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I. INTRODUCTION

The biotechnology industry "stands out in its creation of high quality jobs, the breadth of markets it serves, and its research and development intensity."[1] As of 2014, the North American biotechnology industry consisted of more than 1,280 companies with a market worth greater than $200 billion.[2] Over 1.4 million jobs are directly reliant upon the biotechnology industry within the United States, with those jobs having an average salary above the national median.[3] In 2012, biotechnology companies combined to spend over $9 billion on research and development.[4]

It is this enormous investment and impact on the United States' economy that makes the biotechnology industry so important, and it must be noted that such metrics ignore the improvements in healthcare, pharmaceuticals, agriculture, and more that stem from biotechnological research. Unfortunately, this huge investment makes the biotechnology industry uniquely dependent on the patent system.[5] For example, a new pharmaceutical averages ten years and $1.8 billion to bring to the market.[6] Without the comfort of patent protection at the end of research and development, biotechnology companies would be much less willing to spend enormous sums of money and amounts of time for a resulting product that may be copied and marketed by a competitor at much lower cost.[7] Additionally, the lengthy research and development often requires funding by venture capitalists who look to the resulting patent as a way to recoup the initial investment.[8]

Despite this need for protection, there has been substantial uncertainty surrounding the eligibility of biotechnological inventions in patent law, leading many within the industry to doubt "whether meaningful patent protection remains

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1. Battelle Memorial Institute et al., *State Bioscience Industry Development 2012*, 2 (June 2012), https://www.bio.org/sites/default/files/files/v3battelle-bio_2012_industry_development.pdf.

2. John Raidt, *Patents and Biotechnology*, 11 (U.S. Chamber of Com. Found., 2014), http:www.uschamberfoundation.org/sites/default/files/article/foundation/RaidtPaper.pdf.

3. *Id.*

4. *Id.*

5. *Id.* at 16.

6. *Id.*

7. *Id.*

8. FEDERAL TRADE COMM'N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY, A REPORT BY THE FEDERAL TRADE COMMISSION, Ch. 3, p. 1 (2003) ("Biotech representatives emphasized that patent protection is critical to attract the capital necessary to fund this high-risk investment.").

available in the United States for many biotechnology inventions . . . ."[9] This uncertainty can be traced, in part, to the increasing use of judicially crafted exceptions to subject matter eligibility under Section 101 of the Patent Act as an additional functional requirement to a patent's validity.

These exceptions state that a patent may not be granted for an invention that attempts to claim a law of nature, natural phenomenon, or an abstract idea.[10] However, many years of Supreme Court precedent have led to a muddy understanding of when such exceptions apply. If the improper use of the judicial exceptions continues, an alarming number of patents are at threat of being invalidated. This effect is much more pronounced in the biotechnology industry, as the basic premise of the biotechnology industry rests upon the use of laws of nature and natural phenomena as building blocks. As a result, almost any patent claimed by the biotechnology industry is potentially at risk of being denied or invalidated.

Recently, in *Rapid Litigation Management Ltd. v. CellzDirect, Inc.*, the United States Court of Appeals for the Federal Circuit pushed back against the improper functional use of the judicial exceptions, extending a ray of hope to those in the biotechnology industry.[11] In *Rapid Litigation*, the Federal Circuit both clarified the applicable Supreme Court precedent, as well as set boundaries on the use of judicial exceptions as they relate to laws of nature or natural phenomena. This Note examines that decision, and analyzes why the Federal Circuit made the correct decision by returning the judicial exceptions to a more proper narrow scope that is in accordance with the statutory text and principles behind the patent system.

This Note begins with a brief overview of the statutory law and the precedent regarding subject matter eligibility. Next, this Note describes the patent at issue, followed by the approaches taken by the United States District Court for the Northern District of Illinois and the Federal Circuit. Both approaches are then analyzed with a discussion of why the Federal Circuit's approach properly balances both the statutory requirements and the principles behind patent law. Finally, this Note briefly discusses the fact that the patent at issue in *Rapid Litigation* claims an eligible subject matter does not necessarily make it valid under the other requirements of the Patent Act, minimizing the fears espoused in support of the judicial exceptions.

II. LEGAL BACKGROUND

Congress's power to issue patents is firmly rooted in the Constitution, which states that Congress shall have power "[t]o 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."[12] Pursuant to that power, Congress passed the Patent Act of 1793, securing exclusive rights to the inventor for

9. Brief of the Biotechnology Industry Organization as *Amicus Curiae* Supporting Neither Party at 2, Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc., 827 F.3d 1042 (2016) (No. 2015-1570). The Biotechnology Industry Organization (BIO) is the largest biotechnology trade association, including over 1,100 members worldwide, many of which are companies involved with research and development. *Id.* at 1.

10. *See, e.g.*, Mayo Collab. Servs. v. Prometheus Labs., Inc., 566 U.S. 66, 70 (2012) ("The Court has long held that this provision contains an important implicit exception. '[L]aws of nature, natural phenomena, and abstract ideas' are not patentable.") (quoting Diamond v. Diehr, 450 U.S. 175, 185 (1981)).

11. 827 F.3d 1042 (Fed. Cir. 2016).

12. U.S. CONST. art. I, § 8, cl. 8.

a period of years.[13] Since then, the Patent Act has been amended multiple times, most recently by the America Invents Act (Leahy-Smith Act) in 2011, but many sections have remained largely unchanged since the initial version penned by Thomas Jefferson.[14]

A. Section 101

Section 101 of the Patent Act states that protection may be granted for "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof . . . subject to the conditions and requirements of this title."[15] Courts have broadly construed eligibility holding that "ingenuity should receive a liberal encouragement."[16] Nonetheless, patent subject matter eligibility has been consistently limited in an important fashion: "laws of nature, natural phenomena, and abstract ideas" are not patentable.[17] These judicially-created exceptions were founded on the principle that those are "the basic tools of scientific . . . work, "[18] and a patent upon them would "risk disproportionately tying up the use of the underlying natural laws, inhibiting their use in the making of further discoveries."[19]

At the same time, the Supreme Court has also cautioned against an overbroad interpretation of these exceptions, as "all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas."[20] To immediately disqualify a patent solely on the basis that it involves a law of nature, natural phenomena, or an abstract idea would be to "swallow all of patent law."[21] In an attempt to balance these competing principles, the Supreme Court has warned that the courts should "tread carefully" while construing these implicit exceptions.[22]

B. Mayo Collaborative Services v. Prometheus Labs., Inc.

The Supreme Court was recently confronted with the scope of the judicial exceptions once again in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* ("*Mayo*"). There, the Court considered a patent claiming a method for calibrating the proper dosage of thiopurine drugs in the treatment of autoimmune diseases.[23] In invalidating the patent under Section 101, the Court found that the

13. Diamond v. Chakrabarty, 447 U.S. 303, 307-08 (1980).

14. *Id.* at 308-09.

