Defining Patent Eligibility by Extrapolating the Judicial Outlook of Software onto Biotechnology Patents

Joanna M. Grigas
DEFINING PATENT ELIGIBILITY BY EXTRAPOLATING THE JUDICIAL OUTLOOK OF SOFTWARE ONTO BIOTECHNOLOGY PATENTS

Who in the rainbow can draw the line where the violet tint ends and the orange tint begins? Distinctly we see the difference of the colors, but where exactly does the one first blendingly enter into the other? So with sanity and insanity. 1

I. INTRODUCTION

The U.S. Patent Act delineates whether an invention can receive a patent in the United States by analyzing patent eligibility—whether the invention fits into a patent-protected group—and patentability—whether the statutory provisions pertinent to that specific invention are satisfied. 2 Section 101 operates as a coarse filter for patent eligibility by examining the subject matter and the utility of the claimed invention. 3 Suitable subject matter for patent eligibility includes processes, machines, manufactures, and compositions of matter. 4 Congress encourages the U.S. Patent and Trademark Office (“USPTO”) to examine patent eligibility liberally. 5

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because “anything under the sun that is made by man” is admissible for the subject matter of a patent. The only exceptions to patent-eligible subject matter are laws of nature, physical phenomena, and abstract ideas; even if one of these exceptions falls into a patent-eligible category (process, machine, manufacture, or composition of matter), it will not be patent eligible. While § 101 prescribes whether claims are patent eligible, the courts have struggled to determine an appropriate test or standard to analyze whether the patent claim is a law of nature, physical phenomenon, or an abstract idea, especially in the software and biotechnology industries.

U.S. patent law aims to “promote the progress of science and useful arts” by giving inventors exclusive rights to their inventions for a limited period of time. Major advances in biotechnology and software challenge the patent system because these industries have increasingly flooded the USPTO with patent applications. In response, the USPTO has issued patents that may be considered more upstream in the patent-eligibility continuum by allowing patents on inventions that are closer to the exceptions: laws of nature, physical phenomena, and abstract ideas. In Association for Molecular Pathology v. Myriad Genetics, Inc. (“AMP”), the U.S. Court of Appeals for the Federal Circuit (“CAFC”) determined that isolated DNA was patentable subject matter, though the Supreme Court has granted this matter certiorari to evaluate this evolution

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5 S. REP. NO. 82-1979, at 5 (1952); H.R. REP. NO. 82-1923, at 6 (1952).

6 See Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948) (asserting phenomenon of nature as unpatentable); Rubber-Tip Pencil Co. v. Howard, 87 U.S. 498, 507 (1874) (arguing abstract ideas lack patentability); O’Reilly v. Morse, 56 U.S. 62, 78 (1854) (holding electro-magnetism, law of nature, cannot be patented); see also Gottschalk v. Benson, 409 U.S. 63, 67 (1972) (expounding that newly-discovered § 101 exceptions lack patent eligibility). “The qualities of these bacteria, like the heat of the sun . . . are part of the storehouse of knowledge of all men.” Funk Bros., 333 U.S. at 130. Because they are simply manifestations of laws of nature, they are “free to all men and reserved exclusively to none.” Id. Similarly, abstract ideas and laws of nature, even if just discovered, are fundamental research and work tools. Gottschalk, 409 U.S. at 67.


8 U.S. CONST. art. I, § 8, cl. 8.

9 See Craig E. Walter, Comment, Extraterritorial Software Protection Under § 271(f): A Call to Congress to Fix a Statute That Was Not Broken, 48 HOUS. L. REV. 129, 131 (2011) (observing increase of number of software patents issued); Edwards, supra note 2, at 821 (noting evolution of medicine caused influx of biotechnology patents).

10 See Sovacool, infra note 132 and accompanying text (claiming examiners require more funding to work more efficiently). But see Duffy, supra note 7, at 652 (suggesting new fields become patentable as fields mature).

11 689 F.3d 1303, 1310 (Fed. Cir.), cert. granted in part, 133 S. Ct. 694 (2012) (mem.).
in biotechnology. Conversely, in *Cybersource Corp. v. Retail Decisions, Inc.*, the CAFC held that a credit card fraud invention was too broad to satisfy the patent-eligibility requirement of § 101. While the rules to determine patent eligibility have changed with time, they have never allowed patents to cover fundamental ideas, phenomena, or laws of nature. Otherwise, these patents could lead to a tragedy of the anticommons—where broad, upstream patents block experimentation from occurring downstream—by allowing people who own upstream patents to force downstream investigators to seek licensing or attempt to research ways around the patents.

This Note compares the courts’ interpretation of biotechnology compositions of matter patents in *AMP* to the software business method patents in *CyberSource*. This Note will specifically examine these underlying inventions to show that a workable rule for determining patentability under § 101 needs to be determined. Part II discusses the history and progress of relevant case law surrounding patent eligibility for software and biotech patent claims. Part III analyzes the distinctions the court made between the claims in *AMP* and *Cybersource*. Part IV

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12 Ass’n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 694 (2012) (mem.) (granting certiorari); Ass’n for Molecular Pathology, 689 F.3d at 1309 (allowing patentability because isolated DNA is distinct from molecules in nature).
13 654 F.3d 1366 (Fed. Cir. 2011).
14 Id. at 1376-77 (excluding fraud claims from patentability for being upstream, abstract idea).
17 See infra Part IV.A-C (setting forth parallelism between biotechnology and software patent histories).
18 See infra Part IV.A (discussing how straightforward rules assist research industries with overwhelmingly positive effects).
19 See infra Part II (examining historic backgrounds of biotechnology and software industries struggles to obtain patent rights).
20 See infra Part III (characterizing how court analyzed patent protection in biotechnology and software industries).
examines how innovators should use claim construction to ensure their claims are sufficiently downstream to avoid the § 101 exceptions. Finally, Part V details how Congress, the courts, the USPTO, and innovation ideology should help create a better structure for § 101 by allowing more researchers to work in their fields of interest.

II. GENERAL HISTORY OF PATENT CLAIMS

A. Congress’s Role in the Patent System

Congress has modified the Patent Act several times since its enactment in 1790. The Patent Act of 1793 expanded patentable subject matter to include additional categories of patent-eligible subject matter. Yet, the most significant change affecting patent eligibility in the Patent Act took place in 1952, when Congress clarified terms to help determine whether a patent claim falls into a patent-eligible category.

B. The Supreme Court’s Landmark Cases

The Supreme Court attempted to further delineate the boundaries of patent eligibility in three landmark cases by examining patent claims related to abstract ideas, which are exceptions to § 101. In the 1972
Gottschalk v. Benson decision, the Court held that a patent claim for a process of changing a numbering format was too abstract because it required only mental steps and could be used in any desired field without limits. Six years later, in Parker v. Flook, the Court held that a method claim was unpatentable even though the claim limited the algorithm to only a portion of potential algorithm uses. The Court declared that limiting a formula’s use to one area was a post-solution activity that did not transform an unpatentable claim into a patentable claim. Finally, in the 1981 Diamond v. Diehr decision, the Court created a consistent standard for courts and the USPTO to view patent claims; the Court determined that patent claims should be reviewed “as a whole,” rather than by review after splitting up the claims into separate pieces. The Court decided that a patent claim that used a mathematical formula to calculate correct timing for processing rubber was patent eligible because the formula’s application transformed the article.

Claims should be examined “as a whole.” Diehr, 450 U.S. at 188.

