152 *Id.* at 277.

153 Directive, *supra* note 145, recital 38, at 16.

154 Nicholas C. Whitley, *An Examination of the United States and European Union Patent Systems With Respect to Genetic Material*, 32 Ariz. J. Int'l & Comp. L. 463, 475 (2015).

155 *See supra* Section II(c); Diamond v. Chakrabarty, 447 U.S. 303 (1980).

156 *See supra* Section II(c); Diamond v. Diehr, 450 U.S. 175 (1981).

human body and its elements in their natural environment.[157]

The Directive goes on to state:

> [w]hereas such an element isolated from the human body or otherwise produced is not excluded from patentability since it is, for example, the result of technical processes used to identify, purify and classify it and to reproduce it outside the human body, techniques which human beings alone are capable of putting into practice and which nature is incapable of accomplishing by itself.[158]

This language is reminiscent of the *Chakrabarty* decision in the United States. The *Chakrabarty* decision placed a great deal of weight on the level of human intervention when determining if an invention is patent eligible.[159] Under the Directive, DNA sequences, or other elements isolated from the human body, may be patent eligible if they are produced or isolated through human intervention. A DNA sequence in isolation, however, without an indication of the function of the sequence does not contain technical information and is not patent eligible.[160] To satisfy the industrial application requirement, a gene sequence used to create a protein, or part of a protein, it must be specified which protein is produced or what function it performs.[161]

Similar to DNA sequences, the Directive provides that an invention concerning a product consisting of or containing biological material may be patentable if it is new, involves an inventive step, and is susceptible of industrial application.[162] Even if the biological material previously occurred in nature, it may still be patentable if it "is isolated from its natural environment or produced by means of a technical process."[163]

Essentially biological processes to produce plants or animals, however, are not patent eligible.[164] Essentially biological processes are naturally occurring and do not involve significant human intervention.[165] Additionally, plant and animal varieties themselves are not patent eligible.[166] Inventions which "concern plants or animals," however, may be patent eligible if they are not confined to a particular plant or animal variety. The Directive also does not prejudice the patent eligibility of "inventions which concern a microbiological or other technical process or a product obtained by means of such a process."[167]

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157 Directive, *supra* note 145, recital 20.
158 *Id.* recital 21.
159 *See supra* Section II(c).
160 Directive, *supra* note 145, recital 23.
161 *Id.* recital 24.
162 *Id.* art. 3.
163 *Id.*
164 *Id.* art 4.
165 Whitley, *supra* note 154, at 477.
166 Directive, *supra* note 145, art. 4.
167 *Id.*

Finally, the Directive states that inventions are unpatentable if they are directed to the human body, at any stage of formation or development, the discovery of one of its elements, including the sequence of a gene.[168] While this appears to contradict the recitals earlier in the Directive, Article 5 goes on to clarify, "[a]n element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element."[169] Additionally, in order for a gene sequence to be patentable, the industrial application must be disclosed.[170]

C. An Industrial Application

While the United States Supreme Court has held that naturally occurring, gDNA sequences are not patent eligible, even when isolated from the human body,[171] the disclosure of an industrial application for the gDNA sequence is sufficient to make the same sequence patent eligible in the European Union.[172] Unlike its approach to gDNA, the United States Supreme Court held that cDNA is patent eligible simply because it is not naturally occurring in nature.[173] In the European Union, however, the determination of the patent eligibility of cDNA sequences is centered on the industrial application.[174] Simply producing cDNA from an mRNA sequence does not implicitly satisfy the industrial application requirement. The function of the cDNA sequence must be disclosed for there to be an industrial application. Consequently, a mere recitation of a sequence, even a cDNA sequence, is not sufficient to impart patent eligibility.[175]