15. 35 U.S.C. § 101 (2014). The only change to Section 101 has been the replacement of "art" with "process." *See Chakrabarty*, 447 U.S. at 309.

16. *Chakrabarty*, 447 U.S. at 308-09.

17. Diamond v. Diehr, 450 U.S. 175, 185 (1981) (citing Parker v. Flook, 437 U.S. 584 (1978); Gottschalk v. Benson, 409 U.S. 63 (1972); Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127 (1948)).

18. Gottschalk v. Benson, 409 U.S. 63, 67 (1972).

19. Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1294 (2012); *see also Funk Bros. Seed Co.*, 333 U.S. at 130 ("They are manifestations of laws of nature, free to all men and reserved exclusively to none. He who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of it which the law recognizes. If there is to be invention from such a discovery, it must come from the application of the law of nature to a new and useful end.").

20. *Id.* at 1293.

21. Alice Corp. Pty. Ltd. v. CLS Bank Intern., 134 S. Ct. 2347, 2354 (2014).

22. *Id.*

23. *Mayo*, 132 S. Ct. at 1294-95.

patent was directed to one of the judicial exceptions, a law of nature.[24] The Court determined that the patent was nothing more than a claim upon the natural relationship between the concentrations of certain metabolites in the blood and the effectiveness of a certain thiopurine drug dosage.[25] As a result, the patent lacked anything "sufficient to transform unpatentable natural correlations into patentable applications of those regularities."[26]

From *Mayo*, a two-step framework has emerged for distinguishing between a patent that claims an ineligible concept and patent-eligible inventions that build upon one of those concepts.[27] This analysis starts with an inquiry into whether the challenged patent is "directed to" one of the patent-ineligible concepts.[28] If the answer is no, then the inquiry is complete, and the invention would satisfy the subject matter requirements of Section 101.[29] If the answer is yes to the first step, however, then the Court must continue on to ask whether there is "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.'"[30]

In characterizing the patent's claim, the Court looks for an "inventive concept," considering the elements of the claim both individually and as an ordered combination.[31] Such an inventive concept "'transform[s] the nature of the claim' into a patent-eligible application."[32] This transformation requires more than "well-understood, routine, conventional activity already engaged in by the scientific community,"[33] or an "insignificant post-solution activity."[34] A failure to include this inventive concept is deemed an attempt to patent nothing more than the ineligible concept itself.[35]

The *Mayo* decision has not been free from criticism, however, with some viewing it as an overbroad interpretation of the judicial exceptions,[36] the very thing that the Supreme Court has cautioned against.[37] Further, *Mayo* lacks substantial guidance regarding when a patent is "directed to" one of the judicial exceptions, and even what is considered a "law of nature" or a "natural phenomenon."[38] This push-

24. *Id.* at 1296.
25. *Id.* at 1297.
26. *Id.* at 1298.
27. *Alice*, 134 S. Ct. at 2355.
28. *Id.*
29. *Id.*
30. *Id.* (quoting *Mayo*, 132 S. Ct. at 1294).
31. *Id.* at 2355 (quoting *Mayo*, 132 S. Ct. at 1297).
32. *Id.* (quoting *Mayo*, 132 S. Ct. at 1297).
33. *Mayo*, 132 S. Ct. at 1298.
34. Diamond v. Diehr, 450 U.S. 175, 191 (1981).
35. Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc., 827 F.3d 1042, 1050 (Fed. Cir. 2016).
36. *See* Rebecca S. Eisenberg, *Diagnostics Need Not Apply*, 21 B.U. J. SCI. & TECH. L. 256, 264-66 (2015) (discussing the Supreme Court's "expansive approach" to the identification of laws of nature and natural phenomenon); Philip Merksamer, *Ariosa Diagnostics v. Sequenom: Metastasis of Mayo and Myriad and the Evisceration of Patent Eligibility for Molecular Diagnostics*, 31 BERKLEY TECH. L. J. 495, 509 (2016) ("The Court's cavalier use of the 'law of nature' exception has thus broadened its scope beyond [its] original description. Depending on how lower courts apply *Mayo*, the 'law of nature' exception may encompass any relationship that that arises from a natural process . . . .").
37. *Mayo*, 132 S. Ct. at 1293 (stating that "too broad an interpretation of this exclusionary principle could eviscerate patent law.").
38. *See id.* at 1296-97 (determining the patent is directed to a law of nature without defining "law of nature").

and-pull over the scope of the judicial exceptions also encompasses a debate about whether Section 101 is properly used as a jurisdictional limitation on patents, or a functional limitation that should be used to test their validity.[39] Under a jurisdictional approach, Section 101 provides the "doctrine that maps the boundaries and the patent laws," while under the functional view, Section 101 is used as "a tool for testing the validity of the claims of individual patents."[40] These differing approaches to the scope of Section 101 can be seen underlying the varying applications of the *Mayo* test in the case presented below.