27 409 U.S. 63 (1972).
28 Id. at 67-68, 71 (denying patent eligibility to broad claim covering abstract idea). The claim disclosed an algorithm, which is a process for solving a mathematical problem. Id. at 65. With no end use or particular technology limits, the claim includes any current or future use of binary numeral conversion. Id. at 64, 68.
30 Id. at 586 (observing limited use of algorithm does not render method claim patentable).
31 Id. at 589-90 (prohibiting experienced claim draftsmen from attempting to make claim patent eligible by adding post-solution process).
33 See id. at 188 (stressing patent examination requires claims be reviewed “as a whole”).
34 See id. at 192 (declaring patent eligibility for applications of § 101 exceptions that perform patented functions). Patent laws protect functions include transforming items into different states.
35 See Ebby Abraham, Note, Bilski v. Kappos: Sideline Analysis from the First Inning of Play, 26 BERKELEY TECH. L.J. 15, 24 (2011) (opining Diehr allows algorithm as part of patentable process, unlike earlier Supreme Court cases).
C. Fluctuation in the Judicial Branch to Create Proper § 101 Test

In the early 1980s, the Court of Customs and Patent Appeals established a two-part test to determine patent eligibility called the Freeman-Walter-Abele test.\(^{36}\) The Freeman-Walter-Abele test first asked whether the claim included an algorithm, and if so, whether the claim, in its entirety, preempted the algorithm.\(^{37}\) Although this test was utilized for some time, the CAFC altered the patent-eligibility standard in 1998 in *State Street Bank & Trust Co. v. Signature Financial Group, Inc.* ("State Street")\(^{38}\) by requiring that patent claims produce a “useful, concrete, and tangible result.”\(^{39}\) The *State Street* decision changed the threshold of patent eligibility and permitted business method patents to be patent eligible for the first time.\(^{40}\)

The Supreme Court, in turn, questioned the *State Street* test and opined that the “useful, concrete, and tangible result” requirement should not be part of the patent-eligibility analysis.\(^{41}\) The CAFC responded to this request by establishing the machine-or-transformation test, which acknowledges patent eligibility when the claim is connected to a specific machine or transforms an object into a separate state or item.\(^{42}\) The Supreme Court responded to the latest CAFC attempt at solidifying a


\(^{37}\) *Abele*, 684 F.2d at 905 (setting forth new patent-eligibility test), abrogated by *Bilski*, 545 F.3d 943 (Fed. Cir. 2008). The second step discussed in *Freeman* was not followed in the case because the claims did not pass the first step of the test. Id.

\(^{38}\) Id. at 1374 (requiring patent claims for applications of § 101 exceptions produce “useful, concrete and tangible result”); see also *In re Alappat*, 33 F.3d 1526, 1544 (Fed. Cir. 1994) (concluding claim combines abstract idea with “machine to produce a useful, concrete, and tangible result”), abrogated by *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008).

\(^{39}\) Id. at 1374 (requiring patent claims for applications of § 101 exceptions produce “useful, concrete and tangible result”); see also *In re Alappat*, 33 F.3d 1526, 1544 (Fed. Cir. 1994) (concluding claim combines abstract idea with “machine to produce a useful, concrete, and tangible result”), abrogated by *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008).

\(^{40}\) See *State St. Bank & Trust Co.*, 149 F.3d at 1377 (announcing business method patents can be patent eligible); see also Abraham, supra note 35, at 32-33 (noting before *State St.*, business method claims were not patentable). “Whether the claims are directed to subject matter within § 101 should not turn on whether the claimed subject matter does ‘business’ instead of something else.” *State St. Bank & Trust Co.*, 149 F.3d at 1377.

\(^{41}\) See *Lab. Corp. v. Metabolite Labs., Inc.*, 548 U.S. 124, 136 (2006) (Breyer, J., dissenting) (determining *State St. Bank* test inadequate because Court “has never made such a statement”). Additionally, the Court stated that patent restrictions may harm the medical industry because medical professionals will be prohibited from using the best treatments and will require additional time to make licensing agreements. Id. at 138.

\(^{42}\) See *In re Bilski*, 545 F.3d 943, 954 (Fed. Cir. 2008) (developing machine-or-transformation test as means to determine whether claim is patent eligible), aff’d but criticized sub nom. *Bilski v. Kappos*, 130 S. Ct. 3218 (2010).
patent-eligibility test by explaining that the machine-or-transformation test is not the sole test for determining patent eligibility, but rather a useful tool to be used in evaluation. Instead, the Court urged lower courts to follow the Court’s precedents, like Benson, Flook, and Diehr. While new technological changes require § 101 to dynamically include novel inventions, the lower courts are encouraged to formulate further criteria for patent eligibility.

D. USPTO Responds to the Supreme Court’s View of § 101

The USPTO responded to the Supreme Court’s revisions of patent eligibility by changing its examination guidelines in 2001, 2009, 2010, and 2012. The revised Utility Examination Guidelines (“Guidelines”), drafted in 2001, required the patentee to disclose at least one practical benefit of the invention that is “specific, substantial, and credible,” which implies that the invention is downstream of the exceptions to § 101. In 2009, the USPTO restructured the guidelines by issuing the New Interim Patent Subject Matter Eligibility Examination Instructions to patent examiners. These instructions required that patent claims have tangible limitations so that not all acceptable applications are covered by the patent claim.

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43. See Bilski, 130 S. Ct. at 3227 (acknowledging “machine-or-transformation” test as a useful clue but not sole test for patent eligibility).
44. Id. at 3229-30 (comparing current patent claims to precedent cases of Benson, Flook, and Diehr); see also sources cited supra notes 26-35 and accompanying text (describing Supreme Court analysis of these precedents).
45. Bilski, 130 S. Ct. at 3227, 3231 (leaving open possibility for lower courts to create other limiting criteria for patent eligibility). “[T]he patent law faces a great challenge in striking the balance between protecting inventors and not granting monopolies over procedures that others would discover by independent, creative application of general principles.” Id. at 3228.
46. See infra notes 47-51 (detailing guideline changes that USPTO incorporated into patentability analysis).
47. Util. Guidelines, supra note 3, at 1093 cmt. 4 (expounding utility requirements for patentability); see also Brenner v. Manson, 383 U.S. 519, 535-36 (1966) (reasoning patent eligibility requires public benefit through disclosure of important utility); In re Fisher, 421 F.3d 1365, 1369 (Fed. Cir. 2005) (denying patent eligibility to patent claims with no known utility disclosed). Patent claim drafting has become an art that encourages the broadest scope possible connected with the smallest disclosure allowable. Brenner, 383 U.S. at 534. “[A] patent is not a hunting license . . . [or] a reward for the search, but compensation for its successful conclusion.” Id. at 536.
48. See Hirshfeld, supra note 3, at 1 (asserting new instructions nullify previous subject matter examination instructions). A practical application disclosure is not patent eligible if it “impermissibly covers substantially all practical applications of the judicially excepted subject matter.” Id. at 3.
49. See id. at 3 (prohibiting patentee from claiming all possible applications of invention to prevent monopolies from forming).
2010, the USPTO responded to the Supreme Court’s view of the machine-or-transformation test by encouraging examiners to continue the test’s usage as a tool to determine if the patent claims appear to be patent eligible under § 101. In 2012, the USPTO issued the 2012 Interim Procedure for process claims that involve laws of nature after the Court issued its most recent § 101 case.

III. PATENT PROGRESSION IN INDIVIDUAL INNOVATION FIELDS

A. Evolution of Software Patents

As innovations in the high-tech field continue to develop, the influx of software patent applications encourages the patent system to become more accepting of new software inventions. Initially, the Supreme Court in *Flook* and *Benson* viewed software patents unfavorably because software often relies on algorithms. The *Diehr* decision in 1981, however, lowered the threshold for software patents, as the Court allowed a patent claiming an improved process of molding rubber, even though the

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52 Walter, *supra* note 9, at 131 (considering rise in software patent filings and litigation procedures).

53 See cases cited *supra* notes 28, 30 and accompanying text (forbidding software patents unless narrow usage of abstract ideas lead to useful applications).
claim utilized an algorithm. As a result of these Court rulings, a software patent could only satisfy § 101 by using an algorithm to perform a function or accomplish a process.

2. Further Attempts to Define the Patent-Eligibility Requirements for Software

In 1994, the CAFC’s judgments regarding computer and computer software patent eligibility changed the court’s view of software patents. The CAFC determined that a computer operating with software was covered under § 101. In that same year, the CAFC held that a method claim using an abstract idea in unlimited ways was unpatentable, though the machine claim was patent eligible for being attached to a machine.

While State Street created a more flexible patent-eligibility test by looking for “useful, concrete, and tangible” criteria in the patent, recent decisions have scaled back the threshold inquiry under § 101. In 2007,
the Supreme Court held that software code unconnected to a machine was not patent eligible because it was simply an idea without a physical entity.\textsuperscript{60}

Since 2010, when the Supreme Court announced that the machine-or-transformation test should be used only as a clue for patent eligibility, the courts and patent examiners have been forced to scrutinize software patent claims and the connection of software and hardware without any clear rule or test in place to determine patent eligibility.\textsuperscript{61}

3. \textit{CyberSource} Reviews Software Patents for “Underlying Invention”

In the 2011 case of \textit{CyberSource Corp. v. Retail Decisions, Inc.},\textsuperscript{62} the Federal Circuit’s understanding of § 101 was further challenged.\textsuperscript{63} CyberSource alleged infringement on its credit card fraud patents; however, the District Court for the Northern District of California held that CyberSource’s patents for inspecting credit card fraud were invalid.\textsuperscript{64} On appeal, the CAFC first reviewed claim three, a method claim describing the process of ensuring that credit card transactions on the Internet are legitimate.\textsuperscript{65} Claim three required obtaining an Internet protocol (IP) address or e-mail address for the credit card transaction, creating a list of credit card transactions connected with the IP address, and using any means to determine if the transaction is valid.\textsuperscript{66} Because claim three allowed any method to determine if the transaction was valid and did not require any machine for processing, the claim could be performed mentally; therefore, the court held that the claim was merely an abstract idea requiring mental steps.\textsuperscript{67}

\textsuperscript{60} Microsoft Corp. v. AT&T Corp., 550 U.S. 437, 450 (2007) (explaining software without physical medium lacks patent eligibility); see also Abraham, supra note 35, at 46 (summarizing software per se claims as abstract after Microsoft).

