ARTICLE

PATENTABLE SUBJECT MATTER AS A POLICY DRIVER

Amy L. Landers

I. INTRODUCTION ................................................................. 102

II. PATENTABLE SUBJECT MATTER: A QUESTION OF DIRECTION 104
   A. The Complex Question of Identifying the System’s Purpose .................................................. 105
   B. Taking the Patent Incentive System Seriously ............ 108

III. CURRENT PATENTABLE SUBJECT MATTER INTERPRETATIONS 113
   A. Abstract Subject Matter ................................................. 115
   B. Products of Nature ..................................................... 119

IV. PATENTABLE SUBJECT MATTER AS A TECHNOLOGICAL ARTS TEST ......................................................... 126

V. IMPLEMENTING THE PATENTABLE SUBJECT MATTER THROUGH A CONFLUENCE OF CONSIDERATIONS .......... 131
   A. Fostering Creativity .................................................... 131
   B. Scientific and Technical Infrastructure ....................... 134
   C. The Impact of the Patent System on Competition ....... 137
   D. Social Benefit ........................................................... 139

VI. IMPLEMENTATION: A CONFLUENCE OF CONSIDERATIONS . 141

VII. CONCLUSION .................................................................. 143

* Professor of Law, Drexel University Thomas R. Kline School of Law. The author would like to thank the University of Houston’s Institute for Intellectual Property and Information Law, and the participants of 2015 Symposium, for their feedback on an earlier draft of this piece.
I. INTRODUCTION

Internationally, patents are used as instruments to further economic and social policy.1 One potent policy driver to accomplish such goals is through the legal construction and application of the term “invention.”2 As a British court explained, “whoever controls the meaning of ‘invention’ controls what can be patented and hence an important aspect of industrial policy.”3 Perhaps for this reason, the legal definition of invention is one of the most complex problems in patent law. Many terms in our common law system of decision-making are susceptible to principled interpretation using methods that include consulting legislative intent, considering the terms’ placement within the structure of the relevant statute, referring to the terms’ historical interpretation, and guiding the interpretation with the overall purpose of the law.4 Yet as one Australian court recognized in an parallel context, “[t]o attempt to place upon the idea the fetters of an exact verbal formula could never have been sound” because a singular focus on text is unhelpful to interpret a term that is intended to guide an area of the law that fosters our collective futures.5

Despite this potential power, recent U.S. Supreme Court opinions have not used the doctrine to meaningfully guide the patent system. The Court’s opinions are remarkably silent on the prospective consequences of their decisions. Rather, the Court’s recent patentable subject matter jurisprudence places primary emphasis on construing the requirement’s exclusions.6 In doing so, the Court has relied on a selection of precedents that were written in an era that does not account for our current understandings of scientific, economic, and sociologic systems.7 This reasoning, although emblematic of common law decision-making, forecloses inquiry into a critically important task—the

2. See In re Patent Applications 0226884.3 & 0419317.3 by CFPH L.L.C., [2005] EWHC (Ch) 1589 Pat [10] (Eng.).
3. Id.
7. [placeholder]
work of aligning the patent system with its goals. These decisions appear to be untethered from necessary policy choices to ensure a workable system. This Article examines whether this purely precedent-driven reasoning can be sustained.

Decision makers must expressly and transparently consider policy when addressing patentable subject matter questions. If one takes patents seriously as an incentive system to develop knowledge, create new scientific and technological solutions, and push the frontiers of human development, then “the patent community need[s] a coherent manual for navigating the boundaries of patentable subject matter.” This Article proposes four policy guideposts: (1) fostering scientific creativity; (2) encouraging the creation of an infrastructure; (3) balancing the patent system with free competition concerns; and (4) considering current social needs. As other nations’ law demonstrates, there is space within this substantive patent requirement to expressly consider national policy on a continued basis. A nuanced understanding of knowledge creation and the role of funding, competition, and societal goals can lead to a balanced approach to the patent system that considers granting an exclusive property right among other governmental goals. Although the answers to these questions may be challenging, transparent deliberation within the patentable subject-matter doctrine is an important first step toward resolving them.

This implementable proposal does not discuss exogenous issues, such as any substantive modifications to the existing exclusions from patentable subject matter. This Article assumes the continued existence of the present decision-making structure. Further, this Article assumes the current interpretations of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) remain. This Article does not address other

8. [placeholder]
9. [placeholder]
10. [placeholder]
12. [placeholder]
13. [placeholder]
14. [placeholder]
15. [placeholder]
16. See infra notes 133–135, 163–185 and accompanying text (noting the role of policy considerations in foreign and international patent-eligibility decisions).
17. See infra Part VI (arguing that subject-matter eligibility is an ideal vehicle for patent policy considerations).
18. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15,
changes to the patent system that might be optimal if this proposal is integrated into law. Further, this proposal provides numerous examples of empirical work that acknowledges that the answers to patent law’s complex questions are not easily resolved with current doctrine.19 This Article does not suggest that these particular studies answer all of these questions, nor does it argue that the law should adopt their conclusions without balancing countervailing considerations or without considering alternative sources of information.

II. PATENTABLE SUBJECT MATTER: A QUESTION OF DIRECTION

The Supreme Court’s recent patentable subject matter opinions require a two-step analysis: First, the court must determine whether a claim is directed to one of the patent-ineligible concepts.20 These include abstract subject matter, products of nature, laws of nature, and mental steps.21 If so, the second step is to examine whether there is additional material in the claim that constitutes an inventive concept.22 The Court describes this step as an “inventive concept”—i.e., an element or combination of elements that is ‘sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the ineligible concept itself.”23 To implement this test, the judicial definition of invention has relied heavily on legal constructions penned over centuries of the industrial era.24

Since the most recent of these cases was decided, scores of patent claims have been invalidated.25 As a practical matter, these decisions apply the Supreme Court’s test in a manner that facilitates invalidation of the claims without discussion of relevant policies or prospective consequences.26 For example,

21. Id.
22. Id.
25. Robert R. Sachs, Twenty-two Ways Congress Can Save Section 101, BILSKI BLOG (Feb. 12, 2015), http://www.bilskiblog.com/blog/2015/02/twenty-two-ways-congress-can-save-section-101.html (“In the seven months since Alice Corp. Pty. v. CLS Bank Int’l was decided, over one hundred patents have been invalidated for claiming ineligible subject matter, more than the total number of patents invalidated under Section 101 in the past five years.”).
26. [placeholder]
some recent lower court decisions characterize the claims in a
generalized manner. 27 By characterizing the claims abstractly,
such decisions find that they are abstract. 28 After searching for
an inventive concept that elevates the claim beyond “well-
understood, routine, conventional activities previously known,”
and finding none, the opinions hold the claims at issue are
directed to abstract subject matter. 29 Such decisions do not
engage in the policy or consequences that might drive the
reasoning in other cases. 30

A. The Complex Question of Identifying the System’s Purpose

The law must begin to align the patentability inquiry in
light of the purposes that are said to justify the system’s
existence. As a first step, the patent system’s goals must be
articulated. The starting point is the constitutional aim “to
promote the [p]rogress of [s]cience and useful [a]rts.” 31 Yet
consensus over the system’s purpose is not subject to uniform
agreement. 32 Certainly, the creation of new inventions is a
primary goal, together with the acknowledgement that this right
is necessary to protect the investment of “time, research, and
development” to accomplish the creation of new ideas. 33 The
creation of new knowledge and the disclosure function is
another. 34 Some authorities cite the system’s potential to drive
innovation, job growth, and a successful economy. 35 Others have

27. See, e.g., Intellectual Ventures I LLC v. Capital One Bank (USA), 792 F.3d
1363, 1367–71 (Fed. Cir. 2015) ; Content Extraction & Transmission LLC v. Wells Fargo
Bank, Nat’l Ass’n, 776 F.3d 1343, 1347–49 (Fed. Cir. 2014) ; Ultramercial, Inc. v. Hulu,
LLC, 772 F.3d 709, 715–16 (Fed. Cir. 2014).

28. Intellectual Ventures I, 792 F.3d at 1367 ; Content Extraction & Transmission,
776 F.3d at 1347–48; Ultramercial, 772 F.3d at 715–16.

29. See, e.g., Internet Patents Corp. v. Active Network, Inc., 790 F.3d. 1343, 1348
(Fed. Cir. 2015) (quoting Mayo Collaborative Servs., 132 S. Ct. at 1298); Content
Extraction & Transmission, 776 F.3d at 1348.

30. See, e.g., Mayo Collaborative Servs., 132 S. Ct. at 1305 (“We need not determine
here whether, from a policy perspective, increased protection for discoveries of diagnostic
laws of nature is desirable.”).

(quoting U.S. Const. art. 1, § 8, cl. 8). See generally Dotan Oliar, The (Constitutional)
Convention on IP: A New Reading, 57 UCLA L. REV. 421 (2009) (analyzing the history and
meaning of art. 1, § 8, cl. 8 of the Constitution).

32. [placeholder]


34. Bonito Boats, 489 U.S. at 150–51; Kewanee Oil, 416 U.S. at 481–82.

35. ECON. & STATISTICS ADMIN. & U.S. PATENT & TRADEMARK OFFICE,
(“Innovation protected by IP rights is key to creating new jobs and growing exports.
Innovation has a positive pervasive effect on the entire economy, and its benefits flow
both upstream and downstream to every sector of the U.S. economy.”); see also VANNEVAR
considered the patent system as part of a larger piece of distributive and social justice. In addition, firms use patents as private rights to facilitate licensing, to create defensive portfolios, and as reputational signals.

These purposes are not harmonious. Strong patents favor private control and return on investment. In theory, granting broad protection might encourage stronger financial support for the infrastructure needed for invention. The ability to obtain patents more easily favors disclosure. Limiting patent protection facilitates competition. Similarly, this favors experimentation, and encourages a multiplicity of solutions through diverse sources. Curbing patent protection allows those who engage in follow-on research to devote more resources for such activity. Job growth rates are dependent on a number of

BUSH, SCIENCE: THE ENDLESS FRONTIER, A REPORT TO THE PRESIDENT (1945) (discussing the importance of scientific innovation).


40. Sakakibara & Branstetter, supra note 38, at 80.

41. Suggested citation: Robert P. Merges and Richard R. Nelson, On the Complex Economics of Patent Scope, 90 COLUM. L. REV. 839, 855 (1990) (noting the value of limited protection for certain circumstances, stating “Particularly when the technology is in its early stages, the grant of a broad-gauged pioneer patent to one party may preclude other inventors from making use of their inventions without infringing the original patent.”)

42. See EXECUTIVE OFFICE OF THE PRESIDENT, PATENT ASSERTION AND U.S. INNOVATION 2 (2013) (“Innovators who fear inadvertently infringing existing patents may reduce innovative activity or take costly steps to defend against lawsuits claiming infringement, leading to fewer resources available for wages, job creation, and innovation
factors, and are dependent to some extent on the relation between patents and innovation.\textsuperscript{44} The issues of distributive and social justice are context-dependent.\textsuperscript{45}

This tension between the multiple purposes of patent law is evident in the health care field, which is fraught with high invention costs, a lengthy regulatory review process, and uncertainty.\textsuperscript{46} According to some, the patent system appears to incentivize innovation in the pharmaceutical and chemical fields.\textsuperscript{47} In the words of Novartis, a large health care innovator, developing new solutions “requires substantial investment, and in the case of innovative R&D, strong incentives like those provided by the patent system to enable and fund the costly, risky work that it takes to invent, develop, and bring new therapies to patients.”\textsuperscript{48} On the other hand, patent protection for certain types of inventions within the field can roadblock entire areas of research.\textsuperscript{49} As one Nobel Prize-winning biologist explained, “the tools for manipulating genomes should be in the public domain,” because “it’s actually the case that monopolistic

of new products and services.”).

\textsuperscript{44} The relationship between patents and innovation is a complex one. See, e.g., Yi Qian, Do National Patent Laws Stimulate Domestic Innovation in a Global Patenting Environment? A Cross-Country Analysis of Pharmaceutical Patent Protection, 1978–2002, 89 REV. ECON. & STAT. 436, 436 (2007) (“The actual effect of IPR on innovation, however, remains one of the most controversial questions in the economics of technology.”); Sakakibara & Branstetter, supra note 38, at 78, 98 (studying Japanese innovative response to patent reform and “finding no evidence of an increase in innovative effort or innovative output that could be plausibly attributed to patent reform”).

\textsuperscript{45} [placeholder]

\textsuperscript{46} See Kristen Nugent, Patenting Medical Devices: The Economic Implications of Ethically Motivated Reform, 17 ANNALS HEALTH L. 135, 149, 153 (2008) (“The inventive process is time sensitive, financially risky, and carries no guarantee of commercial success.”).

\textsuperscript{47} See James Bessen & Michael J. Meurer, Of Patents and Property, REG., Winter 2008–2009, at 18, 19 (“In some industries, such as pharmaceuticals, patents provide strong positive incentives to invest in innovation.”); Bronwyn H. Hall & Dietmar Harhoff, Recent Research on the Economics of Patents, 15 (Nat’l Bureau of Econ. Research, Working Paper No. 17773, 2012) (“[A] finding from the empirical literature is that if there is an increase in innovation due to patents, it is likely to be centered in the pharmaceutical, biotechnology, and medical instrument areas, and possibly specialty chemicals.”).


\textsuperscript{49} See Bryan Nese, Bilski on Biotech: The Potential for Limiting Negative Impact of Gene Patents, 46 CAL. W. L. REV. 137, 155–56 (2009) (“There is potential for further delay, or even outright halting, of research due to licensing negotiations between patent holders.”). See generally Michael A. Heller & Rebecca S. Eisenberg, Can Patents Deter Innovation? The Anticommons in Biomedical Research, 280 SCI. 698 (1998) (discussing the negative, anticommon effect that medical patents have on future research opportunities).
control of this kind would be bad for science, bad for consumers
and bad for business, because it removes the element of
competition.” At the same time, free access to certain medicines
serves important societal goals. Further, more lenient
patentability requirements encourage disclosure and
dissemination of knowledge.

Implementing policy requires making choices. Currently,
patent doctrine floats above the fray without engaging with these
difficult questions or articulating real world consequences. The
most recent Supreme Court jurisprudence focuses primarily on
the construction of the judicially created exclusions as part of the
common law. Yet this circumstance does not articulate the
anticipated prospective consequences of these rulings in a
manner that might guide the lower court and the U.S. Patent &
Trademark Office, which must implement these decisions.

Doing so can require understanding patents in context, as well as
making transparent policy choices that can be used to inform the
application of the law by the lower courts.

B. Taking the Patent Incentive System Seriously

One might question whether any changes to the present
system are warranted. Yet there are reasons to think “seemingly
minor changes in the institutional design of patent systems can
have relatively large effects.” Several studies have concluded
that the patent system is not working optimally. These point to
observations that, despite the increased number of patents issued since the 1980s, there has not been a corresponding increase in research and development investment, or “any additional surge in useful innovations and aggregate productivity.”\(^{59}\) Another points out that economists studying the field “have known for some time that patents are not the only — or in most industries the most important — mechanism for preserving incentives for innovation.”\(^{60}\)

Legal scholar Robert Merges expresses similar doubts, stating, “[t]ry as I might, I simply cannot justify our current IP system on the basis of verifiable data showing that people are better off with IP law than they would be without it.”\(^{61}\) A survey of over one thousand early stage technology companies reported that the patents are not a strong incentive to create, develop, and commercialize technology, finding, “startup executives report that patents generally provide relatively weak incentives to conduct innovative activities.”\(^{62}\) In *The Case Against Patents*, economists Boldrin and Levine argue, “it is fair to say that the sector-level, national, and cross-national evidence fail to provide any clear empirical link from patents to innovation or to productivity.”\(^{63}\)

Other work pinpoints specific difficulties for creators caused by the patent system. Some examples find an anti-commons effect in some (although not all) circumstances that cannot be

---


\(^{60}\) Jaffe, *supra* note 58, at 554 (surveying economic research) ; cf. Sakakibara & Branstetter, *supra* note 38, at 98 (analyzing results of Japanese firms responding to changes in Japanese patent reforms, stating “we find no evidence of an increase in innovative effort or innovative output that could be plausibly attributed to patent reform”).

\(^{61}\) ROBERT P. MERGES, *JUSTIFYING INTELLECTUAL PROPERTY* 3 (2011). Merges’ observation may be read as a disclaimer of the classic utilitarian justification for intellectual property, and not advocacy in support of abandoning such rights altogether. After stating that the data supporting the existence of IP rights is “maddeningly inconclusive,” Merges argues that rights-based justifications support governmental support for IP rights.


\(^{63}\) Boldrin & Levine, *supra* note 58, at 7.
resolved through bargaining.\textsuperscript{64} Separately, the patent system can force parties to incur transaction costs that dissipate the social benefits of intellectual property protection in certain circumstances.\textsuperscript{65} This circumstance leads to a decline in research and development. As one economist summarized, “to the extent that firms’ attention and resources are, at the margin, diverted from innovation itself towards the acquisition, defense and assertion against others of property rights, the social return to the endeavor as a whole is likely to fall.”\textsuperscript{66}

On the other hand, there are reasons to maintain the patent system, so long as it is properly implemented. Some evidence suggests that the patent system facilitates funding to build the scientific and technological infrastructure needed to create new inventions and bring them to market.\textsuperscript{67} A study by Sichelman and Graham finds that patenting is particularly important to small and entrepreneurial companies in the biotechnology and medical device fields, which rely on patents to prevent copying and to secure outside financing.\textsuperscript{68} More generally, patents enable collaboration, integration, and licensing.\textsuperscript{69} This can be important for both invention and product development, which rely on a mix


\textsuperscript{65} Bessen & Meurer, supra note 58, at 141 (“[D]uring the late 1990s, the aggregate costs of patents exceeded the aggregate private benefits of patents for United States public firms outside the chemical and pharmaceutical industries.”).

\textsuperscript{66} Jaffe, supra note 58, at 555.

\textsuperscript{67} Brief for Inhouse Patent Counsel, LLC as Amicus Curiae Supporting Respondents, Ass’n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107 (2013) (No. 12-398), http://www.americanbar.org/content/dam/aba/publications/supreme_court_preview/briefs-v2/12-398.resp_amcu_ipc.authcheckdam.pdf (“By patenting gene-based inventions, HGS [Human Genome Services, Inc.] was able to attract funding from the investment community, which HGS used to develop novel therapeutic agents to address unmet medical needs and advance scientific research.”) ; Margaret K. Kyle & Anita M. McGahan, *Investments in Pharmaceuticals Before and After TRIPS* 1167 (Nat’l Bureau of Econ. Research, Working Paper No. 15468, 2012), http://www.nber.org/papers/w15468 (“[A] strong positive association [exists] between TRIPS compliance and R&D effort, with R&D more responsive to IP-protected market size for global diseases than for neglected diseases.”).


of inflows and outflows of knowledge and competencies. Further, patents facilitate contractual relationships with upstream suppliers and downstream manufacturers, and prevent such partners from converting themselves into competitive adversaries.

In addition, patents may serve an incentive function that is not visible in the empirical data. By way of explanation, Professor Merges has argued that:

> [e]ven if the average patent is not particularly valuable, this does not mean that the lure of patents will not act as a powerful stimulus to invention, at least in some cases. . . . Many inventions that turn out to be average are backed by inventors who believe they are special; the power of patents in special cases thus induces inventors to perfect many an average invention.

This viewpoint is consistent with research that examines the positive long term impacts of policy bubbles, sometimes called social bubbles. Unlike economic bubbles, a policy bubble occurs when conduct is motivated by optimistic (some might say irrational) expectations that have the potential to create significant long-term social benefits. In some instances, research and development occur despite the lack of short-term, measurable results. As with the U.S. space program and Human Genome Project, such phenomena are characterized by those who possess, “extraordinary over-optimistic expectations of short-term applications during the development of a project, making them take risks that would not be justified by a standard cost-benefit analysis in the presence of huge uncertainties over long-time scales.” It is not implausible that short-term measurable benefits of patents in the aggregate are difficult to measure but the system is “capable of generating large private

---


71. Teece, supra note 69, at 294 (observing that licensing can bring about “the added danger that the partner may imitate the innovator’s technology and attempt to compete with the innovator”).


74. Id.

returns in many instances, which means that a number of economic actors have an interest in them, creating demands for more research.”

If patents are to work appropriately, the system requires guidance. Not all judicial actions provide reasons for their outcomes—for example, denials of certiorari or jury verdicts. Yet these decisions are incapable of meaningfully advancing the law, because these actions are impervious to engagement. They are not considered judgments. Only opinions supported by articulated reasoning allow for understanding, agreement, disagreement, and the evolution of principles. They require decision-makers to take the risk of being proven wrong. The willingness to commit to an articulated description is the first step in the process, even if the results are imperfect.

As is true in law more generally, articulated reasons are important to ensure reliability and stability in the patent system. As Frederick Schauer stated, decision-makers may be reluctant to commit to the articulation of reasons lest later decision-making become too constrained by prior reasoning. Yet others (whether parties or interested observers) may need these reasons to be articulated precisely because such commitment permits understanding, fosters the ability for third parties to become engaged in offering alternative ways of thinking, and can guide future planning. Moreover, articulated reasons support the system’s legitimacy, promote trust in the system, and optimize accountability.

Assuming incentives toward economic progress are the sole goal of the patent system, simple one-way ratchets (either toward

---

76. Hall & Harhoff, supra note 47, at 35.
77. See Kathleen Waits, Values, Intuitions, and Opinion Writing: The Judicial Process and State Court Jurisdiction, 1983 U. ILL. L. REV. 917, 934 (“If the lower courts know the true reasons which led to a given decision, they can apply those reasons to the relevant cases before them . . . .”).
79. Id.
80. Id. at 641 n.21; Waits, supra note 77, at 930.
81. Cf. Waits, supra note 77, at 921 (“In reality, even the most conservative judge accepts, consciously or otherwise, the law’s need for change and growth.”).
82. Cf. Alex Kozinski, What I Ate for Breakfast and Other Mysteries of Judicial Decision Making, 26 LOY. L.A. L. REV. 993, 994–95, 998 (1993) (describing the judiciary’s concerns to do their work appropriately because “[t]here are awesome forces in our society that extract a heavy price for judicial self-indulgence”).
83. [placeholder]
84. Cf. Schauer, supra note 78, at 657.
85. Id.
86. Id. at 657–58.
higher or lower protection) cannot easily resolve important questions regarding patent rights. Rather, decisions which can guide the system in all of its complexity are important, and the starting place for undertaking this task is articulated reasoning. It is true that patent law has shifted over the past several years in response to certain policy crises at specific points in time. Opening patent doctrine allows continuous recalibration of the system in a manner that preserves and increases the benefits of the patent system, without waiting for moments when the political economy is ripe for change.

Beyond this, patents are capable of accomplishing other societal goals. The law's willingness to accept (or reject) their integration into doctrine cannot meaningfully occur unless there is space to discuss and consider them.

III. CURRENT PATENTABLE SUBJECT MATTER INTERPRETATIONS

In this most recent era, the Supreme Court's patentable subject matter opinions appear to be deliberatively narrow. Like an ice sculpture that is shaped by the parts that have been chipped away, the legal definition of invention is shaped by its exceptions. Decisions lack clarity. Their reasoning rests heavily on a limited field of precedent that is, in turn, written in opaque terms during a different technological era. Further, patentable subject matter determinations rest on conclusions stated as factual findings—that is, substances are held to be “products of nature” and detailed software claims are deemed “abstract.” The Constitutional roots of the promotion clause are duly


89. See Menell, supra note 11, at 1305.

90. See Simone A. Rose, The Supreme Court and Patents: Moving Toward a Postmodern Vision of “Progress”, 23 FORDHAM INT’L. PROP., MEDIA & ENT. L.J. 1197, 1207, 1216–17 (2013) (discussing societal goals such as improving public health, sustainability, and access to knowledge).

91. See, e.g., Menell, supra note 11, at 1291–92 (“[T]he failure of the Bilski majority to elucidate the basis—constitutional, statutory, and/or jurisprudential—for deciphering the boundaries of patentable subject matter leaves other important industries and decisionmakers in the wilderness.”); see also Dan L. Burk, The Curious Incident of the Supreme Court in Myriad Genetics, 90 NOTRE DAME L. REV. 505, 507 (2014).

92. [placeholder]

93. See, e.g., Rose, supra note 90, at 1226–27, 1231; Menell, supra note 11, at 1304.
repeated, but not in a manner that sheds meaning. The deeper questions relating to scientific creativity, public benefits, and the financial infrastructure required to perform for scientific and technical work, are effectively absent.

The Court’s most recent trilogy—*Bilski*, *Mayo*, and *Alice*—have directed that patentability judgments be guided by the long-established judicially created exclusions. The courts have identified certain problematic examples as sources of analogy, including fundamental economic practices, methods of organizing human activities, and mathematical formulae. Other proxies include a preference for tangibility, or at a minimum claims that tend to have a visible or physically measurable impact. For example, the *Bilski* Court stated that “a useful and important clue” to patentability of a process claim, “is tied to a particular machine or apparatus, or . . . transforms a particular article into a different state or thing.” This same preference exists for apparatus claims.

This line of reasoning suggests that court-decided patentability determinations are neutral, true to precedent, and intended to facilitate the “easily administered proxy for the underlying ‘building-block’ concern.” Yet a former patent jurist writes that under the recent Supreme Court decisions:

> [I]t’s not clear what’s in and what’s out. Secondly, the categories overlap one another to my reading. Third, they tend to be subjective. They tend to be indeterminate. They tend to therefore be highly unpredictable, which leads to . . . difficultly advising clients, people knowing what to 

---

94. See *Rose*, supra note 90, at 1203–04, 1215–16 (discussing how patent cases use the IP clause in their decisions).

95. [placeholder]


do, how to act.\textsuperscript{101}

At one level, the Court’s reliance on precedent is characteristic of a common law system of decision-making.\textsuperscript{102} On another, the lack of meaningful integration of the system’s goals may be a manifestation of a reluctance to commit to a specific path, perhaps due to a lack of theoretical consensus.\textsuperscript{103} This may be particularly true for refusals to protect particular claims, where the contours of the Supreme Court’s efforts to rein in patentability are necessarily open-ended.\textsuperscript{104} Further, industries, science, ideas, financial and technological contexts are subject to change that is more rapid than our traditional, precedent-based system might comfortably accommodate.\textsuperscript{105} Patentable subject matter opinions appear caught between grappling with patents as a stable, property-rights based regime within a precedents-based form of decision-making and the fact that invention and innovation exist in an environment of rapid and forward-moving change.\textsuperscript{106} The next subsections will illustrate these points with specificity, and provide examples of alternative reasoning from outside the United States as counter-examples.

A. Abstract Subject Matter

Abstract subject matter represents a significant exclusion from patentable subject matter.\textsuperscript{107} As defined in the 1852 decision \textit{Le Roy v. Tatham}\textemdash that is, “[a] principle, in the abstract, is a fundamental truth; an original cause; a motive . . . cannot be patented.”\textsuperscript{108} Abstract subject matter may represent information that is novel but not considered inventive, because allowing patents for “the basic tools of scientific and technological work” would amount to the granting private control over fundamental tools and thereby “might tend to impede innovation more than it would tend to promote it.”\textsuperscript{109} Thus, claims to abstract ideas are said to “put a chill on creative endeavor and dynamic change”

\begin{itemize}
\item \textsuperscript{101} Paul R. Michel, \textit{The Supreme Court Saps Patent Certainty}, 82 GEO. WASH. L. REV. 1751, 1755, 1758 (2014).
\item \textsuperscript{102} \textit{[placeholder]}
\item \textsuperscript{103} \textit{[placeholder]}
\item \textsuperscript{104} \textit{[placeholder]}
\item \textsuperscript{105} \textit{[placeholder]}
\item \textsuperscript{106} \textit{[placeholder]}
\item \textsuperscript{108} \textit{Le Roy v. Tatham}, 55 U.S. 156, 175 (1852).
\item \textsuperscript{109} \textit{Mayo Collaborative Servs.}, 132 S. Ct. at 1293 (citing Gottschalk, 409 U.S. at 67).
\end{itemize}
that would interfere with the system’s constitutional purpose.\textsuperscript{110}

Of necessity, the abstract subject matter exception is broader in application than it is stated in principle. Specifically, concrete embodiments of abstract ideas are subject to the exception as well.\textsuperscript{111} For example, in \textit{Mackay Radio & Telegraph Co. v. Radio Corporation of America}, the Court pointed out the suspect validity of claim to a directive antenna system that was a physical embodiment of a scientific principle developed by another.\textsuperscript{112} This represents a judicial recognition that claims to a tangible embodiment can preempt a scientific principle—in other words, patents cannot be granted for the mere embodiment of abstract knowledge even if they are embodied in a tangible form.\textsuperscript{113} The \textit{Mackay} Court’s concerns have been echoed in later decisions that find certain software claims unpatentable because they “would pre-empt use of this approach in all fields, and would effectively grant a monopoly over an abstract idea.”\textsuperscript{114}

The most prevalent issues up for decision revolve around the tension between the rule that ideas—and the embodiments of those ideas as seen in \textit{Mackay}—are not patentable, and the rule that the application of ideas to solve problems is patentable.\textsuperscript{115} The \textit{Alice} test would have invalidated the invention at issue in \textit{Mackay Radio}.\textsuperscript{116} That is, \textit{Alice} renders \textit{embodiments} of abstract subject matter ineligible.\textsuperscript{117} Because the \textit{Mackay} claims sought protection for a directive antenna system that was merely a tangible embodiment of an abstract theory, it added no inventive concept of its own and would not therefore be subject to patent protection.\textsuperscript{118} The difficulty is that similar results are achievable through the novelty or nonobviousness requirements.\textsuperscript{119} As has

\begin{thebibliography}{99}
\bibitem{Bilski} Bilski, 561 U.S. at 608 (plurality opinion); see, e.g., \textit{Alice Corp.}, 134 S. Ct. at 2354; \textit{Gottschalk}, 409 U.S. at 71–72.
\bibitem{Collins} For a discussion on the distinction between the patentability of knowledge and embodiments, see Kevin Emerson Collins, \textit{The Knowledge/Embodiment Dichotomy}, 47 U.C. Davis L. Rev. 1279, 1282 (2014).
\bibitem{Mackay} Mackay Radio & Tel. Co. v. Radio Corp. of Am., 306 U.S. 86, 94–95 (1939) (assuming without deciding that the claim was valid, although observing that “it is apparent that if this assumption is correct the invention was a narrow one”).
\bibitem{placeholder} [placeholder]
\bibitem{Bilski2} Bilski, 561 U.S. at 612.
\bibitem{Rubber} Rubber-Tip Pencil Co. v. Howard, 87 U.S. 498, 507 (1874).
\bibitem{placeholder2} [placeholder]
\bibitem{placeholder3} See generally \textit{Alice Corp.}, 134 S. Ct. at 2352 (holding that claims on a “computer-implemented scheme” for managing settlement risk “are drawn to the abstract idea of intermediated settlement, and that merely requiring generic computer implementation fails to transform that abstract idea into a patent-eligible invention”).
\bibitem{Mackay2} Mackay Radio & Tel. Co., 306 U.S. at 89–94 (1939).
\end{thebibliography}
been recognized, the current iteration of the patentable subject matter doctrine appears to be redundant of the other patentability requirements.\textsuperscript{120}

Similarly, \textit{Alice} instructs that a claim limitation that introduces an inventive concept demonstrates patent eligibility, which must be more than “well-understood, routine, conventional activit[y].”\textsuperscript{121} This aspect of the test bears some relation to the nonobviousness inquiry. Under both, the decision-maker must ascertain whether the claim includes an improvement over existing solutions.\textsuperscript{122} This overlap exposes a common foundation of both doctrines—that is, both seek to define and determine \textit{inventiveness}. Further, the claim language must include a specifically articulated inventive concept.\textsuperscript{123} This aspect of the inquiry has a rough correspondence to the written description requirement, in that both require textual disclosure of the inventor’s advance.\textsuperscript{124} At the same time, \textit{Alice’s} inventive concept requirement does not fully serve section 101’s ability to serve as a distinct and meaningful policy driver.\textsuperscript{125}

Leaving the structure of the analysis aside, the application of the abstract subject matter exclusion in the lower courts remains flat and narrowly focused on the doctrinal test rather than recognizing the practical implications of those decisions. For example, the Federal Circuit’s \textit{Ultramercial} decision held that a detailed, eleven-step claim to a process for displaying an advertisement before playing copyrighted video content was “abstract.”\textsuperscript{126} The court’s reasoning states in part:

This ordered combination of steps recites an abstraction—an idea, having no particular concrete or tangible form. The process of receiving copyrighted media, selecting an ad, offering the media in exchange for watching the selected ad, displaying the ad, allowing the consumer access to the media, and receiving payment from the sponsor of the ad all describe an abstract idea, devoid of a concrete or tangible

\begin{itemize}
  \item \textsuperscript{120} See \textit{id.} at 598–609. \textit{But see} Rebecca S. Eisenberg, \textit{Wisdom of the Ages or Dead-Hand Control? Patentable Subject Matter for Diagnostic Methods After In re Bilski}, 3 \textit{CASE W. RESERVE J.L. TECH. & INTERNET} 1, 64 (2012) (“[P]atentable subject matter limitations are not redundant to these other doctrines.”).
  \item \textsuperscript{121} \textit{Alice Corp.}, 134 S. Ct. at 2355, 2359.
  \item \textsuperscript{122} \textit{See id.} at 2358 (citing \textit{Diamond v. Diehr}, 450 U.S. 175, 178 (1981)).
  \item \textsuperscript{123} Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1302 (2012) (noting that the invalid claim was stated in “highly general language”); \textit{buySAFE, Inc. v. Google, Inc.}, 765 F.3d 1350, 1354–55 (Fed. Cir. 2014).
  \item \textsuperscript{124} Mayo Collaborative Servs., 132 S. Ct. at 1300; 35 U.S.C. § 112(a) (2012).
  \item \textsuperscript{125} \textit{Placeholder}; § 101.
  \item \textsuperscript{126} \textit{Ultramercial, Inc. v. Hulu, LLC}, 772 F.3d 709, 714–15 (Fed. Cir. 2014).
\end{itemize}
application.  

Ultramercial cautions that its holding does not extend to all software claims and that “[f]uture cases may turn out differently,” yet there is no guidance from which software developers might extrapolate to determine whether future works might be considered patentable. In other words, these decisions provide no direction to guide software developers to make full use of patents as an incentive system.

Arguably, the Ultramercial opinion can be rationalized on policy grounds. For example, granting patent protection for the claims at issue in Ultramercial is arguably not in the public interest. The inventive contribution of the claims at issue appears to be modest compared to the socially valuable conduct that the claims would pre-empt. More generally, software claims exist in context that implicates patent thickets. Yet the opinion does not discuss these principles expressly, or any others. Rather, the court merely concludes that this high-specified method of displaying copyrighted content on the Internet is “abstract.”

Ultramercial’s reasoning is emblematic of other abstract subject matter cases decided since Alice. There is very little, if any, text devoted to explaining the policy rationale, guiding those in the industry, or demonstrating reasoned consideration of the consequences of these rulings.

In contrast, a report issued by the Chamber of Deputies of Brazil opined that software is not patentable because it “is a purely abstract conception, a mathematical method,” evoking language of the exclusions to patentable subject matter. The report finds that the Brazilian patent office had, in the past, granted software patents without debate and “in clear confrontation of legislation and national interest.” After a robust description of the nature of cumulative invention in the software field, the report explains that “[t]he most grievous issue

127. Id. at 715.
128. Id.
129. [placeholder]
130. [placeholder]
131. Id. at 717.
133. CHAMBER OF DEPUTIES, BRAZIL’S PATENT REFORM: INNOVATION TOWARDS NATIONAL COMPETITIVENESS 281 (2013).
134. Id. at 282.
is that software patents block competition and innovation in the information technology sector,” and that therefore “the institute of patents is not appropriate for the software sector.” However, although the U.S. courts are free to disagree with this conclusion, this report’s analysis of the consequences of patent protection illustrates the type of transparent and meaningful discussion that grapples with the for the patentability analysis within its larger context.

B. Products of Nature

The analysis with respect to products of nature exclusion fares no better than the abstract subject matter exclusion. As background, the Supreme Court’s Ass’n for Molecular Pathology v. Myriad Genetics found that claims to the BRCA1 and BRCA2 gene fragments did not constitute patentable subject matter, and that the patentee’s artificially created cDNA did. In doing so, the Court found the latter constituted discovery; the former was invention. The Myriad Court’s reasoning rests, essentially, on the material’s origin. Specifically, Myriad concluded, “Myriad did not create anything” for the gene fragment claims. Distinguishing the invention at issue in Chakrabarty as a substance that included the human addition of new material into the bacterium at issue, the Court reasoned that the isolation of existing material was valuable, required extensive effort, and yet was nothing more than a claim to pre-existing natural material. In contrast, the patentee’s cDNA claim had its structural origin in a man-made substance.

This Court’s distinction is confidentially factual in its proclamation, made notwithstanding a record replete with contradiction. Contrary to the Court’s ultimate finding, some argued that DNA was not a product of nature because of the distinct chemical changes that occur during the isolation process and others observed the unique functionality of the isolated DNA claims at issue. Also contrary to the Myriad Court’s conclusion,

---

135. Id. at 282–83.
137. Id.
138. Id. at 2117.
140. Myriad Genetics, 133 S. Ct. at 2119 (“[T]he lab technician unquestionably creates something new when cDNA is made.”).
141. Id. at 2116–19.
142. Brief for Respondents at 34–35, Myriad Genetics, 133 S. Ct. 2107 (No. 12-398); Brief for Fédération Internationale des Conseils en Propriété Intellectuelle as Amicus
some argued that cDNA was a product of nature because, as the Petitioner argued, “cDNA simply does not have ‘markedly different characteristics from any found in nature.’” Numerous briefs discussed the preemptive force of finding Myriad’s claims patentable as a policy matter. Others discussed the need for patent protection to facilitate both creative and financial support for the biotechnology industry. As the amicus curiae brief of the American Intellectual Property Law Association stated, “there is every indication that the availability of patent protection for isolated genes (and similar compositions of matter based on structures found in the human body) has fueled an explosion of innovation and biomedical advance.”

Yet the Myriad Court pinned the labels “natural” on DNA fragments, and “inventive” on cDNA without engaging in any of these questions, or any other concerns that are core to the patent system’s existence. A product of a common law system that looks backward to precedent, the Myriad opinion is emblematic of a decision-making process that appears wary of calling attention to legal change. By characterizing its ruling in conclusory terms, the Court did not engage in the more difficult questions about the patent’s systems incentive role in the biotechnological arts, the anticommons problems, the need to provide affordable health care solutions, or the need to foster

Curiae at 3–5, Myriad Genetics, 133 S. Ct. 2107 (No. 12-398) (quoting Diamond, 447 U.S. at 310) (supporting neither party and arguing that isolated DNA is chemically distinct from DNA found in the body) ; Brief for American Intellectual Property Law Ass’n as Amicus Curiae at 9, Myriad Genetics, 133 S. Ct. 2107 (No. 12-398) (supporting neither party and stating that the process of creating the gene fragments at issue “results in the creation of a new chemical entity that did not exist before”).

143. Brief for Petitioners at 51, Myriad Genetics, 133 S. Ct. 2107 (No. 12-398) (citing Diamond, 447 U.S. at 310); see also Brief for American Medical Ass’n et al. as Amici Curiae Supporting Petitioners at 22–25, Myriad Genetics, 133 S. Ct. 2107 (No. 12-398) (expounding that both DNA and cDNA are products of nature, because they lack any inventive contribution); Brief for National Women’s Health Network et al. as Amici Curiae Supporting Petitioners at 33–34, Myriad Genetics, 133 S. Ct. 2107 (No. 12-398).

144. See, e.g., Brief for Petitioners, supra note 143, at 40–48; see also Brief for American Medical Ass’n, supra note 143, at 13–15; Brief for National Women’s Health Network, supra note 143, at 35–36; Brief for Eric S. Lander as Amicus Curiae at 28–29, Myriad Genetics, 133 S. Ct. 2107 (No. 12-398) (supporting neither party).

145. See, e.g., Brief for Respondents, supra note 142, at 16, 35–36, 38–39; Brief for American Intellectual Property Law Ass’n, supra note 142, at 17–19; Brief for Eric S. Lander, supra note 144, at 26–27; Brief for American Bar Ass’n as Amicus Curiae Supporting Respondents at 9, Myriad Genetics, 133 S. Ct. 2107 (No. 12-398) (arguing that DNA fragment “patents help protect the significant investment needed to develop and obtain regulatory approval for new products in the biotechnology industry”).


147. Myriad Genetics, 133 S. Ct. at 2111–12, 2114–19.

148. [placeholder]
The Court did not acknowledge that its decision might impact research investment, or articulate any guiding principles that consider the consequences of its ruling. Concluding that the legal issue of “invention” was resolvable through this type of judicial fact-finding, the Court side-stepped the most difficult issues that had been presented among the numerous briefs filed by the parties and amici. Most significantly, the Court pushed aside the principle that any inventive activity was necessary for a claim to be considered inventive.

Instead, the Supreme Court’s reasoning in Myriad bears some relationship to the ancient philosophical distinction between natural and man-made creations. The Greek notion of *natura-phýsis* refers to the origin of natural objects that are born, evolve, and grow—a bringing forth, growth, and a process of originating. Essentially, “[t]his entire coming-to-be and directing activity of *phýsis* comes about by it by its own agency, so that the source of that movement which is the coming-to-be lies in the thing itself which comes-to-be.”

This principle can be seen in Aristotle’s work, in which he describes nature as both a source of its own production and a force that precipitates changes according to its own predilection.

In a sense, the Myriad Court opinion evokes the Aristotelian distinctions for the patentability of cDNA claims. Greek thought characterized artificial items with an origin in “something else
external to the thing.”\textsuperscript{157} Thus, artificial things do not self-replicate, but require the assistance of man to recreate.\textsuperscript{158} In line with this logic, the Myriad Court held as a factual matter: “[T]he lab technician unquestionably creates something new when cDNA is made.”\textsuperscript{159} The central distinction between the DNA as a product of nature, and cDNA as a work of man-made origin, echoes an ancient philosophical framework.\textsuperscript{160} This conclusion brushes past more recent advances that render this distinction questionable.\textsuperscript{161} Further, this conclusion fails to grapple with the numerous financial, ethical, and social concerns relevant to the question presented.\textsuperscript{162}

Internationally, governments have engaged in the questions relating to “the dynamic relationship between intellectual property protection and social and economic development.”\textsuperscript{163} Since the Statute of Monopolies was enacted in 1623, patenting in Great Britain and its territories have been granted to facilitate development.\textsuperscript{164} This approach is built on the principle that more inventive activity will, in the long term, increase overall welfare and economic growth.\textsuperscript{165} As an Australian Court explained, whether a claim constitutes an invention is a legal conclusion reached after an analysis that is focused on the purpose of the law, stating, “[i]t is a mistake which tends to limit one’s thinking by reference to the idea of making tangible goods by hand or by

\begin{itemize}
  \item \textsuperscript{158} Aristotle explained, “if you planted a bed and the rotting wood acquired the power of sending up a shoot, it would not be a bed that would come up, but wood—which shows that the arrangement in accordance with the rules of the art is merely an incidental attribute . . . .” Id. at 193a.
  \item \textsuperscript{159} Ass’n for Molecular Pathology v. Myriad Genetics, 133 S. Ct. 2107, 2119 (2013).
  \item \textsuperscript{160} [placeholder]
  \item \textsuperscript{161} See Arthur Caplan, The End of Vitalism, 465 NATURE 423, 423 (2010), http://www.nature.com/nature/journal/v465/n7297/pdf/465422a.pdf (noting that the existence of synthetic cells have “shown that the material world can be manipulated to produce what we recognize as life”)
  \item \textsuperscript{162} See generally HUMAN GENETICS PROGRAMME, WORLD HEALTH ORGANIZATION, GENETICS, GENOMICS AND THE PATENTING OF DNA 30–33 (2005).
  \item \textsuperscript{163} HUAIWEN HE & PING ZHANG, IMPACT OF THE INTELLECTUAL PROPERTY SYSTEM ON ECONOMIC GROWTH: COUNTRY REPORT – CHINA 3 http://www.ip.mpgr.de/shared/data/pdf/003_zhang_impact_of_ip_system_on_china_nationa l_economic_growth_paper.pdf (observing that a high level of intellectual property protection, by itself, is not sufficient to transform China into an inventive leader).
  \item \textsuperscript{164} See Schering AG’s Application [1971] 337 RPC 337, 340 (Austl.) (“The purpose of section 6, it must be remembered, was to allow the use of the prerogative to encourage national development in a field which already, in 1623, was seen to be excitingly unpredictable.”); Nat’l Research Dev Corp v Comm’r of Patents [1959] 102 CLR 252, 271 (Austl.).
  \item \textsuperscript{165} Daniel J. Gifford, How Do the Social Benefits and Costs of the Patent System Stack up in Pharmaceuticals?, 12 J. INTELL. PROP. L. 75, 83 (2004).
\end{itemize}
machine, because ‘manufacture’ as a word of everyday speech generally conveys that idea.”

Similarly, in 1959, India restricted the patentability of claims to chemicals, food, and medicines to foster experimentation and to broaden access to certain types of inventions in order to benefit public health. In the recent *D’Arcy v Myriad Genetics*, the Federal Court of Australia held that gene fragments were patentable. The Australian court relied in part on the legislature’s refusal to enact legislation that would have held to the contrary. In connection with this inquiry, a finding had been made that doing so “may adversely affect investment in the Australian biotechnology industry.”

As another example, in the 1980s, the European Union determined to create a patent policy for biotechnology that was explicitly intended to assist its industry. In 1988, the European Commission proposed a directive to protect biotechnological inventions to reduce uncertainty for investment in the field. This early proposal recognized the high risk and cost of research in the field, and recognized that the legal uncertainty within the region would be detrimental to growth in this nascent field. Over the next several years, the European proposal for a unified biotechnology patent standard was slowed by moral, ethical, and medical concerns. As this debate continued, authorities observed that the number of American biotechnology patents, firms, and products was fast outstripping those in Europe. In 1996, the European Council issued a report finding that harmonization of the legal protection of biotechnology was necessary “so that European researchers can see their labours rewarded, industry can make the necessary investment in

169. *Id.* ¶ 205.
170. *Id.* ¶ 158.
171. For an early document suggesting the need to address patent protection for biotechnological inventions, see *Completing the Internal Market*, at 37, COM (1985) 310 final (June 14, 1985).
173. *Id.*
research and development, legal certainty can be improved and the potential job spin-off realized.”

In a move that stands in contrast to the U.S. Supreme Court’s Myriad decision, the European Union adopted a final version of the Biotech Directive in 1998, which provides that isolated biological material is patentable even if that same material exists in nature. Similarly, Rules 26 through 29 of the European Patent Convention expanded the scope of patentable subject matter to include biological materials. These include patents on full or partial gene sequences derived from the human body “even if the structure of that element is identical to that of a natural element.” In 2008, Myriad Genetics obtained approval for a patent to a genetic sequence before the European Patent Office’s Technical Board of Appeal, wherein the Board explained, “an element isolated from the human body or otherwise produced by means of a technical process may constitute a patentable invention.” More broadly, the European Directive is based on an expressed policy directed to facilitate research and development in biotechnology, including the social benefits of facilitating industrial development, research, funding, fighting diseases, and the development of the environment. During the course of formulating the Directive, the European system modified its proposal to include certain exceptions including uses that are “unpatentable [because] their commercial exploitation would be contrary to ordre public or morality . . . .” This is one example of a patentability determination that was explicitly driven by considered policy choices. Similarly, in 2005, German

176. Id. ¶ 1.3.2.
177. Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions, 1998 O.J. (L 213/13) art. 3.2. There are limitations on this principle, including the requirement that the material have industrial applicability and have been isolated or produced by a technical process. Id. arts. 3.2, 5.3.
179. Id. rule 29(2).
180. University of Utah Research Foundation, T 008/05 ¶ 59 (11/19/08) (EPO Tech. Bd App.).
182. Id. art. 6.1.
183. See Geertru Van Overwalle, Policy Levers Tailoring Patent Law to Biotechnology: Comparing U.S. and European Approaches, 1 UC IRVINE L. REV. 435, 494 (2011) (asserting that there are “some seventeen policy levers [that] have been uncovered in current European patent law which have particular effect on the biotech (or adjacent chemical and pharmaceutical) industry”).
national law narrowed the scope of human gene patents to limit the scope of protection to the use(s) of the invention disclosed in the specification.\textsuperscript{184} The reasons for including this limitation included a reason to “trigger a new discussion on desirable limitations for the scope of patents on parts of the human genome” within Europe.\textsuperscript{185} This effort demonstrates legal change that seeks to define patentability within a larger legal and social context.

Perhaps unsurprisingly, the Myriad Court’s factual distinction between the label “natural” for DNA and “inventive” for cDNA has not resonated well in the lower courts. The Federal Circuit’s In re Roslin Institute (Edinburgh) held that a claim to a cloned mammal was not patentable subject matter.\textsuperscript{186} Although the Myriad Court found that lab-created cDNA was patentable although it was a mirror image replica of natural DNA, the Roslin court found that a lab-created sheep too closely mirrored natural animals to satisfy section 101.\textsuperscript{187} Although the Supreme Court’s Myriad disclaimed the relevance of this point, the Federal Circuit’s Roslin held that the lack of any scientifically inventive contribution was fatal to the claim.\textsuperscript{188} If one takes the rationale of the Supreme Court’s reasoning literally, the Roslin court reached the wrong result.\textsuperscript{189} Yet neither provides any guidance in the sense of the European framework.

Similarly, the Federal Circuit’s In re BRCA1 and BRCA2 Based Heredity Cancer Test Patent Litigation, (hereinafter, Amby) side-stepped the Supreme Court’s Myriad distinction.\textsuperscript{190} In addition to its other arguments, the patentee urged to the Amby court that “[i]t is undisputed that the pair of single-stranded DNA primers are designed and created by scientists” in a lab and therefore patent eligible according to the Myriad Court’s reasoning.\textsuperscript{191} The Federal Circuit’s Amby decision

\begin{footnotesize}
\textsuperscript{184} Christoph Ann, Patents on Human Gene Sequences in Germany - On Bad Lawmaking and Ways to Deal with It, 7 GERMAN L.J. 279, 286 (2006).

\textsuperscript{185} Id. at 286–87.

\textsuperscript{186} In re Roslin Inst. (Edinburgh), 750 F.3d 1333, 1339 (Fed. Cir. 2014).

\textsuperscript{187} Id. at 1337 (“Dolly herself is an exact genetic replica of another sheep and does not possess ‘markedly different characteristics from any [farm animals] found in nature.’”) (quoting Diamond v. Chakrabarty, 447 U.S. 303, 310 (1980)).

\textsuperscript{188} Roslin, 750 F.3d at 1337.

\textsuperscript{189} Compare id. at 1335, with Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2116 (2013).

\textsuperscript{190} Univ. of Utah Research Found. v. Ambry Genetics Corp. (In re BRCA1- and BRCA2-Based Heredity Cancer Test Patent Litig.), 774 F.3d 755, 761 (Fed. Cir. 2014).

\textsuperscript{191} Reply Brief for Plaintiffs-Appellants at 21, Ambry, 774 F.3d 755 (Nos. 14-1361, 14-1366); see also Motion for Preliminary Injunctive Relief and Memorandum in Support at 12–13, Univ. of Utah Research Found. v. Ambry Genetics Corp., No. 2:13-cv-00640-RJS
\end{footnotesize}
attempted to circumvent this distinction by noting “[a]fter all, . . . isolated DNA is routinely synthetically created.” The Ambry court then proceeded to distinguish patent-eligible substances as those with a unique function and structure. Essentially, the Ambry court relied on a search for structural distinctions between claimed substances and products of nature, rather than examining their origins as the Supreme Court did in Mayo.

Roslin and Ambry’s analysis is consistent with the history of patent law in the United States that seeks to distance itself from the Elizabethan era practice that allowed patents for ordinary products that were not from new realm. Both decisions did not seek to define invention in a way that considers the larger-scale consequences. By focusing on the invention’s structure and origin, Mayo, Roslin, and Ambry have missed opportunities to align patentability with the purposes of the law.

IV. PATENTABLE SUBJECT MATTER AS A TECHNOLOGICAL ARTS TEST

The patentable subject matter requirement has been described as a technological arts test. That interpretation would appear to create a clear and implementable way to resolve patentable subject matter disputes. Yet that line of separation rests on a term—technological arts—that has a multifaceted and evolving meaning.

(D. Utah July 9, 2013) (“All of Myriad’s patent claims asserted in this case either require the use of inventive DNA synthesized in a laboratory based upon knowledge about the BRCA1 and BRCA2 genes (e.g., gene-specific probes, primers and arrays) and thus are patentable under § 101 based on the Supreme Court’s . . . analysis.”).

192. Ambry, 774 F.3d at 760.
193. Id. at 761.
195. See Ramon A. Kitzke, Historical Background of the English Patent Law, 41 J. PAT. OFF. SOC’Y 615, 644 (1959) (“[T]oo frequently Elizabeth granted patents for purely mercenary reasons, attempting to obtain either a cash payment or a share of the profits from a grant.”).
196. In re Roslin Inst. (Edinburgh), 750 F.3d 1333, 1335 (Fed. Cir. 2014); Ambry, 774 F.3d at 763.
197. See Mayo, 132 S. Ct. at 1294 (focusing on origins); Roslin, 750 F.3d at 1335 (focusing on origin); Ambry, 774 F.3d at 763 (focusing on structure).
199. Thomas J. Misa, Theories of Technological Change: Parameters and Purposes, 17 SCI., TECH. & HUM. VALUES 3, 5 (1992) (“Historians of technology have for the most
may result in a standard subject to malleability, subjectivity, and vagueness. Further, defining patentability on the technological arts places undue emphasis on textual interpretation and under-utilizes the work that the patentable subject matter standard could perform.

Historically, the term “technology” can be traced back to the ancient Greek distinction between episteme and techné. Generally, the former refers to scientific knowledge—in modern parlance, abstract scientific information. According to Plato, scientific knowledge is eternal, as he described, “knowledge of what always is.” This type of information, whether known or yet to be discovered by man, is fundamental, and within a category “that which is, and that which is invisible.” Plato considered the study of science hierarchically superior to the practice of techné, in that the former made “the soul look upward.” Similarly, Aristotle considered scientific knowledge “about universals, things that are by necessity.”

In contrast, techné refers to a very broad concept that has no true English analogue, as it encompasses more than technology and technique. According to Plato, this term refers to a multitude of subjects, including the practical, the art of implementation, as well as things concerning the “growing or construction, or with the care of growing or constructed things.” Aristotle considered techné to be knowledge that supports production that is, “with coming to be; and the exercise of the craft is the study of how something that admits of being and not being comes to be, something whose origin is in the

part abstained from defining their subject, portraying technology in a series of empirical examples and leaving it to their readers to fabricate definitions.” (italics omitted).

200. [placeholder]
201. [placeholder]
204. Plato, On Dialect and “Techné in ROBERT C. SCHARFF AND VAL DUSEK (EDS), PHILOSOPHY OF TECHNOLOGY, 13 (2014)(describing fundamental principles of geometry as "what always is, not what comes into being and passes away").
205. Id. at 14 (“I can’t conceive of any subject making the soul look upward except one concerned with what is, and that which is is invisible”).
209. Plato, supra note 204, at 16.
As another source describes, the Greeks conceived of *techné* as a coming into being through human mediation. Over time, the Greek concept of *techné* evolved into the German term *technik*, a broad term that refers both to all arts of material production and more broadly to “the practical rules and methods used to achieve a given end” in any number of fields. The term was incorporated into American parlance during the early part of the twentieth century by sociologist and economist Thorstein Veblen, who used the term in a manner consistent with the German *technik* to encompass industry, machinery, and the “principles, the knowledge and skills embodied in [their] operation.” Over the 1920s and beyond, the definition of technology lost much of Veblen’s subtlety for a time.

Today, colloquial definitions of technology include concepts that refer to the applied sciences, and the “useful arts.” Similar definitions encompass the means to effectuate physical change or the use of machinery, tools, and chemicals to accomplish useful ends. As the machine age evolved into the electronic era, the term has grown to encompass electronics and less visible mechanisms that perform closely analogous functions, such as software. These definitions, which evoke a visible or tangible effect of technology, are evident in reliance on the machine or transformation test as a “useful and important clue” to patentability. Yet they bypass more subtle current understandings of the term, and may be unduly limiting.

Society is beyond the point where scientific knowledge equates with Plato’s definition “what always is,” because numerous scientific theories have been disproven and replaced over the centuries. The past several decades have yielded

212. Eric Schatzberg, Technik Comes to America: Changing Meanings of Technology Before 1930, 47 TECH. & CULTURE 486, 494 (2006) ; Misa, supra note 199, at 4 (describing technology as a type of knowledge distinct from academic knowledge, but of the same importance).
213. Schatzberg, supra note 212, at 502–03.
214. Id. at 487–88.
215. Id. at 487.
216. See Giovanni Dosi, Sources, Procedures, and Microeconomic Effects of Innovation, 26 J. ECON. LITERATURE 1120, 1125 (1988) (discussing technological innovation as the solution of problems, such as the transformation of heat, shaping materials, producing compounds, and the like).
217. [placeholder]
alterantive understandings of technology.\textsuperscript{220} For example, historian Alex Roland considers technology as the use of “materials, technique, power, and tools or machines,” rather than an end product in itself.\textsuperscript{221} This conception has a rough correlation with the European Biotech Directive, which permits natural substances to be patented if “produced by means of a technical process” even if the result is a product of nature.\textsuperscript{222} This perspective suggests that the definition of technology is sufficiently pliable to meet the policy ends of the European Directive, and would reverse the result in the Federal Circuit’s Roslin decision.

Recognition is emerging that technology is integrated into the social, cultural, creative, and governmental aspects of our lives.\textsuperscript{223} This viewpoint recognizes that contextual factors exert an influence on the technology that is ultimately created.\textsuperscript{224} As one source observes, “[t]echnology, knowledge, government and economics . . . are inseparable and interdependent parts of the infrastructure of production . . . .”\textsuperscript{225} As another, Julie Cohen’s work discusses the influence of technology as it shapes our experiences.\textsuperscript{226} This conception considers technological advance as changeable, formed and forming the context from which it arises.\textsuperscript{227} Echoing this understanding, another viewpoint holds that technology is a practice that exists within certain social, political, and economic conditions and frames our subjective communications.\textsuperscript{228} This latter definition considers technology not as material objects, but rather as a participatory framework that enables communication including social media.\textsuperscript{229} As such, technology frames social, political, and economic practices and thereby depicts “ways of being in the world,” and subjects who
are ready to be that way, and not ready to be other ways.\textsuperscript{230} Technology is no longer exclusively in the realm of engineers. As technology becomes more ubiquitous and easy to manipulate, its definition expands.\textsuperscript{231}

Technology has blurred the line between pure and applied science. Unlike the former era where pure science was primarily observational, technology has made human manipulation of nature possible.\textsuperscript{232} Most recently, some technology possesses the agency to create.\textsuperscript{233} Thus, technology is no longer that which is made by man, but encompasses technology that creates and thereby “replace[s] the power of the human mind” and adopting self-generation capabilities that were formerly categorized solely within the natural world.\textsuperscript{234}

In the end, using the “technological arts” as a shortcut to an understanding of patentable subject matter may satisfy our need to label, to categorize, and to perform statutory construction as the field compels.\textsuperscript{235} Yet performing this exercise must, within the forward-looking purpose of patent law, encompass the definition of technological arts as that term evolves.\textsuperscript{236} Historically formulated definitions can mislead the system; to engage properly, decision-makers must grapple with technology as it evolves.\textsuperscript{237} To do so, policy is the guidepost. As the \textit{Bilski} plurality recognized, “[w]ith ever more people trying to innovate and thus seeking patent protections for their inventions, the 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.”\textsuperscript{238}

\textsuperscript{230} Id.
\textsuperscript{231} \textit{[placeholder]}
\textsuperscript{232} See Arthur M. Melzer, \textit{The Problem with “The Problem with Technology”, in GLOBALIZATION, TECHNOLOGY, AND PHILOSOPHY} 117 (David Tabachnick & Toivo Koivukoski eds., 2004) (“Modern science is built not on idle, speculative reason, nor even on empirical observation as such, but on active manipulation of nature.”).
\textsuperscript{233} \textit{[placeholder]}
\textsuperscript{234} Melzer, \textit{supra} note 232, at 112.
\textsuperscript{235} Application of Gerald Waldbaum, 457 F.2d 997, 1003 (1972).
\textsuperscript{236} Currently, patent law views of technology appears to be holding onto a definition of technology rooted in past precedent, with an origin in the mind of a single inventor (or a small number of them).
\textsuperscript{237} After performing an exhaustive review of the history of the Constitutional foundations of the U.S. patent system, Dotan Oliar concluded that there are few Constitutional limits on patentable subject matter. See Oliar, \textit{supra} note 31, at 453 (“If one tries to speculate about the Framers’ attitude toward business method patents in light of available source material, it is entirely possible that they would have approved of them.”).
\textsuperscript{238} \textit{Bilski} v. Kappos, 561 U.S. 593, 606 (2010).
V. IMPLEMENTING THE PATENTABLE SUBJECT MATTER THROUGH A CONFLUENCE OF CONSIDERATIONS

A. Fostering Creativity

The Supreme Court has identified the primary policy driver for the exclusions for patentable subject matter as pre-emption. According to the Court, “monopolization of those tools through the grant of a patent might tend to impede innovation more than it would tend to promote it,” thereby thwarting the primary object of the patent laws. