Don’t Give Up Section 101, Don’t Ever Give Up

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DON’T GIVE UP SECTION 101,
DON’T EVER GIVE UP

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Although adopting one of the most inspirational quotes of the Twentieth Century to title an article about patent jurisprudence smacks of hyperbole, the challenges facing the U.S. patent system cannot be ignored.¹ One particularly troublesome challenge is a simply phrased, yet incredibly abstract question: what is patent-eligible subject matter?² Patent-eligible subject matter jurisprudence, governed by 35 U.S.C. § 101, has fallen currently into a “morass” and will likely continue its downward spiral as advancements in technology challenge the courts’ perception of the scope and role of patent law.³

Unfortunately, accompanying this confusion are patents’ increasing economic influence.⁴ The U.S. patent system is predicated precisely upon increasing “the

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public storehouse of knowledge” through economic incentives for inventors. However, as economic markets are increasingly interconnected globally, coupled with the increased influence of costly litigation on non-participating parties, the role of a business entity’s patent litigation strategy stands to shape the global market.

As discussed below, § 101 jurisprudence has evolved a great deal within the last decade, a span of years half the statutory duration of patents. Accordingly, an indecisive set of standards determining patent eligibility perturbs organizational patent ventures and negatively impacts downstream investment, as companies are uncertain whether specific categories of inventions will maintain their patent eligibility. Further, inconsistencies in court opinions regarding patent-eligible subject matter casts doubt on the validity of existing patents. Such doubt over property rights has the potential to chill the incentive to invest in important areas of research and development, decrease “the public storehouse of knowledge[,]” stymy the progress of science and technology, and negatively affect the United States’ position in the global market.

Because § 101 jurisprudence has fallen into chaos a natural reaction is to avoid the statute. Such a knee jerk response fails to consider significant policy implications that only § 101 is capable of serving, neglects a century of patent jurisprudence, and wastes a valuable resource that reduces litigation expenses.

This Comment begins by tracing the history of § 101 jurisprudence and discusses how it devolved into the current “morass.” It further explores how two competing theories of § 101 have emerged: the functional viewpoint and the jurisdictional viewpoint. The functional viewpoint considers the criteria for...
patentability set forth in the Patent Act, including § 101, as tools for weeding out non-patentable inventions. Continuing with this metaphor, functionalists argue that § 101—unlike §§ 102, 103, and 112—is a rusted unworkable device that is unable to adequately perform its job. Functionalists believe instead that courts should avoid § 101 and rely on the more accessible and well-oiled tools that are §§ 102, 103, and 112. Jurisdictionalists, on the other hand, insist that § 101 stands as a threshold inquiry—a doctrine that maps the scope of patent law and must be considered prior to investigating §§ 102, 103, and 112.

This Comment argues that the proper role of § 101 is that of threshold inquiry, in line with the jurisdictional viewpoint under a legal and policy rationale. First, on legal grounds the jurisdictional viewpoint of § 101 is supported textually in how it was promulgated and how it relates to other provisions of the Patent Act. Second, the current trend to decide § 101 disputes at the pleading stage, suggests that courts are embracing the jurisdictionalist viewpoint. From a policy perspective, courts, by treating § 101 as jurisdictional, effectively lower the cost of patent litigation while providing greater opportunity for judicial input from the specialized U.S. Court of Appeals for the Federal Circuit and ultimately from the U.S. Supreme Court.

This Comment proceeds in three parts. Part I introduces the rationalization of patent law, the role § 101 plays, and demonstrates the growing concerns with § 101 jurisprudence. Part II highlights the competing § 101 philosophies: functional versus jurisdictional viewpoints. Part III argues that § 101 should be treated as jurisdictional for legal and policy reasons.

I. HISTORICAL FRAMEWORK: THE JOURNEY OF § 101 JURISPRUDENCE

The U.S. Constitution “vests Congress with plenary authority over patents and copyrights.” Thomas Jefferson, charged with the task of drafting an appropriate statute, relied heavily on the principles of English law and sought “to promote the progress of science and useful arts . . . by giving the public at large a right to make, construct, use, and vend the thing invented, at as early a

15. See id.
16. See id.
17. See discussion infra Section III.A.
18. See discussion infra Section III.B.
19. See discussion infra Section III.C.
21. Pennock v. Dialogue, 27 U.S. (2 Pet.) 1, 18 (1829) (noting “[i]t is obvious to the careful inquirer, that many of the provisions of our Patent Act are derived from the principles and practice which have prevailed in the construction of that of England["]

(Stating that “[t]he reason . . . a theory is needed in [Patentable Subject Matter] law is because . . . the rules of [Patentable Subject Matter] law are not self-defining on their face]”).
period as possible; having a due regard to the rights of the inventor.”22 The Patent Act of 1793 embodied this philosophy, defining the patent-eligible subject matter to be “any new and useful process, machine, manufacture, or composition of matter, or any new or useful improvement [thereof].”23 This language remained largely unchanged until the patent laws were recodified in the 1952 Patent Act.24 Accompanying the 1952 Patent Act is the oft-cited legislative quotation, indicating that § 101 should be read to “include anything under the sun made by man . . . .”25 Not everything made by man is worth patent protection, however, as the inventor must demonstrate, among other things, that the invention is novel under 35 U.S.C. § 102 and non-obvious under 35 U.S.C. § 103.26

Further, courts have categorically excluded certain types of inventions from protection under § 101.27 Specifically, courts have determined that discoveries or inventions drawn to laws of nature, natural phenomena, or abstract ideas cannot be considered patent-eligible subject matter.28 Such discoveries or inventions are categorically excluded out of public policy concerns that patent protection over such inventions would “impede rather than ‘promote the Progress of Science and useful Arts . . . .’”29 The present controversy exists

22. Id. at 19.
25. Bilski, 545 F.3d at 976 (Fed. Cir. 2008) (quoting H.R. Rep. No. 1923, 82d Cong., 2d Sess. 6 (1952)). It is important to note that the Court modified slightly the quotation, isolating the famous quotation from the full text, possibly altering a consummate appreciation of legislative intent. The complete sentence reads: “A person may have ‘invented’ a machine or a manufacture, which may include anything under the sun that is made by man, but it is not necessarily patentable under section 101 unless the conditions of the title are fulfilled.” H. Rep. No. 1923, 82d Cong., 2d Sess. 6 (1952).
26. See Martin D. Lerner, Law Note: In re Lowry and Printed Matter, 77 J. PAT. & TRADEMARK OFF. SOC’Y 808, 810 (1995) (noting that the determination of whether something is patent-eligible or ineligible “has little to do with a priori logic and more to do with making a posteriori social and policy decisions look logical and consistent in retrospect”).
27. See infra text accompanying notes 28–29.
29. Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 548 U.S. 124, 126 (2006) (Breyer, J., dissenting) (citing U.S. CONST. art. I, § 8, cl. 8); see also Diehr, 450 U.S. at 185 (“A principle, in the abstract, is a fundamental truth; an original cause; a motive; these cannot be patented, as no one can claim in either of them an exclusive right.”); see also Chakrabarty, 447 U.S. at 309 (“Such discoveries are ‘manifestations of . . . nature, free to all men and reserved exclusively to none.’”).
because these judicially created exceptions, as Justice Frankfurter once noted, are “vague and malleable.”

A. A Look Back at the History and Purpose of § 101

Despite the recent overhaul to the patent system, transitioning from a first-to-invent to a first-to-file system, Congress elected to leave the words of Thomas Jefferson unchanged. Section 101 of the Patent Act defines the subject matter eligible for patent protection as: “[W]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.”

The antique language of § 101 and the abstractness of the judicially created exceptions, coupled with tremendous technological advancements since the late eighteenth century, have rendered modern § 101 jurisprudence “in a state of flux.” Understanding that a newly discovered mineral or Einstein’s mass energy equivalence equation is not patentable subject matter is not as difficult as, for example, determining the eligibility for patenting of business methods, methods for calibrating the proper dosage of drugs to treat autoimmune diseases, isolated gene sequences, or computer software.

The purpose of having a patent system is articulated in the Constitution. To “promote the progress of science and useful arts,” Congress will reward the inventor with a limited exclusive right in the form of a patent. Thus, an inventor is provided a financial incentive for his or her creative efforts with the

34. Roux, supra note 3, at 641. Historically, inventions or discoveries that fell into judicially created categories of patent ineligible subject matter “yielded some of its most enduring, yet most complex patent law jurisprudence.” Leading Cases, 126 HARV. L. REV. 347, 347 (2012); see also Dennis Crouch & Robert P. Merges, Operating Efficiently Post-Bilski by Ordering Patent Doctrine Decision-Making, 25 BERKELEY TECH. L.J. 1673, 1677 (2010) (stating “the lack of a comprehensive definition can also create uncertainty—especially where the volume of case law is relatively low”).
38. See Ass’n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2116 (2013).
40. See Beckerman-Rodau, supra note 4, at 155–56 (citing U.S. CONST. art. I, § 8, cl. 8).
41. Id.
right to exclude others from making, using, or selling the invention, and in return the public storehouse of knowledge is enhanced.\textsuperscript{42} It is universally accepted that the patent regime is grounded in utilitarian considerations and is dedicated to incentivize “inventions that would otherwise not materialize . . . .”\textsuperscript{43} Although not explicitly mentioned in the language of § 101, determining what is patent-eligible subject matter strikes an important balance between normal marketplace pressures facilitating innovative advancement and overbroad restraints on research and development.\textsuperscript{44} If the statute is read narrowly, the incentive fails to achieve its primary purpose: to promote the advancement in the scientific and technical fields.\textsuperscript{45} If the statute is read broadly, the right to exclude creates economic barriers, inhibiting others from engaging in innovative endeavors.\textsuperscript{46} The judicially created exceptions, which exclude from patentability laws of nature, physical phenomena, and abstract ideas, serve the balancing objective to promote innovation.\textsuperscript{47} Courts have accepted the responsibility of determining what inventions are patent-eligible.\textsuperscript{48}

### B. The Supreme Court’s Trilogy: Benson, Flook, and Diehr

Over a nine-year period, the U.S. Supreme Court decided a trio of patent-eligibility cases—\textit{Gottschalk v. Benson},\textsuperscript{49} \textit{Parker v. Flook},\textsuperscript{50} and \textit{Diamond v. Diehr}.\textsuperscript{51} Collectively, the trilogy of cases is considered a judicial “guidepost[,]” shepherding the eligibility determination process for patents per § 101.\textsuperscript{52}

At issue in \textit{Benson} was whether a method that used an algorithm to convert binary-coded decimal numerals into pure binary codes was a patent-eligible process.\textsuperscript{53} The Supreme Court considered the algorithm to have no application...
outside a general purpose computer, and thus the “practical effect would be a patent on the algorithm itself.” Algorithms, like scientific truths, are laws of nature, regarded as a discovery of a fundamental truth rather than an invention, and thus not patent-eligible subject matter. Benson’s claims, the court elaborated, “purport[ed] to cover any use of the claimed method in a general purpose digital computer.” Notably, the Court decided that eligibility determinations of computer-implemented algorithms should be made on a case-by-case basis, rather than create a bright line rule that would govern method claims directed to a computer.

The Flook Court investigated the patent eligibility of method claims designed to calculate and adjust an “alarm limit in a catalytic conversion of hydrocarbons.” The claims were directed broadly to a computer, encompassing nearly any use of respondent’s formula, even a mental computation of the equation. The only difference between the respondent’s invention and existing methods of adjusting alarm limits in catalytic converters was the respondent’s novel algorithm. The Court determined, noting the lack of any physical, tangible elements, the method claims ineligible under § 101 because the respondent’s application contained no patentable inventions despite the novelty of the algorithm and its inventive implementation on a computer.

In the trilogy’s finale, Diehr, the Supreme Court investigated the eligibility of a claimed method that utilized an algorithm to calculate the optimal duration and temperature of a process for turning uncured synthetic rubber into cured precision products. The Court concluded that the claimed method in Diehr, unlike the methods reviewed in Benson and Flook, was indeed patent-eligible subject matter because the claims, “considered as a whole,” did not “foreclose from others the use of that equation in conjunction with all of the other steps in their claimed process.” Therefore, the implementation of an algorithm in a claimed invention does not itself disqualify the invention as patent-eligible subject matter. The inquiry rests, rather, on how the algorithm is implemented.

56. Id. at 1056 (citing Benson, 409 U.S. at 67).
57. See id. at 1062.
58. See Syrowik, supra note 52, at 29 (referencing Parker v. Flook, 437 U.S. 584, 586 (1978)).
60. See id. at 379 (citing Flook, 437 U.S. at 585–86).
61. See id. (citing Flook, 437 U.S. at 594); see also Syrowik, supra note 52, at 29–30 (“[I]nsignificant’ post-solution activity to an otherwise” patent-ineligible process or method does not “transform an unpatentable principle into a patentable process.”) (citing Flook, 437 U.S. at 590).
62. See Syrowik, supra note 52, at 30 (citing Diehr, 450 U.S. at 177–79).
63. See Strobos, supra note 59, at 381 (quoting Parker v. Flook, 437 U.S. 584, 594 (1978)).
64. See id. at 387 (quoting Diehr, 450 U.S. at 187); see also Syrowik, supra note 52, at 30.
or applied in a process; specifically, whether the algorithm “transform[s] and reduce[s] . . . an article ‘[i]nto a different state or thing,’”65 to the point claims no longer preclude the “use of manual labor or thought to perform the same task.”66

C. The Patent “Gold Rush”

After Diehr, § 101 cases flooded the docket of the U.S. Court of Appeals for the Federal Circuit—the appellate court with exclusive appellate jurisdiction over patent cases—and the Federal Circuit, relying heavily on the language of the Diehr opinion, broadened the scope of § 101.67 Notably, in State Street Bank & Trust Co. v. Signature Financial Group, Inc.,68 the Federal Circuit determined that the exception for business method claims, which were considered previously patent-ineligible subject matter, had met its demise.69

In State Street, the Federal Circuit examined a claimed computer software program that pooled several mutual funds into a portfolio, consolidated administration costs, and provided certain taxation advantages.70 The appellate court fashioned a new study, extending patent protection to claimed methods that yield a “useful, concrete and tangible result.”71

Shortly thereafter, citing the “useful, concrete, and tangible” language of State Street, the Federal Circuit in AT&T Corp. v. Excel Communications, Inc.,72 determined that a claimed method for billing long-distance and inter-provider phone calls by inserting a “data field” into a standard phone record73—an invention only involving the transfer of data—was patent-eligible subject matter.74 The court justified this sweeping change to patent jurisprudence as a natural reaction to technological advances and “stand[s] as a testament to the ability of law to adopt to new and innovative concepts, while remaining true to basic principles.”75

65. See Strobos, supra note 59, at 377.
66. Id. at 386; see also Syrowik, supra note 52, at 30.
68. 149 F.3d 1368 (Fed. Cir. 1998).
69. See id. at 1375.
70. See id. at 1371; see also Robert Hulse, Patentability of Computer Software After State Street Bank & Trust Co. v. Signature Financial Group, Inc.: Evisceration of the Subject Matter Requirement, 33 U.C. DAVIS L. REV. 491, 509 (2000).
71. State Street, 149 F.3d at 1375 (quoting In re Alappat, 33 F.3d 1526, 1544 (Fed. Cir. 1994)); see Hulse, supra note 70, at 511.
72. 172 F.3d 1352 (Fed. Cir. 1999).
73. Id. at 1354.
74. See id. at 1358 (“‘That respondents’ claims involve the transformation of an article . . . into a different state or thing cannot be disputed . . . [and] [t]herefore, we do not find in the claim any kind of data transformation.’”) (quoting Diamond v. Diehr, 450 U.S. 175, 184 (1981)); see also ADELMAN ET AL., supra note 67, at 87–88.
75. AT&T Corp., 172 F.3d at 1356.
As a result of AT&T, the judicially created exceptions to subject matter eligibility became so narrow in relevance that the exception only applied when a claimed method existed solely in the abstract. The synthesis of the State Street and AT&T opinions virtually obliterated the filter of § 101, leading to a “gold rush” on patent applications from inventors representing diverse backgrounds.

Although the influence of the § 101 filter began to diminish, difficult questions remained as to whether certain classes of inventions deserved patent protection. State Street, in particular, incited a passionate response within the patent community from those who believed the Federal Circuit’s decision compromised the entire integrity of the patent system. In addition, questions concerning business method patents persisted, and the Federal Circuit had to determine the influence of the State Street decision on inventions of the digital age.

1. Bilski

In 2008 the U.S. Patent and Trademark Office (PTO), citing § 101, refused to grant a method patent in the case of In re Bilski. As Bilski percolated up to the Supreme Court, many considered it an opportunity to bridle the expanding scope of patentable subject matter. Although the Court did not specifically overrule State Street, the opinion exposed a dramatic shift in § 101 jurisprudence, signaling an end of the era of judicial restraint concerning patent reform and favoring individual analysis over categorical assessment.

Bilski developed a method to hedge the risk of price fluctuations of commodities in the energy market. The key claims under review were claims 1 and 4: Claim 1 set out instructions on how to hedge risk and Claim 4...
consolidated the steps articulated in Claim 1 into an algorithm. The patent examiner denied Bilski’s application, citing § 101, as merely an attempt to manipulate an abstract idea—solving an algorithm with no limitation in application. On appeal, the Federal Circuit agreed with the examiner’s rejection, but reached its conclusion on different grounds. The Federal Circuit created the “machine-or-transformation test,” finding the useful, concrete, and tangible test inadequate for § 101 purposes. Applying this new framework, the Federal Circuit affirmed the PTO’s § 101 rejection, concluding that the claimed invention failed to “transform any article to a different state or thing.”

The Supreme Court affirmed, but disagreed with the Federal Circuit’s construction of a single categorical rule for determining patent-eligible subject matter. The Supreme Court considered the Federal Circuit’s use of the “machine-or-transformation” test as the only inquiry for determining the eligibility of a process as patent-eligible subject matter to be premature. Although the Supreme Court considered the “machine-or-transformation test” an important investigative tool for determining whether a process passes § 101 muster, the Court believed it should not be relied upon solely as the exclusive test. The Court, however, did not indicate what the § 101 framework should be.

The Bilski Court’s rejection of a bright line rule and its heavy reliance on cases from the 1970s and 1980s revitalized the § 101 debate. Furthermore, its failure to elucidate a workable § 101 framework effectively punted the uncertainty of patent-eligible subject matter down to the lower courts. With no ascertainable

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86. See id.
87. See Stephen Pessagno, Comment, Prometheus and Bilski: Pushing the Bounds of Patentable Subject-Matter in Medical Diagnostic Techniques With the Machine-or-Transformation Test, 36 AM. J.L. & MED. 619, 628 (2010).
88. See id.
89. A process claim is considered patentable subject matter only “if 1) it is tied to a particular machine or apparatus, or 2) it transforms a particular article into a different state or thing.” Richard M. Lee, Beta-Testing the “Particular Machine”: The Machine-or-Transformation Test in Peril and Its Impact on Cloud Computing, 11 DUKE L. & TECH. REV. 175, 177 (2012) (citing In re Bilski, 545 F.3d 943, 954 (Fed. Cir. 2008)); see also Fusco, supra note 81, at 128; Pessagno, supra note 87, at 628.
90. Pessagno, supra note 87, at 629 (quoting In re Bilski, 545 F.3d 943, 963 (Fed. Cir. 2008) (en banc).
92. See id.
94. See Winters & Brown, supra note 91, at 45.
95. See Crouch & Merges, supra note 34, at 1677 (noting the Court’s attempt to avoid the potential harms of a categorical rule); Peter S. Menell, Forty Years of Wondering in the Wilderness and No Closer to the Promised Land: Bilski’s Superficial Textualism and the Missed Opportunity to Return Patent Law to Its Technology Mooring, 63 STAN. L. REV. 1289, 1304 (2011) (stating
framework, scattered opinions from different jurisdictions continued to challenge the Federal Circuit’s understanding of the overall purpose of § 101.

D. Mayo and the Requirement of the “Inventive Step”: A Rational Deduction with No Definition

Prometheus, an innovator of pharmaceutical research and diagnostics products,96 determined the exact concentrations, correlations, and efficacy of certain thiopurine drugs in the treatment of autoimmune diseases, such as Crohn’s disease and ulcerative colitis.97 The correlative nature of certain metabolites, substances formed in or necessary for metabolic reaction, and their general efficacy in the treatment of certain diseases were well documented in the scientific community.98 The exact numerical correlations, however, remained uncertain.99 Such calculations largely eluded scientists and health care professionals because individuals metabolize compounds at different rates.100 An individual with an active metabolism may be at higher risk of negative side-effects when more metabolites hit the bloodstream, while an individual with a slower metabolism could render treatment ineffective when too little of the metabolite reaches the bloodstream.101

The patents in question in Mayo Collaborative Services v. Prometheus Labs embody the tremendous discovery of an exact and efficient correlation, along with the need to alter treatment based on the metabolite concentrations.102 In 2004, Mayo Laboratories announced the production and sale of a similar test that measured the efficacy of the metabolites with slightly different levels. In response, Prometheus filed an infringement suit.103 Upon review, the district court determined that the patent was invalid because the metabolite correlations embodied were simply a natural phenomenon and therefore were preempted by § 101.104 On appeal, the Federal Circuit relied solely on the pre-Bilski “machine-
or-transformation” test and reversed.\textsuperscript{105} Provided that the Supreme Court had already ruled that the “machine or transformation test” cannot be the exclusive § 101 inquiry, the Supreme Court granted Mayo’s petition for certiorari and remanded the case.\textsuperscript{106}

On remand, the Federal Circuit largely ignored the Supreme Court by using the same pre-\textit{Bilski} inquiry and again concluding that the patent was invalid.\textsuperscript{107} The Supreme Court once again granted certiorari.\textsuperscript{108}

Upon review, the Supreme Court considered whether Prometheus’s claims accomplished more than a mere description of a molecular correlation, a natural law.\textsuperscript{109} The Supreme Court unanimously concluded that the claimed process of calculating the correlative nature of certain metabolites, which assist in the treatment of autoimmune disorders, “effectively claim the underlying laws of nature,”\textsuperscript{110} as the relationship exists independent of human intervention.\textsuperscript{111} The Court considered the claimed administering step, a step referring to doctors who had knowledge of the treatment benefits of thiopurine drugs for autoimmune disorders, “consist[ed] of well-understood, routine, conventional activity already engaged in by the scientific community; and those steps, when viewed as a whole, add nothing significant beyond the sum of their parts taken separately.”\textsuperscript{112} The Court then indicated that in order to “transform an unpatentable law of nature into a patent-eligible application of such a law, one must do more than simply state the law of nature while adding the words ‘apply it.’”\textsuperscript{113} Implicit in this rationale is the requirement of an “inventive step.”\textsuperscript{114}

Following the \textit{Mayo} decision, commentators observed a growing sentiment that the Court created more confusion than clarity.\textsuperscript{115} What exactly constitutes an “inventive step?”\textsuperscript{116} The Court hinted that an “inventive step” is something

\begin{footnotesize}
\bibitem{105}See \textit{id.} at 80.
\bibitem{106}See \textit{id.}
\bibitem{107}See \textit{id.}
\bibitem{108}See \textit{id.}
\bibitem{109}See \textit{id.} (citing Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1297 (2012)).
\bibitem{110}\textit{Mayo}, 132 S. Ct. at 1305.
\bibitem{111}See \textit{id.} at 1296–97.
\bibitem{112}\textit{Id.} at 1298.
\bibitem{113}\textit{Id.} at 1294.
\end{footnotesize}
more than a mere discovery, something that inculcates knowledge to the public; but it did not elaborate further.\textsuperscript{117} Many commentators speculated that without further guidance on what is patent-eligible subject matter, the growing uncertainty would dissuade bioresearch companies from investing in important scientific innovation as research and development became increasingly intertwined with aggressive litigation strategies.\textsuperscript{118} This uncertainty trickled over to another field of biomedical research: the field of genetics, wherein the claims in question elevated the patent-eligible subject matter inquiry from a public policy consideration to a moral consideration.

\subsection*{E. A Myriad of Problems: Questionable Scientific Justification and Moral Concern\textsuperscript{119}}

For decades, many believed breast and ovarian cancer had a genetic component.\textsuperscript{120} Myriad Genetics, a private molecular diagnostics company, confirmed this hypothesis by discovering the precise location and sequence of the incriminating genes, known as the BRCA1 and BRCA2 genes.\textsuperscript{121} In the event either gene is affected by a genetic mutation, an alteration of a nucleotide sequence, a woman’s chances of developing breast cancer increases significantly.\textsuperscript{122} This discovery enabled Myriad to develop genetic examinations to determine a female’s genetic propensity towards developing breast cancer.


119. Why Myriad became front page news was not the existence of an unbelievable fact pattern; rather, it was the public’s realization that Myriad’s actions, barring invalidation of their patents, were legal. See Ngo, supra note 114 (stating “[t]he science at issue . . . is relatively simple, compared to more complex issues in genetics such as genetic modification and activation.”). However, as explained by Amelia Rinehard, law professor at the University of Utah, the public’s attention of patentable subject matter was not a result of Myriad’s restriction of contemporary BRCA1 and BRCA2 diagnostics, rather it was the realization that Myriad’s was acting well within the bounds of their legal rights. See id.

120. J. Mackay & C. M. Szecsei, \textit{Genetic Counselling for Hereditary Predisposition to Ovarian and Breast Cancer}, 21 ANNALES OF ONCOLOGY 334 (2010), http://annonc.oxfordjournals.org/content/21/suppl_7/vii334.long (“A strong family history of breast and/or ovarian cancer has long been recognized as a risk factor and is in some cases indicative of a germline mutation.”).

121. See Ass’n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2112 (2013).

122. Id. (detailing that a mutation “can be as small as the alteration of a single nucleotide . . . [or as large as the] deletion, rearrangement, or duplication of hundreds or even millions of nucleotides”). Increasing odds of developing breast cancer rise from twelve/thirteen percent to between fifty and eighty percent if a mutation is discovered, and between twenty and fifty percent for ovarian cancer. See id.
breast or ovarian cancer. In turn, Myriad obtained a number of patents covering “both isolated human gene sequences and isolated human DNA molecules.” Isolated DNA, unlike naturally occurring chromosomal DNA, can be used to detect a particular DNA sequence, such as BRCA1 and BRCA2 mutations.

The natural human genome consists of twenty-three pairs of chromosomes, totaling forty-six individual chromosomes. All genetic material located within the DNA is stored in a code made up of four base pairs: adenine (A), guanine (G), cytosine (C), and thymine (T). The production of proteins from DNA occurs in two steps: transcription and translation. DNA is “transcribed” into RNA, a singular stranded compound. Introns, or non-coding regions of the RNA, are excised from the RNA through a natural process called “splicing,” which produces messenger RNA (or mRNA), a sequence consisting only of exons. Proteins are synthesized from the mRNA templates.

Myriad’s discovery represented a tremendous advancement in cancer treatment. However, once Myriad began issuing cease and desist letters in an attempt to eliminate competing laboratories from providing lifesaving medical services, health care providers made sure Myriad’s hostile litigation strategy became public. In 2009, a group of doctors, researchers, patients, and medical organizations filed a declaratory judgment action against Myriad seeking to invalidate its patents on § 101 grounds, arguing that isolated DNA is a product of nature and therefore cannot be patentable subject matter. The district court

123. See id.
124. Oren Ginsberg, Unwinding the DNA Double-Helix: An Alternate Resolution to the Federal Circuit’s Decision in Association for Molecular Pathology for Simplifying § 101 Patent Eligibility Determinations, 22 FED. CIR. B.J. 563, 566 (2013); see also Ass’n for Molecular Pathology, 133 S. Ct. at 2113.
126. See Ginsberg, supra note 124, at 567.
127. See id. at 566–67.
128. See id. at 566.
129. See id. at 567.
130. See Rogers, supra note 97, at 489.
131. See id.
132. Id. (“[M]RNA is translated into the encoded proteins ‘via three nucleotide combinations called codons.’ Each codon results in the production of one of the twenty amino acids that make up all proteins or a stop signal that terminates protein creation.”).
agreed with plaintiffs and invalidated Myriad’s patents on summary judgment.\textsuperscript{135} Myriad appealed and the Federal Circuit reversed.\textsuperscript{136}

Cognizant of the moral and policy issues, Judge Lourie, writing on behalf of the majority, began his opinion by cataloging the issues that were not on appeal in \textit{Association for Molecular Pathology v. United States Patent & Trademark Office}.\textsuperscript{137} Judge Lourie then isolated the inquiry to the dispassionate question: “whether the claims to isolated BRCA DNA, to methods for comparing DNA sequences, and to a process for screening potential cancer therapeutics meet the threshold test for patent-eligible subject matter.”\textsuperscript{138}

Relying on the principles of \textit{Diamond v. Chakrabarty}\textsuperscript{139} and \textit{Funk Brothers Seed Company v. Kalo Inoculant Company},\textsuperscript{140} the Federal Circuit intended to set out a workable framework for determining patent-eligible subject matter.\textsuperscript{141} In \textit{Chakrabarty}, the Supreme Court reversed the PTO’s rejection of a patent application claiming a genetically engineered bacterium designed to degenerate hydrocarbons and assist in cleaning up oil spills.\textsuperscript{142} The \textit{Chakrabarty} Court determined that the inventor “ha[d] produced a new bacterium with markedly different characteristics from any found in nature.”\textsuperscript{143} The claims, drawn to a living organism, were “not nature’s handiwork,” and therefore patent-eligible subject matter.\textsuperscript{144} In \textit{Funk Brothers}, the Supreme Court reversed the Federal Circuit, finding that a non-mutually inhibitive root-nodule bacterium utilized to assist seeds in the binding of nitrogen was patent-ineligible.\textsuperscript{145} The invention was simply an “aggregation of [a] select strain[ ] . . . into one product [which] is an application of that newly-discovered natural principle.”\textsuperscript{146} Despite the utility of the discovery, the court felt the mere “combination [of different bacteria strains] does not improve . . . their natural functioning.”\textsuperscript{147}

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  \item \textsuperscript{135} \textit{See id.} at 185.
  \item \textsuperscript{136} \textit{See Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office, 689 F.3d 1303, 1326 (Fed. Cir. 2012).}
  \item \textsuperscript{137} \textit{See id. at 1324} (stating that this case “is not about whether individuals suspected of having an increased risk of developing breast cancer are entitled to a second opinion . . . [or] whether is it desirable for one company to hold a patent or license covering a test that may save people’s lives, or for other companies to be excluded from the market encompassed by such a patent”).
  \item \textsuperscript{138} \textit{Id.} at 1324
  \item \textsuperscript{139} 447 U.S. 303 (1980).
  \item \textsuperscript{140} 333 U.S. 127 (1948).
  \item \textsuperscript{141} \textit{See Chakrabarty, 447 U.S. at 314–18; see also Funk Bros., 333 U.S. at 130–32.}
  \item \textsuperscript{142} \textit{See Chakrabarty, 447 U.S. at 305–06.}
  \item \textsuperscript{143} \textit{Id.} at 309–10 (determining the bacterium’s “claim is not to a hitherto unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter—a product of human ingenuity ‘having a distinctive name, character [and] use.’” (citing \textit{Hartranft v. Wiegmann}, 121 U.S. 609, 615 (1887))).
  \item \textsuperscript{144} \textit{Id.} at 310.
  \item \textsuperscript{145} \textit{See Funk Bros., 333 U.S. at 128–29, 132.}
  \item \textsuperscript{146} \textit{Id.} at 131.
  \item \textsuperscript{147} \textit{Id.}
\end{itemize}
Drawing on these foundational principles, the Federal Circuit in *Myriad* held that the product of nature doctrine turns on the “distinction . . . in the claimed composition’s identity compared with what exists in nature.” 148 Myriad’s claims drawn to isolated DNA and isolated genes, on a chemical level, are different from native DNA located within human bodies as a result of the isolation process. 149 Because Myriad’s isolated DNA is different in “name, character, and use” than that of native DNA, the Federal Circuit determined that isolated DNA is patent-eligible subject matter. 150

On review, rather than addressing the issue as Judge Lourie identified, which highlighted the chemical alteration of DNA during the isolation process, “the Supreme Court granted certiorari on one issue: ‘Are human genes patentable?’” 151 The Supreme Court focused instead on the textual descriptions of Myriad’s patent claims. 152 According to Justice Thomas, writing for the majority, the destruction of the covalent bonds—as relied upon by Judge Lourie—did not save Myriad because its claims focused on the information contained within the DNA sequence, not on the chemical composition of the isolated sequence. 153 Returning to *Chakrabarty* and *Funk Brothers*, the Supreme Court likened the isolation of BRCA1 and BRCA2 to the *Funk Brothers* patent-ineligible discovery of a mixed culture of mutually non-inhibited strains of root nodule bacteria, an ingenious discovery, but nevertheless, by itself did not transform the natural phenomenon—isolated DNA sequences—into patent-eligible subject matter. 154

The varying degrees of expertise on technical and biological matters are readily apparent in comparing the Federal Circuit and Supreme Court opinions in the *Myriad* case. While Judge Lourie—holding a master’s degree in organic chemistry and a Ph.D. in chemistry—methodically chronicled the chemical

148. Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office, 689 F.3d 1303, 1327–28 (Fed. Cir. 2012); see also Ingram, supra note 125, at 405.

149. See Ginsberg, supra note 124, at 567. “Native DNA exists in the human body as one of forty-six adjoined DNA molecules. Isolated DNA and isolated genes comprise a portion of an entire DNA molecule, with the sugar-phosphate backbone chemically severed or cleaved.” Id.

150. Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office, 689 F.3d at 1329 (Fed. Cir. 2012) (citing *Chakrabarty*, 447 U.S. at 309–10); see also Ingram, supra note 125, at 405.

151. Ingram, supra note 125, at 406 (citing Order Granting Petition for Writ of Certiorari, Ass’n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 694, 695 (2012)). Justice Thomas, writing the unanimous opinion of the court, characterized the exclusive authority to synthetically create BRCA cDNA in upholding the validity of such patents, as well as the monopolistic actions taken by Myriad to solidify their position as the singular entity capable of proving BRCA testing. See Ass’n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2113 (2013).

152. See *Myriad*, 133 S. Ct. at 2117–18.

153. See id. at 2118. The Court noted that several of Myriad’s patent descriptions merely specify the scientific “iterative process” of their breakthrough. Id.

154. See id. at 2117.

structure of DNA and the subsequent alteration of that chemical structure in practicing Myriad’s claimed invention, the late Justice Scalia, in concurrence, went as far as to admit his personal scientific inadequacies in reaching his conclusion.\textsuperscript{156} Moreover, the Federal Circuit opinion appears to be more consistent with then contemporaneous § 101 jurisprudence, while the Supreme Court relies on striking a like comparison from a patent decision from the middle of the twentieth century.

The Myriad decision remains subject to strong criticism due to its inconsistent scientific rationale,\textsuperscript{157} unsupported legal analysis,\textsuperscript{158} and continued failure to articulate a meaningful framework for § 101 analysis.\textsuperscript{159} The analysis grew more uncertain, requiring a degree of inventiveness somewhere between the patent-eligible invention of Chakrabarty and the patent-ineligible inventions of Funk Brothers.\textsuperscript{160}

\textit{F. Alice: The Requirement of an Inventive Step Across Subject Matter Eligibility Inquiries}

Alice Corporation holds several patents for mitigating the risk that one party associated with a financial exchange will fail to satisfy its monetary obligation.\textsuperscript{161} Alice Corporation’s particular method of mitigating risk, known as the settlement risk, is implemented on a computer configured to carry out the

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\begin{itemize}
  \item[156.] See \textit{Myriad}, 133 S. Ct. at 2120 (Scalia, J., concurring) (“I am unable to affirm those [fine] details [of molecular biology] on my own knowledge or even my own belief. It suffices for me to affirm, having studied the opinions below and the expert briefs presented here . . . .”).
  \item[157.] Steven Salzberg, Professor of Biomedical Engineering, Computer Science, and Biostatistics in the Institute of Genetic Medicine at Johns Hopkins University’s School of Medicine, quickly pointed out several scientific errors in the first paragraph of the Courts opinion. Steven Salzberg, \textit{Supreme Court Gets Decision Right, Science Wrong, on Gene Patents}, \textit{FORBES} (Jun. 13, 2013, 3:21 PM), http://www.forbes.com/sites/stevensalzberg/2013/06/13/supreme-court-gets-decision-right-science-wrong/#2d0bc7612cc3. As Salzberg notes, the court’s understanding that nucleotides that code are exons is somewhat rudimentary, as “nucleotides that code for amino acids are contained within the exons, but they are not the same thing. It’s not unusual for [twenty-five percent] or even [fifty percent] of the nucleotides in the exons to be ignored when making amino acids.” \textit{Id}. In addition, the court incorrectly defined composite DNA, synthetically created stands of nucleotides consisting only of exons as “cDNA.” \textit{See id}. cDNA actually stands for complementary DNA, replicate DNA stands consisting of those nucleotides that complement the original nucleotide (A compliments T, C compliments G, and vice versa). \textit{See id}.
  \item[158.] See Ingram, supra note 125, at 411; \textit{see also} Samantak Ghosh, \textit{Are All Genes Equal?}, 20 B.U. J. Sci. & TECI. L. 1, 13 (2014) (finding “studies have shown that gene patents inhibit downstream innovation in general”); \textit{see also} Smith, supra note 116, at 125 (noting that the rationale supporting the Court’s decision in Myriad my render isolated proteins, whose nucleotide sequence mirrors that of those natural occurring, no longer patent-eligible subject matter).
  \item[160.] See Ingram, supra note 125, at 411.
  \item[161.] See Alice Corp. Pty. Ltd. v. CLS Bank Int’l, 134 S. Ct. 2347, 2352 (2014).
\end{itemize}
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method for exchanging method obligations using a third party intermediary.\textsuperscript{162} In 2007, CLS Bank sought declaratory judgment against Alice Corp., arguing the patent claims were invalid under § 101.\textsuperscript{163} A divided panel of the Federal Circuit reversed a district court decision on grounds that the claims were not “manifestly evident” to be drawn to an abstract idea.\textsuperscript{164} Reviewing en banc, a fractured Federal Circuit vacated the three-person panel and issued a one-paragraph per curiam opinion affirming the lower court’s decision that the patent is invalid under § 101.\textsuperscript{165}

The Supreme Court granted certiorari and affirmed the Federal Circuit, finding “that the claims at issue are drawn to the abstract idea of intermediated settlement.”\textsuperscript{166} Because a claim drawn to an abstract idea is not probative of patent ineligibility, the Court further investigated the claims to determine the existence of an “inventive concept,” as described in Mayo.\textsuperscript{167} Relying on Benson, the Court reasoned that the implementation of an algorithm, or any other abstract idea, onto a “general purpose digital computer” does “not supply the necessary inventive concept.”\textsuperscript{168} Therefore, the patent was invalid as it was drawn to ineligible subject matter.\textsuperscript{169} This broadened the ambiguous “inventive step” test, set forth in Mayo, to all claims that are drawn to products of nature, natural phenomena, and abstract ideas.\textsuperscript{170} But the Court yet again refused to precisely delineate what an abstract idea is, and provided no further guidance than the prior case law.\textsuperscript{171}

A quick look at the procedural history of the Alice case illustrates the confusion surrounding § 101. The patent in question was invalidated by the

\begin{itemize}
\item \textsuperscript{162} See id.
\item \textsuperscript{163} See id. at 2353.
\item \textsuperscript{164} CLS Bank Int’l v. Alice Corp. Pty. Ltd., 685 F.3d 1341, 1352 (Fed. Cir. 2012).
\item \textsuperscript{165} See CLS Bank Int’l v. Alice Corp. Pty. Ltd., 717 F.3d 1269, 1273 (Fed. Cir. 2013) (en banc).
\item \textsuperscript{166} Alice Corp., 134 S. Ct. at 2352.
\item \textsuperscript{167} See id. at 2357 (detailing the rule that “[a] claim that recites an abstract idea must include ‘additional features’ to ensure ‘that the [claim] is more than a drafting effort designed to monopolize the [abstract idea]’”) (citing Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1294 (2012)).
\item \textsuperscript{168} Id.
\item \textsuperscript{169} See id. at 2360.
\item \textsuperscript{170} Memorandum from Andrew H. Hirshfeld, Deputy Comm’r for Patent Examination Policy, to Patent Examining Corps 1 (June 25, 2014), http://www.uspto.gov/patents/announce/alice_pec_25jun2014.pdf (noting that prior to Alice Corp., the USPTO previously applied a different analysis to claims directed to abstract ideas and claims directed to laws of nature, as well as a different analysis to product and process claims that are directed to an abstract idea).
\item \textsuperscript{171} See, e.g., E-mail from American Intellectual Property Law Association to the Honorable Michelle K. Lee, Deputy Under Secretary of Commerce for Intellectual Property and Deputy Director of the United States Patent and Trademark Office, 3 (July 31, 2014), http://www.uspto.gov/sites/default/files/patents/law/comments/al-a-aipla20140731.pdf (referencing Alice Corp. Pty. Ltd. v. CLS Bank Int’l, 134 S. Ct. 2347, 2355 (2014)). As Justice Thomas indicates in the Myriad opinion, the high court does not set forth “the framework,” just “a framework.” Id.
\end{itemize}
district court, reversed on appeal, vacated by a fractured Federal Circuit sitting en banc, and ultimately invalidated by the Supreme Court.\textsuperscript{172} As Professor Dennis Crouch exhorted, “[i]t is simply ridiculous that after [forty] years of debate, we still do not have an answer to the simple question of whether (or when) software is patentable.”\textsuperscript{173}

Despite the increase in Supreme Court attention to patent jurisprudence, confusion over § 101 persists.\textsuperscript{174} Inventors, patent applicants, lower courts, and litigants continue to seek clarification and consistency.

II. THE FUNCTIONAL V. JURISDICTIONAL PHILOSOPHIES: THE JURISPRUDENTIAL VIEWPOINTS OF § 101 ANALYSIS

So, what can be done with § 101? David Swetnam-Burland and Stacy O. Stitham detailed the two major § 101 philosophies: the functional understanding and the jurisdictional understanding.\textsuperscript{175} The viewpoints drastically differ on the role § 101 should play in a court’s determination of patent-eligible subject matter.

Functionalists view § 101 pragmatically, as an untrustworthy filter that should only be used in the direst of cases. Functionalists, in other words, treat § 101 as a backstop.\textsuperscript{176} Jurisdictionalists, disagree with the minimization of § 101. Instead, they consider the § 101 question to be a threshold inquiry that must be considered prior to investigating other patent invalidity arguments, such as anticipation under § 102 or obviousness under § 103.\textsuperscript{177} Jurisdictionalists further believe that § 101 maps the boundaries of patent law, and stands “as the only barricade against invasive species that periodically threaten to overwhelm the patent ecosystem.”\textsuperscript{178}

A. Functional Philosophy

An obvious response to mitigate the confusion surrounding the “morass” of § 101 is to essentially eliminate it and relying on existing alternatives.\textsuperscript{179} The functional proposal suggests: “[T]he courts should exercise their authority to privilege the other validity defenses (anticipation,

\textsuperscript{172} See supra notes 161–64 and accompanying text.


\textsuperscript{175} See generally Swetnam-Burland & Stitham, supra note 11, at 138–44.

\textsuperscript{176} Id. at 136.

\textsuperscript{177} Id. at 141 (stating that “the jurisdictionalist sees subject matter eligibility as a doctrine that is different in kind from anticipation, obviousness, and the other invalidity defenses found in Sections 102, 103, and 112”).

\textsuperscript{178} Id. at 141.