\textsuperscript{61} See Ex parte Proudler, No. 2009-006599, 2010 WL 2727840, at *2 (B.P.A.I. July 8, 2010) (justifying lack of patent eligibility because no hardware was included in software claim).

\textsuperscript{62} 654 F.3d 1366 (Fed. Cir. 2011).

\textsuperscript{63} \textit{Id.} at 1368 (describing alleged infringement of patent linking credit card fraud to Internet addresses). Retail Decisions requested reexamination of CyberSource’s patent. \textit{Id.} After the USPTO reexamined the patent, the patent was reissued and the district court proceedings continued. \textit{Id.}

\textsuperscript{64} \textit{Id.}

\textsuperscript{65} \textit{Id.} at 1370 (examining method claim for patentability).

\textsuperscript{66} \textit{Id.} (declaring steps of CyberSource’s patent claim three).

\textsuperscript{67} \textit{CyberSource Corp.}, 654 F.3d at 1370-71 (recognizing unpatentability where claim only consists of abstract ideas performed mentally). While the Internet is useful for the first step, the Internet is only a data-gathering source that cannot count as a machine under the machine-or-transformation test. \textit{Id.} at 1370. All of the steps in claim three can be performed in the mind, and the claim lacks limits without any disclosed algorithms. \textit{Id.} at 1372.
CyberSource’s second claim was characterized as a “Beauregard claim” because it required a computer to perform specific processes. A Beauregard claim contains program instructions that perform a specific process on a computer. Claim two described a computer program that requested the computer to obtain credit card information from the customer and validate the information by using data from previous transactions to determine if the transaction was valid. While claim two disclosed that the invention required a computer, the court reviewed the claim for its “underlying invention.” The CAFC held that claim two was not a manufacture claim for storing computer information but was instead a method claim for discovering credit card fraud. Additionally, claim two failed the machine-or-transformation test because the computer did not impose limits on the boundaries of the patent claim nor did the data gathering satisfy the transformation prong of the test. Thus, the court decided that claim two was an abstract idea, similar to claim three, because it lacked any meaningful limits on the claim’s scope.

4. Post-CyberSource Decisions and the Public’s Response

The holding of CyberSource serves as a warning to patent applicants in all professions that patent claims should require a transformation or the use of a machine to reduce the risk that a court will.

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68 Id. at 1373 (defining Beauregard claim for CyberSource’s claim two). A Beauregard claim contains program instructions that perform a specific process on a computer. Id.
70 CyberSource Corp., 654 F.3d at 1373-74 (outlining steps of CyberSource’s Beauregard claim).
71 Id. at 1374 (determining actual, “underlying” invention rather than reviewing claim through claim language alone). “Regardless of what statutory category . . . a claim’s language is crafted to literally invoke, we look to the underlying invention for patent-eligibility purposes.” Id.
72 Id. (characterizing Beauregard claim as process based on claims’ steps).
73 Id. at 1374-76 (realizing claim two fails machine-or-transformation test); see also Research Corp. Techs., Inc. v. Microsoft Corp., 627 F.3d 859, 868-69 (Fed. Cir. 2010) (explaining how claims requiring specific machines cannot be performed using only mental thoughts); SIRF Tech., Inc. v. Int’l Trade Comm’n, 601 F.3d 1319, 1333 (Fed. Cir. 2010) (requiring machine to limit scope of invention and be important part of invention).
74 CyberSource Corp., 654 F.3d at 1376-77 (denying patentability to CyberSource’s claim two and claim three).
determine that the underlying invention is an abstract idea and not patent eligible under § 101.\textsuperscript{75} However, in \textit{Ultramercial, LLC v. Hulu, LLC},\textsuperscript{76} also decided in 2011, the CAFC declared that the machine-or-transformation test is less useful in this more technologically-advanced age, thus courts should view abstract inventions more liberally.\textsuperscript{77} The CAFC held that a method claim for distributing products over the Internet in exchange for viewing advertisements was patent eligible because the transaction with the customer could not be performed mentally.\textsuperscript{78} More recently, in 2012, the CAFC determined that claims linking a program and method to a computer for one field of use failed patent eligibility because the claims lacked actual limits, thus aligning the claim with an attempt to patent an abstract idea.\textsuperscript{79}


\textsuperscript{77} Id. at 1327 (criticizing machine-or-transformation test as antiquated in light of current advances). Section 101 should be dynamic and adaptable to include new inventions. Id. Technology lacking both a physical entity and a mechanical process should not be definitively found patent ineligible because of the old machine-or-transformation test. Id.

\textsuperscript{78} Id. at 1329-30 (announcing patent eligibility results from non-mental step of interaction with customer over Internet). Although the claim did not include a selected method for sending advertisements to consumers, the claimed invention was not too abstract because it included a practical application of using advertisements as a form of currency. Id. at 1330.

\textsuperscript{79} Dealertrack, Inc. v. Huber, 674 F.3d 1315, 1333-34 (Fed. Cir. 2012) (treating patent claims as describing abstract ideas because claims lack true limits). “The claims are silent as to how a computer aids the method, the extent to which a computer aids the method, or the significance of a computer to the performance of the method.” Id. at 1333. See generally id. at 1335 (Plager, J., dissenting) (contending courts should review claims under other patent requirements instead of § 101 when possible); MySpace, Inc. v. GraphOn Corp., 672 F.3d 1250, 1260 (Fed. Cir. 2012) (“[I]nst[ing] that litigants initially address patent invalidity issues in terms of . . . §§ 102, 103, and 112 . . . . [so that it would be] unnecessary to enter the murky morass that is § 101 jurisprudence.”). JASON RANTANEN, DEALERTRACK v. HUBER: UNPATENTABLE “COMPUTER AIDED” CLAIMS, PATENTLYO (Feb. 2, 2012, 2:54 PM), http://www.patentlyo.com/patent/2012/02/dealertrack-v-huber.html (delineating efficient notion of only reviewing § 101 when absolutely required). Judge Plager argued that infringement claims
While software patents continue to challenge patent-eligibility standards, the public has reacted in frustration over the increase in software patent eligibility. As a direct result, some companies, known as non-practicing entities ("NPEs"), thrive by obtaining and using patents for the sole purpose of suing for patent infringement, thereby using patents as a sword to thwart innovation. Despite changes in
the software industry, some programs remain open source so that
competitors can freely use and improve on select software.  

B. Progression of Gene Patents

1. Early Legislative and Judicial Decisions Regarding § 101

Similar to their struggles defining the patent-eligibility boundaries
for software patents, the courts have struggled to define the boundaries of
patent eligibility in a variety of areas of science.  

In 1948, the Supreme Court denied patentability to a patent claim disclosing a mixture of bacteria
strains because the mixture lacked any new bacteria qualities.  

The discovery of the bacteria strains’ functions was merely part of nature and, there-fore, belonged as “part of the storehouse of knowledge of all men.” Conversely, in 1957, the U.S. Court of Appeals for the Fourth Circuit
determined that an isolated and purified vitamin differed in degree of purity and kind because it did not exist in nature in this purified form and had

(suggesting company with NPE characteristics that uses service fees is distinct from NPEs);
When Patents Attack, supra note 81 (acknowledging NPEs as entities exist to sue patent infringers).

83 See Boldrin & Levine, supra note 81, at 326 (describing open source system); James
Ernstmeyer, Note, Does Strict Territoriality Toll the End of Software Patents?, 89 B.U. L. Rev. 1267, 1275 (2009) (articulating that software IP harms efficiency, raises transaction costs, and limits developers’ freedom). Unlike patented software, open source allows competitors to freely utilize software, thus encouraging the free disclosure of ideas. See Boldrin & Levine, supra note 81, at 326.


85 See Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130-31 (1948) (indicating mixture of natural bacteria strains produces same qualities as in nature); see also Am. Wood-Paper Co. v. Fibre Disintegrating Co., 90 U.S. 566, 595 (1874) (refusing patentability because process known “long before”). If patentee discovers a new process to obtain a natural element, the process can be patented, but not the element. See Am. Wood-Paper Co., 90 U.S. at 594. “Even though it may have been the product of skill, it certainly was not the product of invention.” Funk Bros. Seed Co., 333 U.S. at 132.