The EPO Boards of Appeal, however, has clarified that the mere production of a substance and a description of the substance is not necessarily sufficient to create an industrial application.[176] The application must also disclose potential applications for the described substance. The use of the substance cannot be "to use what is claimed to find out more about the natural functions of what is claimed itself."[177] This requirement is based on the fact that "[t]he purpose of granting a patent is not to reserve an unexplored field of research for an applicant."[178] Research "is not in itself an industrial application, but rather research undertaken either for its own sake or with the mere hope that some useful application will be identified."[179] The Board of Appeals further explained the reason for this requirement a year later:

> [P]atents being an incentive to innovation and economic success, the criterion of "industrial applicability" requires that a

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168 *Id.* art. 5.
169 *Id.*
170 *Id.*
171 Ass'n for Molecular Pathology v. Myriad Genetics Inc., 569 U.S. 576, 580 (2013).
172 *See supra* Section III(b).
173 *Myriad*, 569 U.S. at 580 (2013).
174 Lai, *supra* note 106, at 1049.
175 *Id.*
176 *Id.*
177 Case T 0870/04, Max-Planck-Gesellschaft zur Förderung der Wissenschaften e.V., ¶ 22, at 20–21 (EPO Boards of Appeal, 2005).
178 *Id.* at ¶ 21, at 20.
179 *Id.* at ¶ 22, at 21.

> patent application describes its subject invention in sufficiently meaningful technical terms that it can be expected that the exclusive rights resulting from the grant of a patent will lead to some financial or other commercial benefit.[180]

While it is not required that an applicant show actual or potential economic profit, the claimed use has to be reasonably credible.[181] The disclosure must provide a "sound and concrete" technical basis that allows a person of skill in the art to recognize the invention has a practical industrial exploitation.[182] The person of skill in the art should be able to recognize the industrial application without having to do any additional research.[183] The burden is on the applicant to demonstrate that a practical application exists for the substance. The Boards of Appeals has stated "there must be a borderline between what can be accepted, and what can only be categorized as an interesting research result which per se does not yet allow a practical industrial application to be identified."[184] Furthermore, "[e]ven though research results may be a scientific achievement of considerable merit, they are not necessarily an invention which can be applied industrially."[185] The Boards of Appeal's reasoning is similar to the United States Supreme Court's view that even "groundbreaking, innovative, or even brilliant discovery does not by itself satisfy the [patent eligibility] inquiry."[186] The U.S. and E.U., however, have developed divergent approaches to eliminating mere research discoveries from being patent eligible.

D. The Tale of the European Mouse

Similar to isolated DNA sequences, the oncomouse faced a significantly different path in the E.U. patent system than it did in the United States. While the oncomouse patent was granted in the United States less than four years after the application was filed,[187] the oncomouse faced a nineteen year battle in the European Union before the patent was issued.[188] The oncomouse patent was filed in the EU in June of 1985 and the EPO Technical Board of Appeals did not rule that the patent was valid until July 2004, less than a year before the patent would expire.[189]

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[180] Lai, *supra* note 106, at 1050 (quoting Case T 0898/05, ZymoGenetics, Inc., ¶ 4, at 12–13 (EPO Boards of Appeal, 2006).

[181] *Id.*

[182] *Id.* (citing Case T 0898/05, ZymoGenetics, Inc., ¶ 5, at 13 (EPO Boards of Appeal, 2006); Case T 0870/04, Max-Planck_Gesellschaft zur Förderung der Wissenschaften e.V., ¶ 21, at 20 (EPO Boards of Appeal, 2005)).

[183] *Id.*

[184] Case T 0870/04, Max-Planck-Gesellschaft zur Förderung der Wissenschaften e.V., ¶ 6, at 10 (EPO Boards of Appeal, 2005).

[185] *Id.* at 10–11.

[186] Myriad, 569 U.S. at 577.

[187] *See* U.S. Patent No. 4,736,866 (showing a filing date of Jun. 22, 1984 and an issuance date of Apr. 12, 1988).

[188] *Oncomouse Case Puts EPC Rules to the Test*, Managing Intellectual Property (Nov. 1, 2005) http://www.managingip.com/Article/1254868/Oncomouse-case-puts-EPC-rules-to-the-test.html.

[189] *Id.*; Case T 0315/03, The President and Fellows of Harvard College (EPO Technical Board of Appeal, 2004).

After Harvard filed for a patent on the oncomouse with the EPO in 1985, the Examination Division of the EPO denied the application in 1989 based on EPC Article 53(b), which prohibits patents on plant or animal varieties.[190] The Examination Division based the decision on an interpretation of the term "animal variety" that excluded patent protection for all animals per se.[191]t

Harvard appealed the denial to the EPO Technical Board of Appeal.[192] On appeal, the Board held that animals as a per se category are not excluded from patentability under EPC Article 53(b). The Board went on to interpret Article 53(b) as excluding only existing varieties of plants and animals and not new species engineered by biotechnology.[193] This decision is a step towards the approach adopted by the United States Supreme Court in *Chakrabarty*.[194] The Board did not grant the patent, but rather remanded the case to the Examining Division for further inquiry on whether the invention violated public ordre or morality.[195]

In 1992, the Examining Division finally granted the oncomouse patent finding that the mouse was not immoral or contrary to public policy.[196] This decision was based on the belief that the oncomouse's importance in cancer research outweighed any harm suffered to the animal.[197] This, however, was not the end of the oncomouse saga in the European Union. After the EPO announced its intention to grant the oncomouse patent, protests broke out throughout Europe. More than 200 organizations combined to support seventeen oppositions to the patent.[198] The pressure these organizations placed on the EPO led to the European Parliament revoking the oncomouse patent and banning further animal patenting until a formal policy could be established.[199]

While not officially reported, it was widely believed that the oncomouse decision was put on hold until the Biotech Directive was passed.[200] The Directive was implemented during the pendency of the opposition proceedings. Oral arguments for the opposition proceedings were held in 1995 and in 2001. The Opposition Division found that the patent's broad claims directed to non-human mammals could not be allowed under EPC Article 53(a). The Opposition Division did, however, allow narrower claims directed specifically to rodents.[201] Six of the opponents lodged an appeal of the Opposition Division's decision.[202] The Technical Board of Appeal finally held the claims limited to mice were patent eligible and fulfilled the other requirements of the EPC. Consequently, nineteen years after the application was first filed, the oncomouse patent was issued by the EPO.[203]

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190 Gitter, *supra* note 141, at 27.
191 *Id.*
192 Case T 19/90, President and Fellows of Harvard College (EPO Technical Board of Appeal, 1990).
193 Gitter, *supra* note 141, at 27–28.
194 Diamond v. Chakrabarty, 447 U.S. 303 (1980).
195 Gitter, *supra* note 141, at 28.
196 *Id.* at 29.
197 *Id.*
198 *Id.*
199 *Id.*
200 *Id.* at 30 n.216.
201 *Oncomouse Case*, *supra* note 188.
202 *Id.*
203 *Id.*; Case T 0315/03, The President and Fellows of Harvard College (EPO Technical Board of

The European oncomouse case demonstrates the European Union's progression from a restrictive view on patent eligibility of biotechnology inventions during the 1980s to a more inclusive approach to patent eligibility after the passing and implementation of the Biotech Directive. As the European Union has embraced biotechnology patents, as exemplified by the treatment of DNA sequences and the oncomouse case, the United States has moved away from their inclusive, everything under the sun made by man approach to patent eligibility and towards a more restrictive approach. The European Union passed the Biotech Directive to compete with the United States, where biotechnology was flourishing due to cases such as *Chakrabarty*. While the E.U. has now embraced this approach, the United States has taken the European Union's previously restrictive approach which hinders biotechnology development.

IV. The Patent Eligibility Flip-Flop: How the BRCA Case Exemplifies the Switch in US & EU Patent Eligibility Standards

The fate of the BRCA patents in the United States and the European Union illustrate how the two patent systems have reversed course and flip-flopped on their approach to the patent eligibility of biotechnology inventions.