C. Section 103

Moving beyond Section 101, the Patent Act includes several substantive requirements under Sections 102, 103, and 112. Thus, even if a claim is potentially eligible for patent protection under Section 101, the claim must also satisfy the other "conditions and requirements of [the Patent Act]."[41] Sections 102 and 112 are not discussed in this Note, but a brief discussion of obviousness under Section 103 helps visualize the implications of the Federal Circuit's decision.[42]

Under Section 103, "[a] patent for a claimed invention may not be obtained . . . if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious . . . to a person having ordinary skill in the art to which the claimed invention pertains."[43] The Supreme Court has further expanded upon the statutory text, looking at the "scope and content of the prior art," the "differences between the prior art and the claims," and "the level of ordinary skill in the pertinent art."[44]

In 2007, the Supreme Court revised its obviousness jurisprudence in *KSR International Co. v. Teleflex, Inc.*, requiring that a patent seeking to improve upon a prior process "is more than the predictable use of prior art elements according to their established functions."[45] Such an improvement is considered predictable if "a person of ordinary skill has good reason to pursue the known options within his or her technical grasp."[46] If the improvement "only unites old elements with no change in their respective function . . . [and] obviously withdraws what already is known into the field of its monopoly,"[47] that is a "principal reason"[48] for finding the patent obvious.

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39. *See generally* David Swetnam-Burland & Stacy O. Stitham, *Patent Law 101: The Threshold Test as Threshing Machine*, 21 TEX. INTELL. PROP. L. J. 135 (2013).

40. *Id.* at 136.

41. 35 U.S.C. § 101 (2014).

42. The District Court noted that there was a challenge to the '929 Patent under Section 112, but did not decide the issue as it "dispatched the '929 Patent under Section 101, and that [was] enough." Celsis In Vitro, Inc. v. CellzDirect, Inc., 83 F. Supp. 3d 774, 786 (N.D. Ill. 2015). The Federal Circuit did not discuss specificity under Section 112 on appeal. *See generally* Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc., 827 F.3d 1042 (Fed. Cir. 2016) (not discussing specificity within its decision).

43. 35 U.S.C. § 103 (2014).

44. *See* Graham v. John Deere Co., 383 U.S. 1, 17 (1965).

45. KSR Int'l. Co. v. Teleflex Inc., 550 U.S. 398, 417 (2007).

46. *Id.* at 421.

47. *Id.* at 416 (quoting Great Atl. & Pac. Tea Co. v. Supermarket Equip. Corp., 340 U.S. 147, 152-53 (1950)).

48. *Id.*

While the decision within *KSR* encompasses much more, the patent at issue in this Note sought to improve upon a process present within the prior art. Therefore, for the purpose of discussing the obviousness of the patent within this Note, this brief overview will provide the basic framework for analysis.

III. THE PATENT

Celsis In Vitro, Inc. ("*Celsis*") was granted U.S. Patent No. 7,604,929 ("'929 Patent"), entitled "Cellular Compositions and Methods for Their Preparation," on October 20, 2009.[49] Broadly, the '929 Patent recites a claim for an "invention concern[ing] methods of processing preparations of such cells so as to permit their repeated cryopreservation and thawing while retaining substantial viability."[50]

Hepatocytes are a type of liver cell that make up between sixty to eighty percent of the liver's mass,[51] and are commonly used in biological and biopharmaceutical research. Hepatocytes have a multitude of functions[52] that make them especially useful for exploring the mechanisms and predicting the results of drug metabolism.[53] Hepatocytes have also shown a potential to be used in cell transplantations in order to provide liver functions to individuals with liver failure, and in the creation of Bioartificial livers.[54]

All these uses, however, are limited by an insufficient and inconsistent supply of hepatocytes.[55] Hepatocytes can only be obtained from liver resections, or non-transplantable, healthy livers.[56] Cryopreservation has provided somewhat of an answer to this insufficient supply, allowing for the storage of hepatocytes over longer periods of time, but the freezing of hepatocytes typically results in a dramatic decrease in the number of viable cells recovered following thawing.[57] If the hepatocytes are nonviable following thawing, there is a loss of cellular function that makes them essentially useless. This loss of viability, and the following inability to store hepatocytes for later use, is ultimately what led Celsis to the discovery claimed by the '929 Patent.

While the '929 Patent includes a multitude of claims, the first claim is sufficient to represent the invention as discussed in this Note. The first claim sets forth the following steps:

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49. U.S. Patent No. 7, 604, 929 (issued Oct. 20, 2009).

50. *Id.* at [57]. The '929 patent also includes claims that specify the hepatocytes are to be selected from various sources and pooled together, and then subjected to the cryopreservation process. *Supra* note 26. These claims, however, are dependent on the overlying cryopreservation process, and the District Court found it "undisputed that a determination that Claim 1 is invalid dooms all of those dependent claims." Celsis In Vitro, Inc. v. CellzDirect, Inc., 83 F. Supp. 3d 774, 780 (N.D. Ill. 2015), *supplemented by* 94 F. Supp. 3d 940.

51. '929 Patent at col. 1 ll. 16-17.

52. Hepatocytes play a key role in detoxification, modification, and excretion of substances that originate from both within and outside the cell. *Id.* at col. 1 ll. 17-20. Other functions include protein synthesis, protein storage, the transformation of carbohydrates, and the synthesis of cholesterol, bile salts, and phospholipids. *Id.* at col. 1 ll. 25-27.

53. *Id.* at col. 1 ll. 37-58.

54. *Id.* at col. 1 ll. 59-63.

55. *Id.* at col. 2 ll. 22-25.

56. *Id.* at col. 2 ll. 25-27.

57. *Id.* at col. 3 ll. 5-8.