86 Funk Bros. Seed Co., 333 U.S. at 130-31 (recognizing combination as application of “newly-discovered natural principle”). A new law of nature cannot be patented because monopolies on laws of nature are not permitted. Id. at 130. While the mixture was creative, the application from the law of nature did not lead to a “new and useful end.” Id.
great therapeutic value.\footnote{Merck & Co. v. Olin Mathieson Chem. Corp., 253 F.2d 156, 164 (4th Cir. 1958) (approving patentability for product claims due to differences between natural and purified products).}

2. \textit{Diamond v. Chakrabarty} Opens the Door to Biotechnology

Patents Satisfying the Patent-Eligibility Requirement

The Supreme Court greatly expanded the allowable breadth of biotech patents in 1980 in \textit{Diamond v. Chakrabarty}\footnote{447 U.S. 303 (1980).} when it reviewed the patentability of a genetically engineered bacterium that did not exist in nature.\footnote{See id. at 309 (distinguishing man-made bacterium from bacterium found in nature).} Because this bacterium was not a natural phenomenon, the Court declared the bacterium had a ""distinctive name, character, [and] use.""\footnote{Id. at 309-10 (quoting Hartranft v. Wiegmann, 121 U.S. 609, 615 (1887)).} Consequently, the Court granted the bacterium to be patent eligible because it had ""markedly different characteristics"" from natural bacterium and included the potential for an important use.\footnote{Id. at 310 (pointing to both utility and distinct character from natural organism regarding patentability).}

Since the \textit{Chakrabarty} ruling, the USPTO and Congress have attempted to reshape the patent eligibility of biotechnology patents.\footnote{See infra notes 94-97 and accompanying text (detailing how Congress has attempted to control type of acceptable biotechnology patents); see also Eric J. Rogers, Article, \textit{Can You Patent Genes? Yes and No}, 93 J. PAT. & TRADEMARK OFF. SOC’Y 19, 19 (2011) (noting USPTO began granting patents for genes in 1982).} The USPTO explicitly addressed the biotechnology industry’s needs by stating that isolated and purified DNA claims are patent eligible in its 2001 Guidelines.\footnote{See Util. Guidelines, supra note 3, at 1094 cmt. 8 (allowing ownership of isolated and purified DNA). Patents on genes cover only the isolated and purified form, not the genes that exist in nature. \textit{Id. at 1093 cmt. 4.}} A year later, Representative Lynn Rivers of Michigan introduced the Genomic Research and Diagnostic Accessibility Act of 2002, which aimed to create a narrow list of exemptions for gene patents.\footnote{See Genomeic Research and Diagnostic Accessibility Act of 2002, H.R. 3967, 107th Cong. pmbl. (2002) (suggesting bill to alleviate problems accompanying acceptance of gene patenting).} She suggested exemptions for non-commercial researchers and medical professionals involved in genetic testing so that innovation could occur without the need for licensing in these fields.\footnote{Id. at § 3 (discussing potential solution for wide-spread negative effects of gene patents); see also Genomic Science and Technology Innovation Act of 2002, H.R. 3966, 107th Cong. pmbl. 1, 4 (advocating performing study to determine how patent policy impacts innovation). Gene patents harm the general public by drastically increasing patented test costs, requiring researchers to obtain licenses from the patent holders.}

\footnote{Merck & Co. v. Olin Mathieson Chem. Corp., 253 F.2d 156, 164 (4th Cir. 1958) (approving patentability for product claims due to differences between natural and purified products).} \footnote{447 U.S. 303 (1980).} \footnote{See id. at 309 (distinguishing man-made bacterium from bacterium found in nature).} \footnote{Id. at 309-10 (quoting Hartranft v. Wiegmann, 121 U.S. 609, 615 (1887)).} \footnote{Id. at 310 (pointing to both utility and distinct character from natural organism regarding patentability).} \footnote{See infra notes 94-97 and accompanying text (detailing how Congress has attempted to control type of acceptable biotechnology patents); see also Eric J. Rogers, Article, \textit{Can You Patent Genes? Yes and No}, 93 J. PAT. & TRADEMARK OFF. SOC’Y 19, 19 (2011) (noting USPTO began granting patents for genes in 1982).} \footnote{See Util. Guidelines, supra note 3, at 1094 cmt. 8 (allowing ownership of isolated and purified DNA). Patents on genes cover only the isolated and purified form, not the genes that exist in nature. \textit{Id. at 1093 cmt. 4.}} \footnote{See Genomeic Research and Diagnostic Accessibility Act of 2002, H.R. 3967, 107th Cong. pmbl. (2002) (suggesting bill to alleviate problems accompanying acceptance of gene patenting).} \footnote{Id. at § 3 (discussing potential solution for wide-spread negative effects of gene patents); see also Genomic Science and Technology Innovation Act of 2002, H.R. 3966, 107th Cong. pmbl. 1, 4 (advocating performing study to determine how patent policy impacts innovation). Gene patents harm the general public by drastically increasing patented test costs, requiring researchers to obtain licenses from the patent holders.}
obtained little backing, Congressional Representatives Xavier Becerra and David J. Weldon introduced the Genomic Research and Accessibility Act in 2007 to protect human genetic material from being patented so that human beings themselves could not be patented.96 As a result, the new patent act, known as the America Invents Act, includes a passage refusing patentability to claims encompassing human beings.97

3. DNA’s Influence in Research

From 1990 to 2003, the large-scale, international Human Genome Project mapped the entire human genome so that researchers can now sequence and compare individual genomes to find genetic differences.98 Knowledge of the human genome adds an additional layer of understanding to what researchers already knew about DNA.99 Well-known DNA techniques were used in the Association for Molecular Pathology v. U.S. Patent and Trademark Office (“AMP”) to determine which DNA sequences were involved in breast cancer.100

to spend time and energy on negotiating licenses, and allowing monopolies on genetic tests, altogether slowing innovation. H.R. 3967, § 3. Representative Rivers requested that the White House Office of Science and Technology Policy analyze patent policies and report to Congress. H.R. 3967, para. 4.


99 See JEFF HARDIN ET AL., BECKER’S WORLD OF THE CELL 54-55, 59 (Michael Young et al. eds., 8th ed. 2011) (determining genetic makeup of human beings increased public knowledge of how DNA is constructed). DNA nucleotide bases pair up so that adenine (A) binds with thymine (T) and guanine (G) binds with cytosine (C). Id. DNA has noncoding regions, called introns, and coding regions of DNA, called exons, which determine how to form specific proteins. Id. at 669-70. When a change or mutation in a person’s DNA occurs, the mutation can affect the protein of the DNA if it occurs on an exon. Id. at 694-95. Researchers can produce DNA and compare it to a baseline DNA in a laboratory using a procedure called polymerase chain reaction (PCR). Id. at 694-95.

100 Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office (“AMP”), 689 F.3d
4. **AMP** Pushes Patent Eligibility Line Further Upstream

In the mid-1990s, Myriad patented the isolated genes for breast cancer, known as BRCA1 and BRCA2, and the related diagnostic methods for analyzing these genes.\(^\text{101}\) Myriad continues to be the only provider for breast cancer genetic testing and actively enforces its patents against patent infringers.\(^\text{102}\) Because researchers were unable to engage in BRCA1/2 clinical testing, a group of researchers filed suit against Myriad.\(^\text{103}\) The District Court for the Southern District of New York in *Association for Molecular Pathology v. U.S. Patent and Trademark Office*\(^\text{104}\) determined that because Myriad’s claims covering the BRCA genes were products of nature, these claims were not patent eligible.\(^\text{105}\)

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\(^{101}\) Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office, 653 F.3d 1329, 1339 (Fed. Cir. 2011) (outlining history of Myriad’s patent filings), cert. granted, vacated sub nom. Ass’n for Molecular Pathology v. Myriad Genetics, Inc., 132 S. Ct. 1794 (U.S. 2012) (mem.), opinion vacated, appeal reinstated, 467 F. App’x 890 (Fed. Cir. 2012). BRAC1 and the related diagnostic methods were filed in 1994, while BRCA2 and the complementary diagnostic methods were filed in 1995. Id.

\(^{102}\) AMP, 689 F.3d at 1314-16 (highlighting Myriad’s aggressive approach to maintaining genetic breast cancer testing within own facilities). See generally Best Practices for the Licensing of Genomic Inventions, 70 Fed. Reg. 18413 (proposed Apr. 11, 2005) (suggesting non-exclusive licensing as best practice). While Myriad did send a letter to one institution offering a collaborative license, Myriad required the facility to limit the breast cancer tests to Ashkenazi Jewish patients. See AMP, 689 F.3d at 1314-15.