A. Invalidated by the Two-Step

Myriad's BRCA patents fell victim to the *Alice/Mayo* two-step approach to patent eligibility and were invalidated for being directed to patent-ineligible subject matter. In 2013, the Supreme court invalidated Myriad's composition claims directed to the DNA sequences encoding the BRCA1 and BRCA2 genes.[204] A year later, Myriad's claims directed to diagnostic methods and nucleotide primers associated with the BRCA genes met the same fate at the Court of Appeals for the Federal Circuit.[205]

The Federal Circuit's analysis of the primer claims was guided by the Supreme Court's decision in *Myriad*.[206] According to the Federal Circuit, the primer claims are ineligible because the primers are identical to DNA sequences found in nature.[207] While Myriad argued that single-stranded DNA is patentable because it is not found in the human body, the Federal Circuit rejected this argument stating: "[A]s the Supreme Court has made clear, 'separating [DNA] from its surrounding genetic material is not an act of invention.'"[208] The Federal Circuit also found that the claimed primers possess the same function, binding to a complementary nucleotide sequence, as single stranded DNA found in nature.[209] The court stated, "[a] DNA structure with

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Appeal, 2004).

[204] Myriad, 569 U.S. at 580 (2013); *see supra* Section II(e)(iii).

[205] In re BRCA1- and BRCA2-Based Hereditary Cancer Test Patent Litigation, 774 F.3d 755 (Fed. Cir. 2014).

[206] *Id.* at 759.

[207] *Id.* at 760.

[208] *Id.* at 760 (quoting Association for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576, 591 (2013)).

[209] *Id.* at 761.

a function similar to that found in nature can only be patent eligible as a composition of matter if it has a unique structure, different from anything found in nature. Primers do not have such a different structure and are patent ineligible."[210] Consequently, the Federal Circuit held the primer claims directed to patent ineligible and, therefore, invalid.

The Federal Circuit also held Myriad's claims directed to a diagnostic method of screening for mutations in the BRCA genes by comparing a subject's BRCA gene sequence with wild-type BRCA genes invalid as being directed to patent-ineligible subject matter.[211] The court invalidated the claims based on the *Alice/Mayo* two-step analysis. Under the first step of the analysis, the Federal Circuit held that the method claims recite an abstract mental process of comparing and analyzing different gene sequences.[212] Proceeding to the second step, the court found that the elements of the claims that were not directed to ineligible subject matter were not sufficient to make the claims, as a whole, patent-eligible. The techniques used to amplify and analyze the BRCA sequences "do nothing more than spell out what practitioners already knew—how to compare gene sequences using routine, ordinary techniques."[213] In other words, the Federal Circuit did not find an inventive concept sufficient to make the claims patent eligible.

The Federal Circuit's decision was a hard blow for Myriad in light of the Supreme Court's statement made in dicta that "Myriad was in an excellent position to claim applications" of the BRCA sequences.[214] The Supreme Court's statement, however, was dismissed by the Federal Circuit. The Federal Circuit reasoned that no method claims were actually before the Supreme Court in the *Myriad* case. Furthermore, the Federal Circuit noted that the method claims contemplated to be patent-eligible in *Myriad* were narrower in scope than the claims currently before them.[215] Consequently, the method claims failed to pass the *Mayo/Alice* two-step and the court held them invalid.[216]

B. Saved by the Technical Process and the Industrial Application

Like the oncomouse, the BRCA patents faced a much different fate in the European Union. Unlike the oncomouse, however, the European Union held the BRCA patents were direct to patent eligible subject matter while the United States held the patents invalid. The BRCA patents were not strongly patented in Europe.[217] The BRCA patents were restricted by the EPO, however, on the basis of lost priority and not patent eligibility.[218] The EPO's approach to the BRCA patents was governed by a strict legislative application of the relevant parts of EPO law.[219] This approach was, again, in contrast to the United States case law governed approach to analyzing

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[210] *Id.* (internal citations omitted).
[211] *Id.* at 761–62, 764.
[212] *Id.* at 763.
[213] *Id.* at 764.
[214] Myriad, 569 U.S. at 596.
[215] *In re BRCA*, 774 at 765.
[216] *Id.*
[217] Lai, *supra* note 106, at 1062.
[218] *Id.* at 1063.
[219] *Id.* at 1057.

the eligibility of the BRCA patents. The EPO's approach to the BRCA patents is evidenced in the treatment of four separate patents.

1. *EP0705902 "17q-Linked Breast and Ovarian Cancer Susceptibility Gene*

The '902 patent claimed the BRCA1 sequence as well as short strands of the BRCA1 sequence (or probes).[220] The application claimed priority to a U.S. patent application filed on September 2, 1994[221] that contained errors in the BRCA1 sequence.[222] Fifteen of the nucleotides in the cDNA sequence in the priority application were incorrect. These errors did not result in an insertion or deletion in the amino acid sequence or result in a stop codon.[223] The Opposition Division as well as the Board of Appeal, however, applied a strict interpretation of the phrase "same invention" to conclude that there was no priority to the U.S. application as the application did not disclose the "same invention."[224] Consequently, the '902 patent was only able to claim priority to a later filed U.S. patent application (filed March 24, 1995).[225] As a result, the '902 claims were limited to the BRCA1 probes.[226]

While the claims of the '902 patent were restricted based on priority, the Board of Appeal also addressed if the claims were directed to patent eligible subject matter. The Board analyzed the claims in light of Article 52(2) of the EPC as well as the Biotech Directive. Because the probes were obtained by a technical process and were isolated elements of the human body, the Board found the probes are patentable subject matter.[227] This finding by the Board of Appeal is the opposite outcome of the Federal Circuit's decision on the eligibility of the BRCA primers in *In re BRCA*.[228]

Finally, the Board of Appeal also found that the probes have an industrial application. The probes are useful for diagnostics and can be used commercially to detect the presence of BRCA1 alleles and consequently assess an individual's risk of developing breast cancer.[229]

2. *EP0705903 "Mutations in the 17q-linked Breast and Ovarian Cancer Susceptibility Gene.*

The '903 patent claimed a method for diagnosing a predisposition for breast and ovarian cancer with respect to thirty-four mutations and their related probes.[230]

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220 *Id.* at 1058.
221 U.S. Pat. App. No. 08/300,266.
222 Case T 1213/05, Univ. of Utah Research Found. v. Sozialdemokratische Partei der Schweiz, ¶ 8, at 21 (EPO Boards of Appeal, 2007).
223 Lai, *supra* note 106, at 1057.
224 *Id.* at 1058.
225 U.S. Pat. App. No. 08/409,305.
226 Case T 1213/05, Univ. of Utah Research Found., at ¶ 34, at 41.
227 *Id.* at ¶¶ 43–45, at 46.
228 In re BRCA1- and BRCA2-Based Hereditary Cancer Test Patent Litigation, 774 F.3d 755, 760 (Fed. Cir. 2014).
229 Case T 1213/05, Univ. of Utah Research Found., at ¶ 62, at 57.
230 Lai, *supra* note 106, at 1059.

Similar to the '902 patent, however, the '903 patent claims were narrowed from a method covering thirty-four mutations to only a single frame-shift mutation and its related probe.[231] Myriad did not lose priority for the frame-shift mutation because the errors in the priority document[232] did not affect the detection of the frame-shift mutation or the nucleotides of the associated probe.[233]

The Board's reasoning when analyzing the claims of the '903 patent was very similar to their reasoning when assessing the '902 patent.[234] The Board found that the probe had been obtained through a technical process and was, therefore, an isolated element of the human body.[235] Furthermore, like the probe in the '902 patent, the Board found that the probe claimed in the '903 patent has an industrial application.[236]

3. EP0699754 "Method for Diagnosing a Predisposition for Breast and Ovarian Cancer"

The '754 patent covers methods of diagnosing a predisposition for breast and ovarian cancer based on the BRCA1 sequence.[237] The '754 was initially fully revoked in 2004 due to Myriad registering the incorrect genetic sequence, resulting in the '754 patent losing priority.[238] The Board of Appeal, however, reversed this decision when Myriad reduced the scope of their claims to only cover methods for diagnosing predisposition based on the frame-shift mutation discussed in regards to the '903 patent.[239] By narrowing of the scope of the claims corrected the priority issue with regards to diagnosis based on the frame-shift mutation. The Board distinguished this case from the case involving the '902 patent by stating that the sequence errors in the priority document did not affect the technical feature of the diagnostic method claim in the way it did the product claims in the '902 patent.[240]

Additionally, the Board upheld a long-settled understanding that diagnostic methods performed on tissue samples are patent eligible. Diagnostic methods performed on the human or animal body, however, are not patent eligible.[241]

4. EP0785216 "Chromosome 13-Linked Breast Cancer Susceptibility Gene BRCA2"

The '216 patent is the only EPO-granted patent directed to BRCA2. The claims of the '216 patent were originally granted for the gene, disease-associated mutations, as well as breast cancer-predisposing mutations.[242] The patent was narrowed,

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231 *Id.*; Case T 0666/05, Univ. of Utah Research Found. v. Institut Curie, ¶ I, at 1 (EPO Boards of Appeal, 2008).
232 *See supra* Section IV(b)(i).
233 Case T 0666/05, Univ. of Utah Research Found., ¶ VI, at 3.
234 Lai, *supra* note 106, at 1060.
235 *Id.*
236 *Id.*
237 *Id.*
238 *Id.* (citing Institut Curie v. Myriad Genetics, Inc., European Patent Office Opposition Division, Division Revoking the European Patent EP0699754 (3 Nov. 2004).
239 Case T 0080/05, Univ. of Utah Research Found. v. Institut Curie, ¶ VI, at 3–4 (EPO Boards of Appeal, 2008).
240 Lai, *supra* note 106, at 1060.
241 *Id.* at 1061.
242 *Id.*

however, to a single claim directed to a nucleic acid sequence containing a BRCA2 mutation that is associated with a predisposition to breast cancer in Ashkenzai Jewish women.[243] Because the mutation had been disclosed prior to the priority date of the '216 patent, a distinguishing technical feature was needed to overcome issues of novelty and obviousness. Because the mutation had not previously been associated with Ashkenzai Jewish women, this limitation was added as a distinguishing technical feature.[244]

While the BRCA patents were not granted strong patent protection in the European Union, this was due to lack of priority and not patent eligibility concerns.[245] The presence of a technical process for obtaining the BRCA sequences and probes, as well as their industrial application in diagnostics, was sufficient to overcome patent eligibility challenges.[246] This outcome is in stark contrast to the invalidation of the BRCA patents in the United States.

V. The Need to Harmonize U.S. and E.U. Patent Eligibility Standards

In the 1980s, the United States embraced biotechnology patents. Decisions such as *Diamond v. Chakrabarty*[247] led to the U.S. becoming the birth place of biotechnology and the biotech industry flourished in the United States. Patent eligibility in the U.S. during this time encompassed everything under the sun made by man. To determine if an invention was patent eligible courts would look to if the invention had markedly different characteristics than what was found in nature, the level of human intervention in the invention, and if the invention possessed significant utility.[248]

Conversely, while biotechnology was flourishing in the U.S., the European Union's restrictive approach to patent eligibility was hindering the development of biotechnology in Europe. Recognizing the problem, the European Union implemented the Biotechnology Directive which expanded the scope of what inventions are considered patent eligible.[249] The Biotech Directive brought the European Union's approach to patent eligibility in line with the approach taken by the United States and made it easier to obtain biotechnology patents in the E.U.[250]

The United States approach to patent eligibility, however, began to change in 2010. The Supreme Court took a sharp turn away from the inclusive approach to patent eligibility with the adoption of the *Alice/Mayo* two-step.[251] The two-step approach, which focuses on the search for an inventive concept, is restrictive in

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243 *Id.*
244 *Id.* at 1061–62.
245 *Id.* at 1061.
246 *Id.* at 1061-62.
247 447 U.S. 303 (1980).
248 *Id.*
249 Lai, *supra* note 106, at 1072–74.
250 *Id.* at 1072.
251 Mayo, 566 U.S. at 71-73.

practice, particularly when analyzing the patent eligibility of biotech inventions.[252] As a result of the *Alice/Mayo* two-step test, diagnostic patents are essentially impossible to patent in the United States without the addition of a method of treatment limitation to the diagnostic claim.[253] This is in contrast with the European Union approach that diagnostic methods are patent eligible if they are conducted on tissue samples and not directly on a human or animal body.

The European Union implemented the Biotech Directive to align more closely with the United States patent eligibility standards and be able to compete with the U.S. in the competitive field of biotechnology. During the E.U.'s shift, however, the United States modified its approach to patent eligibility in such a way that it now resembles the restrictive E.U. approach in place before the Biotech Directive. Consequently, there is again a great divergence in how the United States and the European Union approach determining what is patent-eligible subject matter.

At a time when the world is striving to harmonize patent law across the globe, it is time to, once-again, harmonize U.S. and E.U. standards for patent-eligibility. Harmonization of patent laws allows for an easier international application process and promotes a strong patent system. In a strong patent system, patent rights are granted to particular inventions in a predictable manner and patent infringement is, similarly, enforced in a predictable manner. A predictable patent system provides inventors with the ability to protect their rewards for successful inventions and to make educated decisions on where to allocate resources when developing new technologies.[254]

It is unclear, however, if the E.U. will again adjust their standards to mirror those in the United States or if the U.S. will shift to embrace its previous broad, inclusive approach to eligibility. Some in Europe may embrace the opportunity to reign in patent protection and roll back the Biotech Directive, as there is still significant opposition to biotechnology patents in Europe.[255] Similarly, in the United States, patent eligibility standards are hotly debated, with some embracing the current restrictive approach and others calling for a reform to patent eligibility standards.

In the 1980s, the European Union acknowledged the detrimental consequences of having a restrictive patent eligibility standard and responded by implementing a predictable system, with clearly outlined requirements for determining what is considered patent eligible. Were the United States—whether through legislation or

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[252] *Id.*

[253] *See e.g.*, In re BRCA1- and BRCA2-Based Hereditary Cancer Test Patent Litigation, 774 F.3d 755, 760 (Fed. Cir. 2014); Cleveland Clinic Found. v. True Health Diagnostics, LLC, 859 F.3d 1352, 1362 (Fed. Cir. 2017); Ariosa Diagnostics, Inc. v. Sequenom, Inc. 788 F.3d 1371, 1377 (2015) (invalidating diagnostic method claims). *But see* Vanda Pharm. v. West-Ward Pharm., 887 F.3d 1117, 1134 (Fed. Cir. 2018) (holding that diagnostic claims which included a method of treatment step were valid); U.S PATENT AND TRADEMARK OFFICE, MEMORANDUM FROM USPTO ON RECENT SUBJECT MATTER ELIGIBILITY DECISION: *Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals* (June 7, 2018), https://www.uspto.gov/sites/default/files/documents/memo-vanda-20180607.PDF (stating that claims containing a method of treatment should be presumed to patent eligible).

[254] Richard S. Grunner, *Why We Need a Strong Patent System and When: Filling the Void Left by the Bilski Case*, 28 SANTA CLARA HIGH TECH. L.J. 499, 543 (2012).

[255] Lai, *supra* note 106, at 1072–74.

Supreme Court precedent—to shift its current, more restrictive patent eligibility standards back to the broad, inclusive, *Chakrabarty* approach, its eligibility standards would be more in line with those in Europe. This alignment would promote strong, global patent protection and harmonize the international patent standards, and return the U.S. patent standard to one in which all things under the sun made by man are eligible for patent protection.