> (A) subjecting hepatocytes that have been frozen and thawed to density gradient fractionation to separate viable hepatocytes from non-viable hepatocytes;
>
> (B) recovering the separated viable hepatocytes; and
>
> (C) cryopreserving the recovered viable hepatocytes to thereby form said desired preparation of hepatocytes without requiring a density gradient step after thawing the hepatocytes for the second time, wherein the hepatocytes are not plated between the first and second cryopreservations, and wherein greater than 70% of the hepatocytes of said preparation are viable after the final thaw.[58]

In essence, the '929 Patent process takes a pool of hepatocytes that have been subjected to the previously known freeze-thaw cycle, and then separates out the viable and nonviable cells by utilizing density gradient centrifugation,[59] resulting in a pool of viable hepatocytes that have demonstrated an ability to withstand the cryopreservation process. That pool of hepatocytes is then cryopreserved once again, relying on the discovery that hepatocytes that survive one cryopreservation are more likely to be able to withstand a second round of the freeze-thaw cycle. This process is stated to result in a pool of hepatocytes that will exhibit greater than seventy percent viability when thawed for the second time, without the use of another gradient centrifugation separation.[60] Celsis believed this was a significant improvement over the prior art which allowed hepatocytes to only be frozen once before they were required to be used or discarded.[61] This process allows for the creation of a pool of frozen, but viable, hepatocytes that may be sold for research purposes.[62]

IV. THE CASE

A. A Long History of Litigation

Since its grant, the '929 Patent has been the subject of a long court battle over the patent's validity and the possibility of infringement. Celsis originally filed an action for patent infringement against CellzDirect, Inc. and Invitrogen Corp. (collectively "LTC")[63] in June 2010.[64] Following the initial filing, both Celsis and LTC filed multiple motions, resulting in litigation spanning more than five years.

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58. *Id.* at col. 19 ll. 62-64, col. 20 ll. 12-19.

59. Density gradient centrifugation separates out cells on the basis of their density. Here, the '929 Patent employs Percoll density gradient centrifugation, a process which was first published in 1978. *See* Hakan Pertoft et al., *Density Gradients Prepared from Colloidal Silica Particles Coated By Polyvinylpyrrolidone (Percoll)*, 88 ANALYTICAL BIOCHEMISTRY, at 271 (1978).

60. '929 Patent at col. 2 ll. 13-20.

61. Celsis In Vitro, Inc. v. CellzDirect, Inc., 83 F. Supp. 3d 774, 777-78 (N.D. Ill. 2015).

62. *Id.* at 778.

63. CellzDirect, Inc. and Invitrogen Corporation were named defendants in the original suit brought by Celsis In Vitro, Inc. CellzDirect and Invitrogen merged with a third corporation to create Life Technologies Corporation (LTC), as they are referred to by both the District Court and the Federal Circuit. Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc., 827 F.3d 1042, 1046 n.1 (Fed. Cir. 2016).

64. *Celsis In Vitro Inc.*, 83 F. Supp. 3d at 780.

But within that period, neither the District Court, nor the Federal Circuit, definitively ruled on the validity of the '929 Patent.[65] Finally, in March 2015, the United States District Court for the Northern District of Illinois provided such a ruling.[66]

B. The District Court's Opinion

In the pendency of the litigation over the '929 Patent, the Supreme Court decided both *Mayo* and *Alice*, ultimately providing the District Court with "the roadmap" for determining the validity of the '929 Patent.[67] Utilizing the *Mayo* test, the District Court invalidated the '929 Patent on the grounds that "[d]iscovery of a natural law simply does not qualify as patentable subject matter; nor does any other part of the '929 [P]atent's claims display the requisite inventiveness to satisfy § 101."[68]

Following the first step of the *Mayo* test, the District Court looked to determine whether the '929 Patent was directed to one of the patent ineligible concepts, a law of nature, natural phenomenon, or an abstract idea.[69] The District Court based its approach to the first step of the *Mayo* test on the USPTO's 2014 Interim Eligibility Guidance, which provided that a claim is "directed to a judicial exception when a law of nature, a natural phenomenon, or an abstract idea is recited (i.e., set forth or described) in the claim."[70] Using this, the District Court was quick to characterize the ability of hepatocytes to survive multiple freeze-thaw cycles as a recited law of nature.[71] That determination was deemed sufficient to conclude that the '929 Patent was directed to one of the patent ineligible concepts, satisfying step one of the *Mayo* test.[72]

In searching for the "requisite inventive concept" under step two, the District Court was seemingly unimpressed with the simplicity of the repetition utilized by the '929 Patent, determining that it was a "straightforward application of the truth that hepatocytes are inherently capable of surviving multiple freeze-thaw cycles."[73] Celsis argued that as the prior art of cryopreserving "taught away from multiple freezings," the repetition of the cryopreservation process must be considered inventive.[74] Relegated to a footnote by the District Court, Celsis supported this contention with a Western District of Wisconsin ruling stating that "if inventors engage in activities that run counter to scientific thought, those activities can hardly be considered conventional under § 101."[75] The Illinois District Court in *Celsis* properly noted that such a case carries no precedential value, but then moved to distinguish the Wisconsin case by stating that the patent at issue "creatively marshaled techniques that no scientist would have thought to apply to the particular field at the time."[76] In contrast, the District Court believed that the "'929 Patent

65. *Id.* at 780-81.
66. *See generally id.* at 774.
67. *Id.* at 781 n.4.
68. *Id.* at 786.
69. *Id.* at 783.
70. 2014 Interim Guidance on Patent Subject Matter Eligibility, 79 Fed. Reg. 74,622 (Dec. 16, 2014)).
71. *Celsis In Vitro Inc.*, 83 F. Supp. 3d at 783.
72. *Id.*
73. *Id.* at 784.
74. *Id.*
75. *Id.* at 784 n.7 (quoting Ameritox, Ltd. v. Milennium Health, L.L.C., 88 F. Supp. 3d 885, 907 (W.D. Wis. 2015)) (emphasis omitted).
76. *Id.*

directly follow[ed] from the discovery of a law of nature . . . and the patent directs the employment of methods that were routinely used in the prior art for precisely the same purpose . . . ."[77]

Following its failed search for an inventive concept, the District Court held that the '929 Patent recited a claim for nothing more than "the natural fact that, in a normal population of hepatocytes . . . some sub-population is capable of surviving the process of being frozen and thawed at least two times."[78] The discovery of the fact is then followed by a process that applies "only well-understood, routine, and conventional cell separation and cryopreservation steps admittedly in common use long before the time of the claimed inventions."[79] As a consequence, the District Court invalidated the '929 Patent as ineligible subject matter under Section 101.[80]