\(^{103}\) AMP, 689 F.3d at 1315-16 (articulating why plaintiffs filed suit against Myriad); see also Richard Li-dar Wang, *Biomedical Upstream Patenting and Scientific Research: The Case for Compulsory Licenses Bearing Reach-Through Royalties*, 10 YALE J.L. & TECH. 251, 296 (2007-08) (questioning Myriad’s monopoly because Myriad discovered breast cancer DNA deletion much later than in Europe); see also Ontario to Offer New Genetic Test for Breast, Ovarian Cancer, CBC News, (Jan. 8, 2003, 1:33 PM), http://www.cbc.ca/news/health/story/2003/01/06/test_genetic030106.html (indicating Myriad may attempt to thwart independent breast cancer tests from occurring in Canada). Researchers stopped performing clinical genetic testing, even though their facilities and staff are capable of handling such tests. See AMP, 689 F.3d at 1315. Other plaintiffs are patients who are unable to receive the BRCA testing because their insurance does not cover the test or the price for testing is too high as a result of Myriad’s patents. Id. at 1315. While the British Columbian government halted breast cancer tests last year, the Ontario government plans to ignore Myriad’s DNA claims so that breast cancer tests can occur. Ontario to Offer New Genetic Test for Breast, Ovarian Cancer, supra.


\(^{105}\) Id. at 237-38 (finding Myriad’s patent claims invalid). The method claims were also determined to be mental processes. Id. at 237.
After Myriad appealed, the CAFC majority determined that the BRCA gene claims were patent eligible. Judge Lourie determined that the isolated DNA had a “distinctive chemical identity” from natural DNA because human intervention cleaved covalent bonds in the isolated DNA. Judge Lourie, who holds a Ph.D. in chemistry, reasoned that while biologists may view genes by their functions, DNA claims are best characterized by their chemical structure.

Instead of simply looking for distinctions between the natural and man-made species, Judge Moore suggested in her concurring opinion that a second step should be used to determine whether the new species created a novel utility. She concluded that shorter isolated DNA sequences possess a different chemical structure and have many advantageous applications. While longer isolated DNA sequences lack any expanded utility, Judge Moore reasoned that these DNA sequences were patent eligible for policy reasons. She described how both Congress and the USPTO have historically allowed longer DNA strands to be patentable; therefore, the “settled expectations of the biotechnology industry . . .[and] the inventing community” should not be taken lightly.

Judge Bryson’s dissent in AMP argued that the DNA claims were...
“the same, structurally and functionally” because the language and focus of the claims required the use of genetic rather than chemical principles. Judge Bryson stated that many of Myriad’s DNA claims were too broad because they covered the same sequence as the natural DNA, which thereby allowed both the natural and claimed genes to code for the same proteins. He concluded that, because the key function of Myriad’s DNA claims was that the isolated DNA would act in the same manner as natural DNA, functional differences, rather than structural differences, were crucial to the claims. Additionally, Judge Bryson did not state any reasoning or precedent to support the importance of covalent bond cleavage over the breakage of other chemical bonds. Ultimately, in contrast to the majority’s holding that Myriad’s genes should be patent eligible, Judge Bryson predicted that allowing the Myriad DNA claims to be patented ultimately harms downstream innovation.

C. Supreme Court Alters the Patent-Eligibility Standard

In March 2012, the Supreme Court in Mayo Collaborative Services v. Prometheus Laboratories, Inc. challenged the status quo of patent-eligibility standards for biotech applications followed by the courts and the
USPTO. The Court determined that a process claim that reviewed the efficacy of dosages in people was simply a law of nature, making it ineligible for a patent. The Court held that the claim simply “tell[s] doctors to apply the law somehow when treating their patients” using well-known steps. While the machine-or-transformation test is often helpful in determining patent eligibility, the Mayo Court did not find that a transformation occurred during any steps of the claim. Additionally, the

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120 Mayo, 132 S. Ct. at 1297-98 (stating claims lack patent-eligibility because steps are well-known and measure law of nature); see also Memorandum from Andrew H. Hirshfeld, Assoc. Comm’r for Patent Examination Policy, U.S. Patent & Trademark Office, to Patent Examining Corps. (Mar. 21, 2012), available at http://www.uspto.gov/patents/law/exam/mayo_prelim_guidance.pdf (requiring patent examiners to use Interim Bilski Guidance but deny claims covering § 101 exceptions). The process claim in Mayo was to administer a drug to determine the level of a certain product within the patient. Mayo, 132 S. Ct. at 1295. If the drug level was too low, the patent would receive an increase in the drug dosage, in contrast, if the level was too high, the dosage was decreased. Id. The Court analyzed each step individually and found that the combination of steps did not make the claim patentable. Id. at 1298. But see Sachs, Punishing Prometheus: Part II—What is a Claim?, supra note 119 (acknowledging Court ignored precedent to view invention as whole).

121 Mayo, 132 S. Ct. at 1299-300 (holding claim at issue lacks persuasiveness necessary to overcome § 101 requirement); see also Diamond v. Diehr, 450 U.S. 175, 192-93 (1981) (allowing patentability of process utilizing mathematical algorithm because patentee did not patent equation); Parker v. Flook, 437 U.S. 584, 593-94 (1978) (stating limiting calculator is unpatentable for claiming algorithm without inventive application).

122 Mayo, 132 S. Ct. at 1303 (refusing to allow claim that passed machine-or-transformation test to be patent eligible). The first supposed transformation—selecting people—was extraneous. Id. The second transformation—changed metabolite level in the body—was overcome by utilizing a different system to read metabolite levels. Id. Thus, the Prometheus claim failed the machine-or-transformation test. Id.
Court refused to view § 101 after finding the claim passed all other statutory requirements because the Court believed that this would cause § 101 to become "a dead letter." The Supreme Court has recently granted a writ of certiorari in AMP to review whether human genes are patentable.

D. The Anticommons Theory and Solutions for Patent Eligibility

One theory often discussed in connection with the patent system is the anticommons theory. The anticommons theory describes the consequences of too many parties possessing the ownership rights to one particular resource. The largest risk is that the privatization of upstream research will affect the downstream area of the industry. When a new area of research is patented to a patentee who does not fully understand this particular field, this broad upstream patent can require technical experts in that same field to request licenses from the clueless patentee. The two

\[\text{[References]}\]
largest fields affected by upstream patents are pure research tools, like genetic tests; and research targets, including drug candidates and therapeutic targets, like genes.\textsuperscript{129}

Researchers have become innovative in attempting to solve the anticommons problem.\textsuperscript{130} Some suggest compulsory licensing schemes to encourage researchers to utilize new innovations and prevent the anticommons issue.\textsuperscript{131} Others suggest that Congress and the USPTO should make changes to the patent system.\textsuperscript{132} Even alterations to the courts' control and perspective could alleviate some of the flaws in the patent system.\textsuperscript{133} In some cases, new entities are utilizing software's open-licensing agreements. \textit{Id.}

Wang, supra note 103, at 297-302 (addressing areas of research where upstream patents affect innovation most). Research target patents harm downstream innovation by avoiding licensing, allowing only limited licenses, and potentially leading to vertical monopolies. \textit{Id.} at 297-98. “Pure research tool” patents cause delays in research and charge high prices because the tools can be used for a wide-range of research, thus patentees require “case-by-case license negotiations.” \textit{Id.} at 298-99-300.

See \textit{infra} notes 131-136 and accompanying text (delineating ways anticommons problem can be resolved).

See Filliben, supra note 125, at 254-55 (reasoning Congress should enact compulsory licensing scheme); Wang, supra note 103, at 319-21 (suggesting waivable compulsory licensing scheme should be adopted). While the compulsory licensing scheme can be waived, this license would enable researchers to perform experiments and pay royalties once certain outcomes are obtained. Wang, supra note 103, at 319.


See Thomas, supra note 80, at 233-34 (demonstrating necessity for courts to utilize policy levers to tailor remedies); Press Release, Stephanie Cirkovich, Pub. Info. Officer, Southern District of N.Y., Ten SDNY Judges to Participate in Patent Pilot Program Starting November 26 (Nov. 3, 2011), available at http://www.nysd.uscourts.gov/file/news/patent_pilot_program_press_release (introducing pilot program to increase judicial expertise in patent lawsuits); Rose, supra note 132 (exposing Myriad holding as unharmonious with Constitution). Several commentators, including Burk and Lemley, encourage the Court of Appeals for the Federal Circuit to advance policies through policy levers by adjudicating according to the specific industry’s needs. See Thomas, supra note 80, at 233-35. The United States District Court for the Southern District of New York and fourteen other federal
source concept to increase innovation and communication.134 Litigious parties can also utilize the patent system strategically to ensure that their rights are protected.135 Overall, the balance of allowing patent eligibility must be weighed against the market as a whole to ensure that innovation continues.136

IV. ANALYSIS

A. CyberSource Alters the Scope of Patent-Claim Analysis

In CyberSource, the CAFC reviewed the appellants’ claims by investigating what the patent claims’ steps of detecting credit card fraud actually entailed.137 While past courts have critically viewed claims to determine whether the statements are patent eligible, the court in CyberSource went a step further by looking at the “underlying invention” claimed.138 The CAFC questioned whether the Internet is considered a

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134 See Daniel R. Bestor & Eric Hamp, Peer to Patent: A Cure for Our Ailing Patent Examination System, 9 NW. J. TECH. & INTELL. PROP. 16, 5, 22-23 (2010) (examining USPTO pilot program that uses “crowdsourcing” to assist patent examiners with patent filings); Jay Bradner: Open Source Cancer Research, TEDxBOSTON 2011 (May 2011) http://www.ted.com/talks/jay_bradner_open_source_cancer_research.html (justifying use of open source science information in academia to vastly increase innovation); see also Beldiman, supra note 16, at 49 (citing biotechnology open source such as nonexclusive licenses and reach-through obligations). As an example, instead of keeping a new molecule a secret, an academic laboratory published its findings and freely sent molecule samples to other laboratories. Jay Bradner: Open Source Cancer Research, supra. As a result, the use of open source and crowdsourcing quickened the innovative solutions to cancer and other areas of science. Id. Similarly, a pilot program, Peer to Patent, allows registered peer reviewers to review patent, locate prior art, rank prior art, and forward top ranked prior art to patent examiners to assist examiners in locating the best prior art for patent examinations. See Bestor & Hamp, supra, at 21. Peer to Patent is the second pilot program and, unlike the first pilot, USPTO will pay a large amount of the cost, suggesting the program may become permanently part of the USPTO in the future. Id. at 23, 25.

135 See Navigating the Murky Morass of Section 101, supra note 75 (explaining how litigants can use patentability in upcoming litigations to their advantage). Patentability can be raised early in litigation to help an alleged infringer avoid a long discovery process. Id.

136 See Reback, supra note 80, at 2 (claiming that excessive patents are equally as bad as limited patents); see also Big and Clever, ECONOMIST, Dec. 17, 2011, at 116, available at http://www.economist.com/node/21541826 (arguing need for large and small companies to promote innovation effectively). While large companies have the ability to influence the economy, survive globalism, and change “vast systems” like health care, small companies are useful for transforming entire systems with the use of new ideas. See Big and Clever, supra, at 116.

137 CyberSource Corp. v. Retail Decisions, Inc. (CyberSource), 654 F.3d 1366, 1370, 1374 (Fed. Cir. 2011) (analyzing claims by reviewing claims step-by-step).

138 Id. at 1374 (reviewing underlying improvement of patent claims). New uses of language
machine under the machine-or-transformation test and, more importantly, whether the Internet is a necessary and substantial part of the claim.\textsuperscript{139} Although the appellants asserted that the claim required the Internet, the CAFC decided that the Internet was only used for data gathering.\textsuperscript{140} Claim three did not disclose any formula to determine if a credit card transaction was valid or include any transformation, so the court declared claim three to be an abstract idea.\textsuperscript{141} The CAFC similarly rejected the Beauregard claim, claim two.\textsuperscript{142}

Consequently, the court’s ruling in \textit{CyberSource} may now challenge the validity of future software claims.\textsuperscript{143} Software claims must be complex enough to require a computer or other machine to carry out the process.\textsuperscript{144} Because the court specifically questioned whether a patent claim was written to try to dodge patent ineligibility, software patent applicants should ensure their claims include more than mental steps.\textsuperscript{145} Additionally, the lower courts could potentially apply \textit{CyberSource} to other industries.\textsuperscript{146} The claims in \textit{CyberSource} were seen as abstract ideas...
because they lacked definable limits. If the claims were viewed on a continuum ranging from patent eligible to patent ineligible, the CyberSource claims would be at the more upstream, patent-ineligible end of the spectrum. Upstream innovations are those that are, at a fundamental level, like the exceptions to patent eligibility: laws of nature, physical phenomena, and abstract ideas. The patenting of upstream inventions can affect downstream progress by stifling innovation, just as the theory of anticommons predicted.

B. Myriad’s Upstream Patent Claims May Be Invalid Under Mayo

Before the CAFC reviewed AMP, the USPTO specifically permitted the patentability of isolated DNA claims if all the patentability requirements were met. Despite the USPTO’s positive stance toward isolated DNA claims, other government agencies can usurp the USPTO’s control and change the patent-eligibility rules. While the CAFC could have simply agreed with the USPTO that isolated and purified DNA claims were patentable, each justice chose to analyze the claims according to his or her own patent standards.

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147 See CyberSource, 654 F.3d at 1366, 1374 (treating claims as patent ineligible because lack of claim limitations encompasses impermissible abstract idea).
148 See id. at 1369-70 (citing exceptions to patent eligibility as necessary for work of all researchers); see also supra note 15 and accompanying text (defining patent eligibility along spectrum).
149 See Wang, supra note 103, at 253 (determining that loosened standards of patentability causes rise in upstream patents).
150 See Poulsen, supra note 15, at 228 (asserting upstream patenting harms innovation via anticommons theory); see also Wang, supra note 103, at 273 (describing negative results from broad patenting).
151 See Util. Guidelines, supra note 3, at 1094 cmt. 8 (admitting isolated and purified DNA may be patentable if all requirements are met); Rogers, supra note 92 and accompanying text (tracing USPTO’s history of granting gene patents); see also supra note 2 and accompanying text (discussing all requirements for patentability).
152 See Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office, 653 F.3d 1329, 1380-81 (Fed. Cir. 2011) (Bryson, J., concurring in part and dissenting in part) (explaining why USPTO lacks dispositive authority regarding patent eligibility), vacated sub nom. Ass’n for Molecular Pathology v. Myriad Genetics, Inc., 132 S. Ct. 1794 (U.S. 2012) (mem.), opinion vacated, appeal reinstated, 467 F. App’x 890 (Fed. Cir. 2012). Judge Bryson stated that the USPTO reasoning for isolated DNA patentability was not thorough, that the USPTO’s opinion is questionable because the Department of Justice’s brief declares patent ineligibility, and that the Supreme Court refused to defer to the USPTO to determine patent issues in the past. Id.
153 Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office (AMP), 689 F.3d 1303, 1325-33 (Fed. Cir. 2012) (majority opinion) (explaining each judge’s view on whether isolated DNA claims are patent eligible), cert. granted in part, 133 S. Ct. 694 (U.S. 2012) (mem.); id. at 1340-48 (Moore, J., concurring) (same); id. at 1348-58 (Bryson, J., dissenting)
Instead of creating separate methods to analyze whether the isolated DNA claims were distinct, the CAFC should have followed CyberSource’s analysis by reviewing the DNA claims for the “underlying inventions.”154 If the court analyzed Myriad’s DNA claims by reviewing the “underlying invention,” Judge Bryson’s dissenting opinion would likely have prevailed because Myriad’s true invention claimed the BRCA1/2 genes.155 Myriad’s isolated BRCA1/2 genes declare a natural phenomenon: the exact same DNA sequences as the human genes BRCA1/2.156 As such, these isolated DNA claims should not be patent eligible under § 101.157 The isolated DNA claims are too far upstream in the patent-eligibility continuum.158

The CAFC in AMP had difficulty determining whether the isolated DNA claims were patent eligible because the Supreme Court has not issued a bright-line test for patent eligibility.159 Instead, the ruling in Mayo suggests that the Supreme Court may not fully grasp the patent field.160 While the Court was confident in declaring the claim in Mayo as patent ineligible, the Court did not follow the precedents for analyzing the claim as a whole, nor did it give much credit to the machine-or-transformation test.161 While the Court is currently considering whether genes are patentable in AMP, if the Court does not issue clear guidelines then the

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154 See CyberSource Corp v. Retail Decisions, Inc., 654 F.3d 1366, 1374 (Fed. Cir. 2011) (considering underlying invention described in patent claims).