\textsuperscript{179} Id. at 138–39.
obviousness, indefiniteness, written description, etc.), and insist that litigants present those defenses first.” As Swetnam-Burland and Stitham explain, the frustration caused by § 101 within the judiciary cannot be more apparent than Judge Plager’s decision in *MySpace, Inc. v. Graphon Corp.*

In *MySpace*, Judge Plager compared § 101 jurisprudence to oenologists, explaining that trying to define an abstract idea is like describing wine—it depends primarily on the individual. Judge Plager continued his criticism of § 101 in his dissent in *DealerTrack, Inc. v. Huber*, insisting that the court should use its inherent power to avoid entering the “jurisprudential morass of § 101” and consider other statutory defenses; “specifically[,] §§ 102 and 103, and in addition §§ 112 and 251.” Adopting a doctrine of avoidance, theoretically, would streamline the litigious process, as litigation will not be bogged down by the uncertainty and likely appeal of a § 101 determination. The significance of § 101 would be lessened, serving only as a dysfunctional “backstop” in those “rare cases.”

The functional theory assumes that § 101 is a disreputable and insoluble mess; avoidance of which would encourage litigants to realize its frivolousness. Supporting this notion of futility, functionalists call attention to studies demonstrating that the majority of patent claims rejected as patent-ineligible subject matter under § 101 by the USPTO were also denied a patent on other grounds. The fallacy in this logic, however, is that it assumes vivid clarity of other patent doctrines, equates the patent prosecution process undertaken by the

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180. *Id.* at 139.
181. *Id.* at 153. In *MySpace*, Judge Plager lamented:
   
   In an attempt to explain what an abstract idea is (or is not) we tried the machine or transformation’’ formula—the Supreme Court was not impressed. We have since acknowledged that the concept lacks of a concrete definition: “this court also will not presume to define ‘abstract’ beyond the recognition that this disqualifying characteristic should exhibit itself so manifestly as to override the broad statutory categories of eligible subject matter . . . .[.]” *MySpace, Inc. v. Graphon Corp.*, 672 F.3d 1250, 1259 (Fed. Cir. 2012) (citations omitted).
182. *Id.* at 1259. Judge Plager also points out that the Court’s “opinions spend page after page revisiting our cases and those of the Supreme Court, and still we continue to disagree vigorously over what is or is not patentable subject matter.” *Id.* (citations omitted).
183. 674 F.3d 1315 (Fed. Cir. 2012).
184. Swetnam-Burland & Stitham, *supra* note 11, at 136 n. 4 (referencing *DealerTrack*, 674 F.3d at 1335 (Plager, J., dissenting)).
185. *Id.* at 139–40.
186. *Id.* at 139. “[C]ases in which ‘it is clear and convincing beyond peradventure’ that a patent claim is ‘over the line’ of abstractness that can be caught by the ‘coarse filter’ of Section 101.” *Id.* (citing *MySpace, Inc.*, 672 F.3d at 1261).
187. *Id.* at 139–40.
188. *Id.* at 139.
USPTO with courts’ determination regarding the validity of a patent,\(^\text{189}\) it rigidly requires courts to investigate each possible rejection of a claim\(^\text{190}\)—a practice already undertaken by the USPTO\(^\text{191}\)—and would essentially render § 101 a “dead letter.”\(^\text{192}\)

**B. Jurisdictional Philosophy**

The jurisdictional philosophy sees beyond the morass § 101 has become.\(^\text{193}\) Instead of considering § 101 a backstop, jurisdictional proponents view § 101 as a gatekeeper, a “barricade” or a “tool” designed to weed out bad patents.\(^\text{194}\) Jurisdictionalists argue that the text of § 101 and judicial opinions serve as evidence of this gatekeeping quality. For example, the majority and concurring opinions in *Bilski* both label § 101 as a “threshold” question, as have numerous other Federal Circuit opinions.\(^\text{195}\) As a “threshold” inquiry, jurisdictionalists believe, it is the primary duty of the courts to decide whether the claimed invention is patent-eligible subject matter before considering the more fact-intensive questions of whether the claim is novel and nonobvious.\(^\text{196}\)

Further, the jurisdictional approach empowers § 101 to be not only a threshold inquiry, but also a question of jurisdiction.\(^\text{197}\) If courts were to consider both § 101 and subject matter jurisdiction in a similar manner, the § 101 inquiry becomes a question courts must consider “even if [it must] make that assessment on a *sua sponte* basis.”\(^\text{198}\)

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189.  *See* Microsoft Corp. v. i4i Ltd. P’ship, 131 S. Ct. 2238, 2242 (2011) (citing 35 U.S.C. § 282 (2012)) (stating “[a] patent shall be presumed valid” and “[t]he burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity.”).

190.  *See* Swetnam-Burland & Stitham, *supra* note 11, at 140.

191.  706 Rejection of Claims [R-07.2015], *Manual of Patent Examining Procedure*, USPTO, http://www.uspto.gov/web/offices/pac/mpep/s706.html (last visited June 27, 2016) (stating “[t]he goal of examination is to clearly articulate any rejection early in the prosecution process so that the applicant has the opportunity to provide evidence of patentability and otherwise reply completely at the earliest opportunity”). The USPTO’s goal is to articulate *any* rejection, not *a* rejection.  *See* id.


194.  *Id.* at 140–41.

195.  *Id.* at 141; *see also* Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office, 689 F.3d 1303, 1324 (Fed. Cir. 2012) (identifying 35 U.S.C. § 101 as the “threshold test”); Ultramercial, LLC v. Hulu, LLC, 657 F.3d 1323, 1326 (Fed. Cir. 2011) (stating that “§ 101 itself . . . is merely a *threshold* check”) (emphasis added); Classen Immunotherapies, Inc. v. Biogen IDEC, 659 F.3d 1057, 1064 (Fed. Cir. 2011) (noting the difference between “the threshold inquiry of patent-eligibility, and the substantive conditions of patentability”).


197.  *See* id. at 141 (noting that the jurisdictional view “can be analogized to federal subject matter jurisdiction jurisprudence”).

198.  *Id.* (citing Diggs v. Dep’t of Hous. & Urban Dev., 670 F.3d 1353, 1355 (Fed. Cir. 2011)).
1. The Judicial Authority to Raise Matters Sua Sponte

The term *sua sponte*, in legal parlance, “describes a decision or action undertaken by a court on its own motion as opposed to an action or decision done in response to a party’s request or argument.”

Generally, federal appellate courts will not consider issues not previously and timely argued by the parties either in briefs or at oral arguments. However, the courts retain discretion to raise certain issues themselves, a practice occurring more frequently in the Federal Circuit.

Historically, a court’s power to raise issues *sua sponte* is rooted in the courts of equity, where the supreme duty of the court was to balance the interests before granting relief. Legal questions are generally designated as questions of facts, questions of law, or a combination of the two. Because questions of law concern the application or interpretation of the law in question, they are excluded from the jury and reserved for the court.

Questions of facts, however, are reserved for the finder of fact, typically when the issue involves weighing the

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201. See *id.* at 331.

202. See Richards v. Chase Elevator Co., 158 U.S. 299, 301 (1895) (“While patent cases are usually disposed of upon bill, answer, and proof, there is no objection, if the patent be manifestly invalid upon its face, to the point being raised on demurrer, and the case being determined upon the issue so formed. We have repeatedly held that a patent may be declared invalid for want of novelty, though no such defense be set up in the answer.”); Hill v. Wooster, 132 U.S. 693, 698 (1890) (“The parties to the present suit appear to have been willing to ignore the question as to patentability in the present case, and to have litigated merely the question of priority of invention, on the assumption that the invention was patentable. But neither the Circuit Court nor this court can overlook the question of patentability.”); Slawson v. Grand Street, R.R. Co., 107 U.S. 649, 652 (1883) (“If [letters- patent] are void because the device or contrivance described therein is not patentable, it is the duty of the court to dismiss the cause on that ground whether the defence be made or not. It would ill become a court of equity to render a money decree in [favor of a complainant] for the infringement of letters-patent which are void on their face for want of invention. Every suitor in such a cause should, therefore, understand that the question whether the invention, which is the subject-matter in controversy, is patentable or not is always open to the consideration of the court, whether the point is raised by the answer or not.”); see also Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 483 (1974) (“[N]o patent is available for a discovery, however useful, novel, and nonobvious, unless it falls within one of the express categories of patentable subject matter of 35 U.S.C. § 101 . . . .”); see also SmithKline Beecham Corp. v. Apotex Corp., 403 F.3d 1331, 1352–55 (Fed. Cir. 2005) (exemplifying a court’s *sua sponte* § 101 argument as grounds for finding a patent invalid).


204. BLACK’S LAW DICTIONARY 1442 (10th ed. 2014).
credibility of witnesses. Questions of law, unlike questions of facts, are more likely to be raised by a court sua sponte in the interest of judicial neutrality. Judicial neutrality is preserved when party input is not considered in the determination of matters of law and as such should only impact questions of law.

Over the years, the Federal Circuit has treated a number of patent law questions as matters of law, including § 101. The Supreme Court has also treated § 101 as a threshold matter, most notably in Bilski. Another overt example is Justice Breyer’s dissent in Metabolite Laboratories. The majority in Metabolite dismissed the case on grounds that certiorari was “improvidently granted.” Yet in his dissent, Justice Breyer indicated his position on § 101 sua sponte in the absence of any previous mention of § 101 by the lower courts or the parties. Although a dissenting opinion casts no precedent, it is noteworthy that three out of the four justices required to grant certiorari joined the dissent of a case dismissed as improvidently granted. Further, the Mayo opinion’s analysis correlates closely to that of Metabolite’s sua sponte opinion. This correlation suggests that Metabolite essentially directed the Federal Circuit to the Supreme Court’s intentions regarding § 101 analysis, as well as supports the belief that current members of the Supreme Court consider § 101 a jurisdictional question.
As detailed below, the ability of courts to raise § 101 matters sua sponte plays a paramount role in policy considerations. 216

III. SECTION 101 IS A JURISDICTIONAL STATUTE

The following section will examine the requirements for patentability, and will demonstrate the inherent gatekeeping function of § 101 as compared to §§ 102 and 103.

A. Section 101 Textual Analysis: Legal Grounds Supporting § 101 as an Inquiry of Primary Consideration

A proper analysis of a statute’s text “starts with the specific words of the statutory provision being interpreted.” 217 The text should be interpreted by considering how the provisions “cohere[] with the general structure of the statute.” 218 Therefore, to adequately consider how the patentability provisions “cohere” within the general structures of the statute, a comparison of the general structure of each provision is required. Simply put, how does § 101 differ from its patentability counterparts?

Again, § 101 reads:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title. 219

The statute begins with “[w]hoever invents or discovers,” which serves to limit patent protection to “inventors.” 220 The statute then proceeds to enumerate the types of inventions considered to be eligible for patent protection. If an inventor creates an article that falls into one of the several enumerated categories—process, machine, manufacture, or composition of matter—the article is patent-eligible subject matter. 221 Section 101, accordingly, may be considered a limiting statute, because patent protection is limited to those who “invent” certain classes of inventions.

In contrast, §§ 102 and 103 can be considered limiting factors. Section 102 states that “[a] person shall be entitled to a patent unless” it is anticipated, 222 and § 103 states “[a] patent for a claimed invention may not be obtained” if it is

216. See infra Section III.C.
218. Id. at 355.
220. Id.; John Burke, Examining the Constitutionality of the Shift to “First Inventor to File” in the Leahy-Smith America Invents Act, 39 J. LEGIS. 69, 76 (2013) (stating that “[t]he Patent Clause prevents Congress from granting patent rights to anyone except inventors”).
222. Id. at § 102 (emphasis added).
logically deducible by “a person having ordinary skill in the art.”  

Section 101 itself articulates the difference between its own purpose and that of the other requirements: stating that patentability “may obtain a patent therefore, subject to the conditions and requirements of this title.” Section 102, however, does not suggest that the provision is subject to additional conditions and requirements for patenting, and § 103 only references § 102. In other words, § 101’s language opens the gate for an inventor while §§ 102 and 103 present ways that the gate can be closed.

Moreover, the legislative intent, coupled with the longstanding doctrine to avoid “redundancies” in statutory law, suggests that §§ 102 and 103 are amplifiers of § 101—directing the inquiry against prior art.

Judge Giles S. Rich, co-author of the 1952 Patent Act, treated § 101 as an inquiry of first consideration. Judge Rich understood the 1952 Patent Act to divide the patentability statutes into it “logical components,” a “clearcut” intention to clarify “what had been a hodgepodge of separate enactments” into three distinct provisions. Judge Rich characterized the provisions as a succession of locked doors that must be successfully opened, commencing with the opening of § 101. Nothing in the legislative history of §§ 102 and 103 suggests the intent of Congress to modify then existing patent law.

In addition to rather clear legislative history, further support for § 101 standing as a gatekeeper with respect to the patentability statutes exists upon consideration of how the individual patent statutes interrelate with one another and upon examining how their individual functional purpose is accomplished. For example, one could infer from a close reading of the patentability statutes that §§ 102 and 103 were born out of § 101; nevertheless, fragments of the inquiry

223. Id. at § 103 (emphasis added).
224. Id. at § 101 (emphasis added).
225. See id. at § 102 (beginning with “[a] person shall be entitled to a patent unless . . . .”); see also id. at § 103 (stating that “[a] patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102”).
226. See In re Application of Bergy, 596 F.2d 952, 963 (C.C.P.A. 1979). Unlike §§ 102 and 103, prior art is entirely irrelevant to a § 101 inquiry. Id. at 962–63.
229. See Bergy, 596 F.2d at 959–60.
230. See id. at 960.
Section 101 seems to necessitate a novelty inquiry—§ 102’s primary purpose—via the use of the term “new.” Congress never intended, however, to test novelty under § 101, believing it was an inquiry historically reserved for § 102. To prevent the redundancy between “new,” located in § 101, and “novel,” found in § 102, the reading of the former requires the subject matter to have never existed, whereas reading of the latter requires the subject matter to have never been disclosed previously.

Similar to the apparent redundancy between “new” and “novel” found in § 101 and § 102 respectively, § 103’s requirement that the article be nonobvious seems to duplicate § 101’s requirement of an “invention.” Prior to the 1952 Patent Act, the nonobvious requirement existed only in the elaboration of § 101’s use of the term “new.” It was only after the 1952 Patent Act that the requirement of nonobviousness explicitly appears in the statutory language. Section 101, however, again retains some function in determining nonobviousness, as Congress did not intend to alter the historical requirements of “invention” with the passage of § 103 and the nonobviousness requirement.

Section 101 simply broadens the inquiries of §§ 102 and 103 to ascertain whether the claimed invention is of the kind contemplated by Congress as possibly patentable. In addition, although §§ 102 and 103 direct the investigation at prior art, a § 101 inquiry does not address the status of other patents, which again represents the inherent structural difference between § 101

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234. The novelty criteria are named in § 101, then amplified and defined in § 102. See Demaine & Fellmeth, supra note 231, at 384.

235. It is a well-established doctrine of salutary interpretation to consider the utility of each individual term with the presumption that the legislature does not use redundant, or “superfluous words.” Id. at 385.

236. See id. at 381–82.

237. See id. at 381 (“Prior to the 1952 Patent Act, patent statutes provided only that inventions must be ‘new.’ It was the courts that elaborated on the definition of ‘new’”).

238. See id. at 382.

239. See id. at 381–82.

240. See In re Application of Bergy, 596 F.2d 952, 963–64 (C.C.P.A. 1979) (“[I]f they turn out to be new, useful, and unobvious within the meaning of those terms as used in the statute.”); see also Olson, supra note 45, at 195 (2009) (“[C]ourts and the PTO have traditionally ruled that particular classes of subject matter are outside the realm of patentability.”).
and §§ 102 and 103. In other words, § 101 proceeds through a categorical inquiry, whereas §§ 102 and 103 operate on the subject matter individually. Nothing can be more inherently obvious than to investigate the subject matter at its genus, before defining it at its species.

Therefore, the textual interrelationship between the individual statutes, coupled with the intention of the co-author of the 1952 Patent Act, undoubtedly suggest the legislative intention to establish § 101 as inquiry of first consideration.

B. Courts Treat § 101 as Jurisdictional

A recent string of cases suggests a growing understanding by the courts of the jurisdictional nature of § 101. In Ultramercial v. Hulu, the Federal Circuit affirmed a California district court’s grant of a 12(b)(6) motion finding the patents in question invalid under § 101. In buySAFE, Inc. v. Google, Inc., the Federal Circuit again affirmed a Delaware grant of a 12(c) motion finding that “the claims were directed to an abstract idea.” In Planet Bingo, LLC v. VKGS, LLC, the Federal Circuit affirmed a Michigan district court’s grant of summary judgment. In Bascom Global Internet Servs. v. AT&T Mobility LLC, Judge Chen reiterated that courts may “dispose of patent-infringement claims under § 101 whenever procedurally appropriate.”

In OIP Techs., Inc. v. Amazon.com, Inc., Judge Mayer explicitly endorsed the threshold and jurisdictional nature of § 101. Judge Mayer sanctioned the disposal of the case, citing the benefits of expediting litigation—thus sparing litigants discovery and claim construction costs—and serving to curb “vexatious suits brought by the owners of vague and overbroad . . . patents.” In Genetic Techs. Ltd. v. Merial L.L.C., Judge Dyke reaffirmed the Federal Circuit’s
position that “in many cases it is possible and proper to determine patent eligibility under . . . § 101 on a Rule 12(b)(6) motion.”

This recent string of Federal Circuit decisions suggests a shift in the court’s conception of § 101, and supports the growing trend of courts considering § 101 not only as a threshold issue, but a jurisdictional issue.

C. Policy Rationale for Treating § 101 as Jurisdictional

In addition to the legal arguments supporting the jurisdiction viewpoint, there are also policy reasons for treating § 101 as jurisdictional.

Under the utilitarian philosophy of patent law, the purpose of a patent system is to incentivize invention and weigh society’s interests in patentability of certain subject matter. Ideally, patent examiners would individually investigate each application to determine whether the right to exclude competition from the market will both recoup the cost of research and development and still cultivate the advancement of the public storehouse of knowledge. Unfortunately, such individualistic and comprehensive examination is not feasible. Sections 102 and 103, on their own, fail to ensure efficient examination and are unable achieve the utilitarian goals of the U.S. Patent system. Sections 102 and 103, rather, serve to ensure that the public storehouse of knowledge is adequately increased despite the patent system’s public exclusion rights. They simply are not meant to handle the responsibility of determining which types of articles the patent system should consider giving patent protection.

To increase efficacy, the patent regime must be dedicated to initially investigating claims on a categorical approach. Such categorically based distinctions are best suited to identify and screen out overbroad patents that run afoul of the systems utilitarian goals. As discussed above, the jurisdictional view of § 101 gives the court the authority to raise the matter sua sponte. The

253. Id. at 1373 (noting also that “evaluation of a patent claim’s subject matter eligibility under § 101 can proceed even before a formal claim construction”) (citing Bancorp Servs., L.L.C. v. Sun Life Assurance Co. of Canada (U.S.), 687 F.3d 1266, 1273 (Fed. Cir. 2012) (“[C]laim construction is not an inviolable prerequisite to a validity determination under § 101.”)).

254. See Olson, supra note 45, at 184.

255. See id. at 201.

256. See id. at 201.

257. See id. at 203.

258. See id. at 201 (stating that “[i]f it is determined that the incentive of patents is not needed for a class of inventions, then it is a waste of time and resources to engage in any of the tests set out in sections 102, 103, and 112 of the Patent Act”).

259. See id.

260. See id. at 195; see also Demaine & Fellmeth, supra note 231, at 363 (stating “sections 101, 102, and 103 must be analyzed in order,” and “only sections 102 and 103 ‘guard . . . the public interest by assuring that patents are not granted which would take from the public what which it already enjoys’”).

261. See supra Part I.
utilization of such a prerogative would not only increase judicial efficacy, but also could assist in the cataloging of developing inventions.

1. Avoiding Costly Discovery

Implicit in the functional viewpoint’s theory is a rigid application of a mandate that directs courts to “proceed through discovery to claim construction, followed by summary judgment practice where invalidity issues such as anticipation and obviousness may be addressed.” According to the American Intellectual Property Law Association, the cost of a lawsuit where the risk is between $1,000,000 and $25,000,000 is, on average, $1,600,000 through the end of discovery, and $2,800,000 through final disposition of the case.

E-discovery is the primary culprit, as well as extensive prior art searches that contribute greatly to the rising litigation costs. Adopting a functionalist perspective would essentially guarantee that these costly aspects of litigation would occur, unless a case settled early. The functionalist principle also relies heavily on §§ 102 and 103, statutory inquiries that investigate prior art. The jurisdictionalist viewpoint, on the other hand, considers § 101 to be a question of law that can be decided, in theory, with little to no discovery, and that prior art is irrelevant to a § 101 analysis.

Calls for patent reform focus largely on reducing the high costs of patent litigation, which many believe drive most of the abuses in the patent system. Although the early disposition of a case on § 101 grounds may be cause for some alarm, especially before claim construction, it is far more problematic to close entirely the opportunity for courts to quickly resolve obvious invalidity cases—
saving millions in litigation expenses and “stem[ing] the tide of vexatious suits brought by the owners of vague and overbroad” patents.269

2. The Moral Compass

The Supreme Court’s methodology of issuing ambiguous rulings and rejecting bright line frameworks is the only reasonable recourse for non-elected officials charged with the responsibility of determining, with little legislative guidance, matters with implications extending far from the purview of the judiciary.270

Such ambiguity allows the Supreme Court to consider, as Professor Tun-Jen Chiang suggests, the morality of its decision and the economic analysis of patentability jurisprudence.271 The judiciary, either consciously or subconsciously, already considers morality—most exemplified in the Myriad decision—which is not captured by bright line patentability tests, inconsistent with § 101 jurisprudence, and grounded in a suspect scientific foundation.272

The ability of the courts to raise a § 101 question, challenging the eligibility of subject matter sought to be patented, provides an additional avenue for the judiciary to protect the public from mischievous conduct and technologies that truncate continuing technological research.273 Although sometimes exasperating, operating under a flexible standard is a necessary evil, which positions § 101 as a threshold against morally bankrupt patents until a more


270. See supra Part I.

271. See Chiang, supra note 12, at 1861 (“I am not arguing that PSM law ought to be moralistic or that patents ought to be granted or denied on moral grounds. I am simply saying that moral concerns are in fact built deeply into the fabric of existing PSM debates, and this fact should be recognized.”). As Chiang states “[t]he surface consensus among scholars and judges that moral values play little or no role in [patentable subject matter] law paints an inaccurate portrait.” Id. at 1860. This systematic blindness to actual understanding of patentable subject matter law, Chiang believes, is why progress in the field has been unsuccessful. See id. at 1860–61.

272. Id. at 1875. Myriad is first and foremost about a moral concern: “[t]he case was brought, why it attracted media attention, and why it went all the way up to the Supreme Court” without understanding the moral concern. Id. The surge of media attention was simple: the first page of the writ of certiorari asks, “Are human genes patentable?” Id. at 1862. This provocative question, coupled with the pre-litigation actions of Myriad, captured the nation’s attention, and forced the Supreme Court to rule on an incredibly technical issue. Id.

empirical analysis can be developed and implemented through the proper channels.

The proper channels are the political branches of government, but should also include the Federal Circuit, a specialized court, for purposes of developing the nuances of § 101 jurisprudence where Congress cannot. Although the patent community’s frustration with the Supreme Court is reasonable, looking to the Supreme Court for guidance concerning § 101 is foolhardy. The Supreme Court, instead, is best positioned to determine decisions core to the very foundation of patent law—such as matters invoking morality concerns—while the Federal Circuit should be left to determine more substantive decisions concerning patent law. Accordingly, the Federal Circuit ought to drive the creation of a workable § 101 framework. Not only would the expertise of the court balance against the complexities of technology driving most of the analytical confusion, but the sheer number of § 101 cases the Federal Circuit considers and the number of specialized judges and law clerks should also compel a more workable framework through trial and error.

Further, treating § 101 as a matter of jurisdiction helps grow the body of law as specialized judges, *sua sponte*—whether through an opinion narrowly fashioned to address the specific set of facts or an opinion attempting to establish a more general framework—can continue to inch § 101 doctrine forward towards a more workable framework, while serving the dual purpose of decreasing the cost of patent litigation. Meaningful efforts to clarify § 101 likely require continual evaluation and engagement by the Federal Circuit—by soliciting amicus briefs and provoking engaging dialogue within the patent community.

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274. *Id.* at 568.

275. *See*, e.g., Oppenheimer, *supra* note 8, at 35; *see also* Robert H. Sloss, *Have We Seen This Movie Before? The Supreme Court Again Takes Up Patent-Eligibility in Alice Corp. v. CLS Bank Int’l*, PROCOPIO, 3 (Dec. 19, 2013), www.procopio.com/uploads/model/Block/4658/.../patent-eligibility-2013-2720.pdf (stating that “while one hopes that the Supreme Court’s ruling will bring much-needed clarity to section 101, the past few years give us reason to be skeptical”).


V. CONCLUSION

As Judge Mayer noted, at a more fundamental level, the plenary authority granted to Congress to issue patents is “not unbounded.” The authority, incentivizing advancement in the fields of Science and Arts by securing a limited exclusionary right, is both a “power and a limitation.” The power is limited by the Constitution, and only § 101, not §§ 102, 103 or 112, remains capable of “ensur[ing] that the nation’s patent laws remain tethered to their constitutional mooring.”

Calls to remove § 101 altogether overlook the important role the statute plays. It is an important safety net for the public—serving as a moral gatekeeper covering patents that pass muster under the other patentability requirements, but still represent a moral and utilitarian conundrum. Therefore, the jurisdictional threshold qualities of § 101 represent an opportunity for courts to raise such § 101 concerns sua sponte when public policy demands. Public policy is served, in return, by proactively filtering such classes of morally bankrupt patents, by potentially decreasing the costs of patent litigation, and by allowing litigants to challenge the case on the pleadings, thereby avoiding unnecessary discovery, while at the same time, granting both the federal district courts and the Federal Circuit the capability to continue to move the § 101 ball forward.

281. Id. (quoting Graham v. John Deere Co., 383 U.S. 1, 5 (1966)).
282. Id.