By disposing of the claim under the *Mayo* test, the District Court mentioned, but did not analyze, the patent under the machine-or-transformation test,[81] a commonly used test to help determine subject matter eligibility. The machine-or-transformation test looks to the "[t]ransformation and reduction of an article 'to a different state or thing' [as] the clue to the patentability" of an invention.[82] That test is considered an "important and useful clue," but the Supreme Court has "neither said nor implied that the test trumps the 'law of nature' exclusion."[83]

The District Court also noted that it was careful in its opinion not to confuse the requisite inventive concept under step two of the *Mayo* test with the novel and nonobviousness requirements under Sections 102 and 103.[84] In an additional brief note, the District Court recognized that the '929 Patent was "somewhat unique," in that despite the lack of inventive concept, the patent was more narrowly drawn than the patent at issue in *Mayo*, as it did not "lock up the natural law in its entirety."[85] However, the District Court believed that LTC's ability to "engineer around the patent" was not sufficient to overcome preemption concerns, as the ability to patent even a narrow set of routine steps would allow claims for other narrow, routine combinations of steps, eventually resulting in the patenting of the natural law in its entirety.[86]

C. Appeal to the Federal Circuit

On appeal, the Federal Circuit reversed and remanded the case in a unanimous opinion, holding that the '929 Patent was simply not directed to a law of nature.[87] At

77. *Id.*

78. Celsis In Vitro, Inc. v. CellzDirect, Inc., 94 F. Supp. 3d 940, 940-41, *supplementing Celsis In Vitro, Inc.*, 83 F. Supp. 3d 774 (N.D. Ill. 2015).

79. *Id.*

80. *Celsis In Vitro, Inc.*, 83 F. Supp. 3d at 786.

81. *Id.* at 784.

82. Gottschalk v. Benson, 409 U.S. 63, 70 (1972).

83. Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1303 (2012) (emphasis omitted).

84. *Celsis In Vitro, Inc.*, 83 F. Supp. 3d at 784-85.

85. *Id*. at 785.

86. *See id.* The District Court's opinion also briefly touched upon patent specificity and definiteness under Section 112, but ultimately chose not to decide the issue, as "[w]hat ha[d] gone before ha[d] dispatched the #929 Patent under Section 101, and that [was] enough." *Id.* at 786.

87. *See* Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc., 827 F.3d 1042, 1047 (Fed. Cir. 2016).

step one, the Federal Circuit looked beyond the recitation or description of a law of nature. Instead, the Federal Circuit looked to the essence of the patent as a whole to determine that the '929 Patent was "directed to a new and useful method of preserving hepatocytes."[88] In coming to this result, the Federal Circuit distinguished multiple cases in which it, and the Supreme Court, had determined that patents were directed to an ineligible judicial exception.[89]

One such case, *Ariosa Diagnotics, Inc. v. Sequenom, Inc.*, claimed a method for detecting "paternally inherited cffDNA [cell-free fetal DNA]" in the blood or serum of pregnant women.[90] There, the Federal Circuit invalided the patent as claiming a natural phenomenon: the existence and location of the cffDNA.[91] At step two, the Federal Circuit concluded that the *Ariosa* claim was directed to the existence of cffDNA, an ineligible concept under the judicial exceptions.[92] The Federal Circuit determined that that was instantly distinguishable from the present case, as the "end result of the '929 patent claim[] is not simply an observation or detection . . . [r]ather, the claims [were] directed to a new and useful laboratory technique for preserving hepatocyte cells."[93]

LTC put forth an argument that a focus on the patent's claimed application of the hepatocytes' ability to survive multiple freeze-thaw cycles would be an improper "shoehorn[ing]" of the step two analysis into the first step.[94] Instead, LTC argued that the first step of the *Mayo* test solely focuses upon whether the patent claims a natural law or phenomenon, ignoring the actual application of that claim.[95] The Federal Circuit summarily rejected this argument, stating that LTC's approach would "'eviscerate patent law'"[96] by precluding the patenting of any invention that "touches on something natural."[97]

While the determination that the '929 Patent was not directed towards an ineligible concept at step one was sufficient to dispose of LTC's claims, in dicta, the Federal Circuit continued to analyze the '929 Patent under step two of the *Mayo* test.[98] Again disagreeing with the District Court, the Federal Circuit determined that the '929 Patent would still be valid under step two.[99] In particular, the Federal Circuit looked to the Supreme Court's statement that claims "'directed to' a patent-ineligible concept, yet also 'improv[ing] an existing technological process,' are sufficient to 'transform[] the process into an inventive application' of the patent-ineligible concept."[100] The Federal Circuit was not swayed by LTC's attempted argument that all of the steps involved in the '929 Patent were previously known and well-understood. While the Federal Circuit did acknowledge that both the individual steps

88. *Id.* at 1048.

89. *Id.*

90. Ariosa Diagnotics, Inc. v. Sequenom, Inc., 788 F.3d 1371, 1373 (Fed. Cir. 2015), *cert. denied*, 2016 U.S. LEXIS 4087 (2016).

91. *Id.* at 1376.

92. *Id.* at 1376.

93. Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc., 827 F.3d 1042, 1048 (Fed. Cir. 2016).

94. *Id.* at 1050.

95. *Id.*

96. *Id.* (quoting Mayo, 132 S. Ct. at 1293).

97. *Id.*

98. *Id.*

99. *Id.*

100. *Id.* (quoting Alice Corp. Pty. Ltd. v. CLS Bank Intern., 134 S. Ct. 2347, 2358 (2014)) (alterations in original).

of the freeze-thaw cycle, and the ordered combination of one freeze-thaw cycle, were routine and conventional, the repetition of the entire cryopreservation process for a second time was sufficiently inventive.[101]

Returning to *Ariosa*, the Federal Circuit once again distinguished between the two patents, stating that because the *Ariosa* patent used "steps of preparing, amplifying, and detecting genetic sequences [that] were already being done," the only difference was the steps being completed on the newly discovered cffDNA.[102] The '929 Patent, on the other hand, included a new process, even if the individual steps and ordered combination were previously known.[103] In particular, the Federal Circuit looked to prior art having taught away from multiple freezings, and utilizing methods with only one freeze-thaw cycle.[104] From this, the Federal Circuit found that the inventors of the '929 Patent discovered that some hepatocytes are able to survive multiple rounds of cryopreservation, and then applied a new and improved method for preserving those hepatocytes.[105] The Federal Circuit cautioned that to require any more from an inventor would be to "discount the human ingenuity that comes from applying a natural discovery in a way that achieves a 'new and useful end.'"[106]

The Federal Circuit ended its opinion on two final notes. First, the Federal Circuit addressed the ease of execution or obviousness of application, noting—as did the District Court—that those principles are examined under separate provisions of the Patent Act and beyond the scope of Section 101.[107] Second, the Federal Circuit made it clear that preemption "is not the test for determining patent-eligibility," but accepted the District Court's findings that the '929 Patent does not lock up the natural law in entirety as evidenced by LTC's ability to engineer around the patent.[108]

D. Looking to the Supreme Court

In illustrating the difference between an invalid patent directed towards a law of nature and the '929 Patent, the Federal Circuit used its prior decision in *Ariosa v. Sequenom*.[109] That case is of particular interest due to the differing opinions of the judges expressed in the denial of a rehearing *en banc*.

In a concurring opinion to the denial, Judge Lourie, joined by Judge Moore, expressed disappointment with the outcome of the case, but believed that under current Supreme Court precedent they were bound to such a result.[110] In a separate concurring opinion, Judge Dyk stated a belief that the *Mayo* test was too restrictive, but also believed that the Federal Circuit was "bound by the language of *Mayo*, and any further guidance must come from the Supreme Court, not [the Federal Circuit]."[111] A final dissenting opinion by Judge Newman took a more narrow

101. *Id.* at 1051-52.
102. *Id.* at 1051.
103. *Id.*
104. *Id.*
105. *Id.*
106. *Id.* at 1051-52 (quoting Alice Corp. Pty. Ltd. v. CLS Bank Intern., 134 S. Ct. 2347, 2354 (2014)).
107. *Id.* at 1052.
108. *Id.*
109. *Id.* at 1048-50.
110. Ariosa Diagnostics, Inc. v. Sequenom, Inc., 809 F.3d 1282, 1286-87 (Fed. Cir. 2015) (Lourie, J., concurring) (denial of rehearing *en banc*).
111. *Id.* at 1287 (Dyk, J., concurring).

approach to the *Mayo* test, believing that the "[p]recedent does not require that all discoveries of natural phenomena or their application in new ways or for new uses are ineligible for patenting; the [Supreme] Court has cautioned against such generalizations."[112]

These conflicting opinions help exemplify the internal unrest within the Federal Circuit regarding the application of the *Mayo* test and the scope of the judicial exceptions. This underscores the guidance needed not only by the District Courts and Federal Circuit, but also those who would seek to patent an invention resting upon a law of nature, natural phenomenon, or abstract idea.

On June 27, 2016, the Supreme Court denied certiorari for *Ariosa*, leaving the Federal Circuit's plea for guidance unanswered.[113]

V. ANALYSIS

This case presented differing conclusions to the *Mayo* test at both steps, as well as the scope of Section 101. The following analysis is broken down into the steps of the *Mayo* test, including a discussion of why the Federal Circuit's approach better exemplifies the principles and scope of the judicial exceptions, and a final word on the potential validity of the '929 Patent under Section 103.

A. "Directed to"

The first step of the *Mayo* test requires a court to determine whether the patent is directed towards one of the patent ineligible concepts, a law of nature, natural phenomenon, or abstract idea.[114] The District Court's approach to this step solely asked whether there was a judicial exception recited or described within the patent claim. As soon as that determination was made, it was considered sufficient to move to step two's search for an inventive concept. The Federal Circuit, on the other hand, looked to the essence of the patent as a whole to determine what it was that the inventors were seeking to protect. The Federal Circuit showed more of a concern with what the inventors were seeking to "tie up" with the grant of the patent, rather than the bare wording of the patent. Of the two, the Federal Circuit's "essence of the patent" approach stays the most faithful to the principles leading to the creation of the judicial exceptions in the first place.

The judicial exceptions were created to prevent the improper monopolization of the "basic tools of scientific and technological work."[115] If the patent doesn't seek to do just that—or actually do that—then the principles guiding the exceptions are moot as applied to that patent. This is not to say that the District Court was incorrect in asserting that the patent recites or describes one of the judicial exceptions—regardless of the dubious labelling as a "law of nature"—but the Supreme Court has cautioned against "mak[ing] the determination of patentable subject matter depend simply on the draftsman's art . . . ."[116] Such a bare analysis does not serve the principles behind the judicial exceptions, and encourages strategic drafting of patent

112. *Id.* at 1294 (Newman, J., dissenting).

113. Ariosa Diagnostics, Inc., v. Sequenom, Inc., 788 F.3d 1371 (Fed. Cir. 2015), *cert. denied*, 136 S. Ct. 2511 (2016).

114. Alice Corp. Pty. Ltd. v. CLS Bank Intern., 134 S. Ct. 2347, 2355 (2014).

115. Gottschalk v. Benson, 409 U.S. 63, 67 (1972).

116. *See* Parker v. Flook, 437 U.S. 584, 593 (1978).

applications to simply avoid stating a natural law or phenomenon. The first step of the *Mayo* test doesn't ask whether the patent includes or rests at some level upon a judicial exception—it asks whether the patent is *directed to* that exception. It is true that the '929 Patent does, at some level, rest upon the hepatocytes' natural characteristics, but the essence of the patent as a whole is not that ability. It is a discreet process used to preserve those hepatocytes which are capable of surviving multiple rounds of cryopreservation. The underlying natural ability of the hepatocytes is necessary for the method to operate, but it is in no way the essence of the patent, nor is that what the inventors sought to protect.

Inventions within the biotechnology industry will almost invariably will rest upon some law of nature or natural phenomenon. That is the fundamental basis of biotechnology: taking the natural world, understanding it, and manipulating it. Patents exist to encourage that innovation through the grant of an exclusive right to exclude others from making, using, or selling the invention. The judicial exceptions were created to prevent the "monopolization of [the laws of nature, natural phenomenon, and abstract ideas] through the grant of a patent [that] might tend to impede innovation more than it would tend to promote it."[117] However, an overbroad application of those same exceptions would cause the same barrier to innovation that the exceptions were created to prevent, and the Supreme Court has consistently cautioned as such.[118] Step one of the *Mayo* test should be the selective gatekeeper to the judicial exceptions, weeding out those patents that truly do attempt to claim an impermissible building block from those that merely "embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas,"[119] but the District Court's approach would turn it into a waterfall. Such an approach would lead to a high volume of patents being tested for "sufficient inventiveness" under Section 101 and the *Mayo* test, a section that is only supposed to set forth the boundaries for patent eligibility. If the '929 Patent is not deserving of protection because it lacks an improvement over the prior art, or because it is too simple, such a determination is properly the domain of an obviousness determination under Section 103, not a subject matter eligibility analysis under Section 101.

The Federal Circuit provided guidance on step one of the *Mayo* test in a way that stays true to the fundamental principles underlying the judicial exceptions, but also allows for an application with teeth when necessary. In sum, the Federal Circuit was apt in stating: "'an invention is not rendered ineligible for patent simply because it involves' one of the patent-ineligible concepts . . . to preclude the patenting of an invention simply because it touches on something natural would 'eviscerate patent law.'"[120] Under the Federal Circuit's precedent set here, this should be prevented from happening.

B. Searching for an Inventive Concept

The analysis of the second step of the *Mayo* test must start with a caveat. As the '929 Patent was properly determined to not be directed towards a law of nature under

117. Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1293 (2012).

118. *Id.*; *see also Alice*, 134 S. Ct. at 2354; Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2116 (2013).

119. *Mayo*, 132 S. Ct. at 1293.

120. Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc., 827 F.3d 1042, 1050 (Fed. Cir. 2016) (quoting *Alice*, 134 S. Ct. at 2354).

step one of the *Mayo* test, the Federal Circuit's approach to step two of the *Mayo* test came as dicta. While this portion of the opinion is not precedential, the following uses the Federal Circuit's reasoning regarding the '929 Patent to demonstrate why this approach should continue to be applied.

Under the second step of the *Mayo* test, the reviewing court must look to whether a patent that has properly been determined to be directed to one of the judicial exceptions includes a sufficient "inventive concept." This ensures that the patent is more than a claim for the ineligible concept itself. In order to be considered an inventive concept, the patent must claim more than a "well-understood, routine, conventional activity already engaged in by the scientific community."[121] Instead, the invention must be "sufficient to 'transform[ ] the process into an inventive application' of the patent-ineligible concept."[122]

The District Court believed the "patented process lack[ed] the requisite inventive concept."[123] The repetition of the known steps of the cryopreservation process was not considered sufficiently inventive by the District Court to overcome what it believed as the bare truth that the '929 Patent was really an attempt to patent the hepatocytes' underlying natural ability.[124] In contrast, the Federal Circuit saw Celsis's new technique as a process that improved the prior art.[125] The Federal Circuit was quick to accept that both the individual steps and the ordered combination of steps were already known, but deemed that the second repetition was "far from routine and conventional."[126]

While it is true that the ability of certain hepatocytes to survive the second freeze-thaw cycle is a natural characteristic that should be beyond the scope of any patent, it is also important to recognize that the '929 Patent does not stake a claim to that ability. Once again, the principle behind the creation of the judicial exceptions is relevant—that no patent improperly tie up the "building blocks of human ingenuity."[127] The District Court's approach did not focus on that principle; instead, the District Court focused on a perceived simplicity of the method and the obviousness of the steps taken. By doing so, the District Court was asking for more than should be required under Section 101.

Section 101 states that a patent may be granted for any "new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof . . . *subject to the conditions and requirements of this title*."[128] Nowhere within that statutory language are any references to the simplicity of an invention or the obviousness to a person skilled in the art. As the Supreme Court has stated, "[t]he obligation to determine what type of discovery is sought to be patented must precede the determination of whether that discovery is, in fact, new or obvious."[129] Thus, a question of novelty "is of no relevance in determining whether the subject matter of a claim falls within the § 101 categories of possibly patentable subject matter."[130] In

121. *Mayo*, 132 S. Ct. at 1298.
122. *Rapid Litig*., 827 F.3d at 1050 (quoting *Alice*, 134 S. Ct. at 2358).
123. Celsis In Vitro, Inc. v. CellzDirect, Inc., 83 F. Supp. 3d 774, 783 (N.D. Ill. 2015).
124. *Id.* at 784.
125. *Rapid Litig*., 827 F.3d at 1050.
126. *Id.* at 1051.
127. *Alice*, 134 S. Ct. at 2354.
128. 35 U.S.C. § 101 (2014) (emphasis added).
129. Parker v. Flook, 437 U.S. 584, 593 (1978).
130. Diamond v. Diehr, 450 U.S. 175, 188-89 (1981).

the same vein, neither is a question of obviousness relevant to the subject matter analysis.[131]

The second step of the *Mayo* test asks only whether "the elements of each claim both individually and 'as an ordered combination'" are sufficient to "'transform the nature of the claim' into a patent eligible application."[132] This does not ask for a determination of whether that transformation would be obvious to someone within the scientific community should they have been the one to discover the underlying natural principle, nor does it ask if the invention is novel. Such an analysis is properly performed under the other "conditions and requirements of" the Patent Act—Sections 102, 103, and 112.[133] The Federal Circuit toed that line very carefully, but ultimately stayed within the ambit of Section 101. Such an approach, even if seemingly unnecessarily formalistic, should wisely be carried forward.

C. Freeze, Thaw, Repeat

As alluded to above, just because the '929 Patent is eligible subject matter under Section 101 does not mean that the patent is necessarily valid. In fact, the '929 Patent should be tested for obviousness under Section 103. While an in-depth discussion of the obviousness standard is beyond the scope of this Note, it is briefly touched upon here because it aids in exemplifying that just because a patent is eligible under Section 101, this does not mean that the patent is valid, and that the Patent Act provides for such situations.

The obviousness of the '929 Patent was actually addressed by the Federal Circuit in an affirmation of a preliminary injunction determining that Celsis had a likelihood of success on the merits in regards to an obviousness challenge to the '929 Patent.[134] However, there was never a definitive ruling on the merits of the '929 Patent under Section 103. Instead, the main legal challenge ended up being focused on Section 101. Further, both the District Court and the Federal Circuit, in their respective opinions, stated that they were careful not to tread on the requirements of Sections 102 and 103.[135]

Dissenting to the Federal Circuit's affirmation of the preliminary injunction, Judge Gajarsa stated that proof of "obviousness does not require that each element of the claimed invention must be present in the prior art," but even if such a standard was required, every element was present.[136] According to Judge Gajarsa, the invention can be broken down into three steps: "(1) thawing cryopreserved hepatocytes; (2) using density gradient fractionation to separate viable and non-viable cells; and (3) refreezing and rethawing the hepatocytes."[137] Each of those steps were known previously to an ordinary person skilled in the art—Celsis's own expert testified as such.[138] In analyzing the effect of such testimony, it must be noted

131. *Flook*, 437 U.S. at 593 (1978) ("The obligation to determine what type of discovery is sought to be patented must *precede* the determine of whether the discovery is . . . new or obvious.") (emphasis added).

132. *Alice*, 134 S. Ct. at 2355 (citation omitted).

133. *See* 35 U.S.C. §§ 102 (novelty), 103 (obviousness), 112 (specification).

134. *See* Celsis In Vitro, Inc. v. CellzDirect, Inc., 664 F.3d 922, 929 (Fed. Cir. 2012).

135. *See* Celsis In Vitro, Inc. v. CellzDirect, Inc., 83 F. Supp. 3d 774, 784 (N.D. Ill. 2015); Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc., 827 F.3d 1042, 1052 (Fed. Cir. 2016).

136. *Celsis In Vitro, Inc.*, 664 F.3d at 933 (Gajarsa, J., dissenting).

137. *Id.*

138. *Id.*

that the Federal Circuit itself has stated that a simple repetition of known steps "until success is achieved" can support a finding of obviousness.[139]

Even more, the Supreme Court has remarked that an "obviousness analysis cannot be confined by . . . overemphasis on the importance of published articles and the explicit content of issued patents."[140] Instead, "a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ."[141] A person skilled in cryopreservation, would be able, upon realizing that a subset of hepatocytes can survive multiple rounds of cryopreservation, to complete a simple repetition of routine, well-understood steps. Such an invention is a "product not of innovation but of ordinary skill and common sense,"[142] and should have been properly determined to be obvious under Section 103 despite its eligibility under Section 101. If the repetition of steps was to be deemed obvious, all that would remain is the discovery that a certain subset of hepatocytes can survive multiple rounds of cryopreservation. On its own, that discovery would be insufficient to support a patent, and could properly be denied as directed towards a law of nature or natural phenomenon.

That fact notwithstanding, the '929 Patent was not faced with such a challenge, and this is now a moot point. However, an acknowledgement that the '929 Patent may have been invalid under Section 103 helps affirm that a limited application of Section 101's subject matter eligibility requirement does not necessarily mean that a flood of simplistic patents—tying up all of nature—will result. Instead, this limited application would require courts to confine the analysis of patents to the proper section of the Patent Act, providing clarity in what is required for a valid patent to be granted in the biotechnology industry.

VI. CONCLUSION

With this opinion, the Federal Circuit has properly limited the application of the *Mayo* test. This limited use of the judicial exceptions underlines that "[t]he rule that the discovery of a law of nature cannot be patented rests . . . on the [] fundamental understanding that they are not the kind of 'discoveries' that the [Patent Act] was enacted to protect."[143] Continued application of the Federal Circuit's new guidance will lead to a much lower likelihood that patents in the biotechnology industry will be improperly invalidated under Section 101.

Moving forward, this should result in courts being much more hesitant to quickly "discount the human ingenuity that comes from applying a natural discovery"[144] by declaring it ineligible under Section 101. This approach should give those within the biotechnology industry renewed hope that the Federal Circuit has begun questioning the use of Section 101 as a functional barrier to patentability, and has instead properly limited it to outlining the jurisdictional limits of what is eligible for patent protection. But this should not be expanded to say that a patent that

139. Perfect Web Technologies, Inc. v. InfoUSA, Inc., 587 F.3d 1324, 1330 (Fed. Cir. 2009) (holding that the repetition of three known steps until the desired result is achieved was obvious).

140. KSR Int'l. Co. v. Teleflex, Inc., 550 U.S. 398, 419 (2007).

141. *Id.* at 418.

142. *Id.* at 421.

143. Parker v. Flook, 437 U.S. 584, 593 (1978).

144. Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc., 827 F.3d 1042, 1051-52 (Fed. Cir. 2016).

survives the *Mayo* test is necessarily valid. Instead, challenges to patents that claim eligible subject matter will be properly confined to other sections of the Patent Act.

This opinion also signals that the Federal Circuit has become skeptical of imprudently labelling something a "law of nature."[145] Perhaps, in the not-too-distant future, the Federal Circuit will take on defining the term, limiting its use in the legal system in a manner consistent with its use in the sciences. Finally, while this opinion has not alleviated concerns within the biotechnology industry regarding patent protection for diagnostic claims, it exemplifies that the Federal Circuit is willing to push back the scope and application of the judicial exceptions. Perhaps further refinement will lead to diagnostic claims being eligible once again.

145. *See id.* at 1048 (stating that the Federal Circuit "need not decide whether the court's labeling is correct" in reference to the District Court's identification of a "natural law.").