155 See AMP, 689 F.3d at 1350 (expounding that Myriad’s DNA claims’ value is DNA’s function, not DNA’s structure); see also Brief for the United States as Amicus Curiae in Support of Neither Party at 5, Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office, 689 F.3d 1303 (Fed. Cir. 2012) (No. 2010-1406), 2012 WL 2884115, at 4 (opining that isolated gene claims are not patent eligible).

156 See AMP, 689 F.3d at 1354 (finding natural and Myriad’s isolated DNA contain same DNA sequence).

157 See supra notes 2-3 and accompanying text (describing requirements and exclusions for patent eligibility).

158 See supra note 15 and accompanying text (acknowledging continuum exists for patent eligibility).

159 See Bilski v. Kappos, 130 S. Ct. 3218, 3229-30 (2010) (advocating for judicial utilization of precedent cases to determine patentability); AMP, 689 F.3d at 1329 (describing patent eligibility exceptions without discussing any bright-line rule).

160 See supra note 19 and accompanying text (discussing ambiguity and potential errors in § 101).

161 See Mayo Collaborative Servs v. Prometheus Laboratories, Inc., 132 S. Ct. 1289, 1297-1305 (2012) (announcing patent eligibility cannot be achieved for claims regarding mere transformation within human body); see also Bilski, 130 S. Ct. at 3227 (demonstrating that machine-or-transformation test is useful but not sole test for patent eligibility); Diamond v. Diehr, 450 U.S. 175, 188 (1981) (considering patent eligibility by viewing patent claims “as a whole”).
CAFC will continue to have trouble analyzing claims without a clear test or the ability to avoid the § 101 analysis until the other requirements of patentability have been satisfied.162

While Mayo requires courts to view § 101 as a far more restrictive patent-eligibility requirement, the CAFC majority in the AMP case viewed § 101 more leniently, which may suggest why the Supreme Court has again granted certiorari to the AMP case.163 Advocates for a ruling in favor of DNA’s patentability in AMP think that the pharmaceutical and biotechnology industries need patents to encourage research, as the likelihood of success in creating actual innovations in these industries is slim.164 Patents also prevent competitors from simply copying the original institution’s work.165 Although creating a successful invention in these industries is quite challenging, abstract ideas should not be patent eligible, even under the guise of isolated DNA patents.166

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162 See Petition for a Writ of Certiorari at i, Ass’n for Molecular Pathology v. Myriad Genetics, Inc. (AMP), 689 F.3d 1303 (Fed. Cir. 2012), available at http://patentdocs.typepad.com/files/petition-for-certiorari.pdf (stating question requesting review of whether human genes are patentable), cert. granted in part, 133 S. Ct. 694 (U.S. 2012); see also Hirshfeld, supra note 120, at 2-3 (encouraging patent examiners to continue using Bilski Guidelines until further notice).

163 See Ass’n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 694, 695 (2012) (mem.) (granting certiorari regarding question one); Mayo Collaborative Servs., 132 S. Ct. at 1297-1305 (announcing patent eligibility cannot be achieved for claims regarding mere transformation within human body); Petition for a Writ of Certiorari for Plaintiff-Appellant at i, Ass’n for Molecular Pathology v. Myriad Genetics, Inc. (AMP), 689 F.3d 1303 (Fed. Cir. 2012), available at http://patentdocs.typepad.com/files/petition-for-certiorari.pdf (highlighting request for review of whether human genes are patentable); see also AMP, 689 F.3d at 1349 (citing obstacles to genetic multiplexing tests and whole-genome sequencing); Brief for the United States as Amicus Curiae in Support of Neither Party at 5, Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office, 689 F.3d 1303 (Fed. Cir. 2012) (No. 2010-1406), 2012 WL 2884115, at 4 (announcing isolated DNA claims are “product of nature” and therefore patent ineligible); Ghoshray, supra note 117, at 537 (explaining gene patents harm innovation by preventing others from investigating, reviewing, or developing processes); MacKenzie, supra note 16, at 392 (alleging Myriad’s patents grant monopoly on natural gene). Scientific entities cannot design cheaper diagnostic processes or review Myriad’s testing because the court permitted gene patentability. Ghoshray, supra note 117, at 537.

164 See Thomas, supra note 80, at 215-16 (portraying pharmaceutical and biotechnology industries as requiring patents to undertake high research costs).

165 See Thomas, supra note 80, at 216 (realizing initiators would use original party’s success for own personal benefit without patent issuance).

166 See AMP, 689 F.3d at 1350 (citing slight material change did not greatly alter genes from natural genetic form); see also Brief for the United States as Amicus Curiae in Support of Neither Party, supra note 117, at 4 (announcing isolated DNA claims are “product of nature” and therefore patent ineligible); Ghoshray, supra note 117, at 537 (explaining gene patents harm innovation by preventing others from investigating, reviewing, or developing processes); MacKenzie, supra note 16, at 392 (alleging Myriad’s patents grant monopoly on natural gene); Wang, supra note 103, at 273 (determining gene patents as negatively affecting downstream research).
C. Bridging the Gap Between Software and Biotechnology

Just as the Supreme Court encouraged courts to utilize the precedents of Benson, Flook, and Diehr, certain industries should inspect all cases regarding patent eligibility, even those outside the industries’ specific field. For instance, CyberSource demonstrates that, in addition to Diehr’s requirement that the court should look at claims “as a whole,” courts can inspect claims for their “underlying invention.” Because the Supreme Court in Mayo analyzed the steps of the claim separately—instead of analyzing the claim steps “as a whole” as Diehr requires—the patent community is uncertain if the holding of Mayo overturned Diehr’s patent-claim analysis without providing any explanation. If lower courts are able to distinguish future cases from the incorrect analysis in Mayo (viewing each step separately to ensure the survival of the black letter law of reviewing patent claims “as a whole”), then CyberSource’s investigation of software patent claims could expand the strict § 101 analysis to biotechnology and pharmaceutical patent claims. While this type of analysis could easily affect rulings in these industries, the industries themselves may be better suited by using open-source sharing to encourage innovation.

The software industry consists of both patented and open-source software. Because the software industry does not require large investment costs, some analysts argue that software patents are

167 See Bilski v. Kappos, 130 S. Ct. 3218, 3229-30 (2010) (comparing issue at hand to precedent cases for guidance regarding patent eligibility); supra note 26 and accompanying text (describing precedential case law on patent eligibility); see also Noonan, supra note 75 (assuming CyberSource analysis may be applied in cases regarding patent eligibility in other industries).


169 See Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1292 (2012) (reviewing claim steps one by one, instead of reviewing claims “as a whole”); see also Hirshfeld, supra note 120, at 2-3 (announcing patent examiners should continue using old § 101 guidelines for patent eligibility).

170 See Noonan, supra note 75 (suggesting court may review “underlying invention” in future cases for any type of patent claim).

171 See supra note 134 and accompanying text (employing use of open source in scientific research field).

172 See supra note 80 and accompanying text (stipulating both patented and open-source software simultaneously exist).
Opposition toward patents is strong in the software industry because open-source software allows programmers to utilize and improve upon software code freely. Following this trend, the notion of open source is being applied to the USPTO and the scientific academic arena. The Peer to Patent pilot program at the USPTO allows online users to rank prior art references and send the highest ranked references to patent examiners, which in turn helps reduce the heavy workload of USPTO examiners. Similarly, in the biotechnology industry, after one academic laboratory fully disclosed a new molecule that binds with a cancer protein, numerous research institutions were able to utilize the information in a variety of ways that would have been impossible for the single academic laboratory to do alone.

If the CAFC restricted patent eligibility in the biotechnology and pharmaceutical industries, like the court has in the software field, research institutions could use information regarding gene sequences without fear of litigation. Because gene patents are research targets that are very upstream in the patent-eligibility continuum, allowing gene sequence information to be classified as common knowledge would greatly increase productivity in the diagnostic testing and research fields. The facts of the AMP case exemplify this flaw in the current U.S. patent system: Myriad discovered a gene sequence deletion far later than researchers in Europe because Myriad’s monopoly prevented other institutions from reviewing or creating new diagnostic tests. Requiring the biotechnology and pharmaceutical industries to disclose research targets would increase competition, lower litigation regarding infringement, and encourage

173 See supra notes 80-82 and accompanying text (contending software patents lack necessity in software industry).
174 See Boldrin & Levine, supra note 81, at 326 (noting open source software yields innovation through free disclosure of ideas).
175 See supra note 134 and accompanying text (outlining how other sectors are utilizing open source to encourage innovation).
176 See Bestor & Hamp, supra note 134, at 21 (explaining open source use of prior art in USPTO pilot program).
177 See Bradner, supra note 134 (articulating open source disclosure allowed much greater returns than single laboratory could produce alone).
178 See supra note 133 and accompanying text (indicating judiciary should tailor remedies through patent experience and policy levers).
179 See Poulos, supra note 15, at 227 (detailing how tragedy of anticommons could occur in biotechnology sector); Wang, supra note 103, at 296-97 (recognizing protection of research targets harms competition); see also Filliben, supra note 125, at 252 (describing anticommons theory).
180 See Wang, supra note 103, at 296 (sugesting lengthier discovery in United States due to monopoly on gene sequence).
innovation. Reducing the lower courts’ expansive view of the biotechnology and pharmaceutical industries’ patents would be in accordance with the Supreme Court’s view of the patent system in Mayo, and in doing so harmonize the more expansive biotechnology and pharmaceutical industries’ patent case law with the more limited software patent case law.  

D. Further Solutions to Harmonize the Patent System

If free disclosure of upstream research disincentivizes some entities from partaking in more upstream research, academic institutions can take over the upstream research role. Scientific research can potentially benefit from the use of more open source disclosure of upstream information. Congress could also assist in this process by creating a public domain to house this knowledge. The Human Genome Project is one example of how a public domain allows an entire scientific industry to advance a number of research objectives.

Alternatively, Congress can require compulsory licensing of upstream inventions. A compulsory licensing scheme with reach-through royalties would be ideal because researchers could freely use

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181 See Poulsen, supra note 15, at 227 (explaining how anticommons may occur in biotechnology sector); Wang, supra note 103, at 296-97 (noting how research targets can harm competition); see also Filliben, supra note 125, at 252 (examining anticommons theory); supra note 134 and accompanying text (observing upstream knowledge lowers likelihood of anticommons theory and benefits public).

182 See Mayo Collaborative Servs. v. Prometheus Labs., Inc, 132 S. Ct. 1289, 1298 (2012) (holding claims as patent ineligible for including only well-known steps for law of nature); supra notes 132-133 and accompanying text (discussing need for harmonization). But see sources cited supra note 119 and accompanying text (arguing Mayo upsets balance in patent law by overturning precedents).

183 See Lawrence Higgins, Patently-O Bits & Bytes, PATENTLYO (Feb. 5, 2012, 7:01 PM), http://www.patentlyo.com/patent/2012/02/patently-o-bits-bytes-by-lawrence-higgins.html (determining universities possess many patents that could be useful to pharmaceutical companies); MacKenzie, supra note 16, at 393 (predicting academic institutions can focus on upstream research if private corporations lose interest).

184 See supra note 134 and accompanying text (providing that open source in academia resulted in expansive research results).

185 See Mitchell & Rennus, supra note 132, at 39 (encouraging Congress to create public domain for information). Groups like the ACLU and PUBPAT should lobby Congress to institute legislative changes for the patent system. Id.

186 See supra note 98 and accompanying text (tracing positive effects of Human Genome Project).

187 See Filliben, supra note 125, at 254 (reasoning why Congress should enact compulsory licensing scheme); Wang, supra note 103, at 319-21 (proffering that waivable compulsory licensing scheme could encourage innovation); see also Mayo Collaborative Servs., 132 S. Ct. at 1305 (highlighting that Congress can promulgate “more finely tailored rules where necessary”).
information and only pay royalties once the research is concluded.\textsuperscript{188} This type of licensing streamlines negotiations because both parties will have a clear assessment of their contributions.\textsuperscript{189} A royalty cap determined separately for each case could ensure that downstream research can occur while allowing independent researchers to receive credit for their own discoveries.\textsuperscript{190} The compulsory licensing scheme could also allow an option for researchers to “opt out” in favor of voluntary licensing if they prefer to pay royalties upfront.\textsuperscript{191}

While the USPTO has begun to utilize open-source information for patent examiners in the pilot program, it could also employ some additional practices to create greater harmony with the courts and Congress.\textsuperscript{192} The USPTO has struggled to keep up with the rising trend of companies and individuals filing more patent applications.\textsuperscript{193} Patent applications are now more complex and lengthier than ever before.\textsuperscript{194} Although patent examiners try to respond quickly and precisely, often overly broad patents are issued and good patents are wrongfully rejected.\textsuperscript{195} Increased USPTO funding would allow for more patent examiners to be hired so that the examiners could analyze patent applications and issue patents more carefully.\textsuperscript{196}

The courts can also help alter the patent system by tailoring remedies according to the specific background of the case.\textsuperscript{197} Courts should also be more restrictive about patent eligibility in response to the

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\item See Wang, supra note 103, at 318-19 (developing useful licensing scheme to reduce anticommons issues).
\item See id. at 254 (seeking royalties post-research accurately calibrates royalty fees).
\item See id. at 320 (stressing royalty cap determined on case-by-case basis to provide fair credit to both parties).
\item See id. (allowing researchers to select voluntary licensing if preferred).
\item See Besior & Hamp, supra note 134, at 22 (examining USPTO pilot program that utilizes crowd sourcing); Sovacool, supra note 132, at 436 (arguing USPTO would positively benefit from additional funding). See generally Moore, supra note 132, at 1288-89 (alleging disconnect between judiciary, legislature, and patent system).
\item See Sovacool, supra note 132, at 411 (evaluating rising rate of applications and effect on examiners).
\item See id. (noting applications are lengthier and more complex).
\item See id. at 412 (finding examiners lack skill to determine patentability properly); see also supra note 81 and accompanying text (condemning broad and redundant patents).
\item See Sovacool, supra note 132, at 436 (concluding additional funding would help streamline USPTO).
\item See Chien & Lemley, supra note 80 (suggesting court should alter remedies according to competition conditions); Thomas, supra note 80, at 233-34 (encouraging judiciary to utilize policy levers to tailor remedies); see also supra notes 81-82 and accompanying text (suggesting innovation is impaired by patent redundancy); infra note 199 and accompanying text (stating methods judiciary can utilize to streamline patent-eligibility issues).
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over-patenting caused by the USPTO. The pilot program that requires that certain judges become more proficient in patent cases at the district court level should be expanded to include all district courts. The courts could also take a more drastic measure to avoid patent-eligibility issues by avoiding § 101 analysis unless no other patentability requirements are at issue; however, this solution does not resolve the underlying issues of § 101 or give litigants any definite answers. Overall, if judges become better versed in patent cases and the courts improve the balance of innovation with over-patenting issues, the court system will be in greater harmony with Congress and the USPTO. As a result, § 101 would become a clearer threshold to patent applicants and litigants, and less litigation would occur regarding § 101’s threshold patent-eligibility requirement.

V. CONCLUSION

Recent lower court cases for patent eligibility show a divide between the software and biotechnology industries. While both industries have challenged the boundaries of patent eligibility under § 101, the courts, Congress, and the USPTO should firmly declare that laws of nature, physical phenomena, and abstract ideas are not patent eligible. Unfortunately, while the court in CyberSource created a strict rule so that courts can analyze the patent claims for their “underlying invention,” the court in AMP simply allowed isolated DNA claims to be patent eligible. This ruins the harmony of patent eligibility and prominently exemplifies the disconnect present in the courts regarding patent law. Yet, the Supreme Court may reverse the AMP ruling to bring some symmetry to patent law, regardless of the industry.

In order to maintain a strong patent system and to reduce patent litigation, Congress, the USPTO, and the courts should instill some new practices. Congress should advocate change by either requiring a public domain for innovative information or requiring a compulsory licensing scheme to enable other researchers to utilize upstream inventions.

198 See supra notes 81-82 and accompanying text (arguing patent redundancy harms innovation).
199 See Cirkovich, supra note 133 (describing new district court program).
200 See sources cited supra note 79 and accompanying text (rejecting analysis of § 101 when other patentability requirements can solve case with greater ease).
201 See Moore, supra note 132, at 1288 (indicating strong disconnect between courts, Congress, and USPTO).
202 See sources cited supra notes 81-82 and accompanying text (highlighting negative effects of patent redundancy on innovation).
Increased funding and additional time to examine patent claims would help the USPTO issue patents in a more efficient manner. The courts should become more restrictive with the patent-eligibility requirements. Additionally, the courts should expand the pilot program to encompass all district courts, so that judges in each district court can become more experienced with patent issues.

Overall, these changes would allow innovation to grow as the framers of the Constitution desired. The alterations would also decrease litigation by uniformly rejecting patent claims that are overly broad and upstream. The advances in the biotechnology and software industries suggest that the use of open source can be helpful in a variety of settings by utilizing the strengths of the Information Age with current ideas. If these types of changes are incorporated, perhaps more research will be accomplished, more software streamlined, and overall, more inventions created.

Joanna M. Grigas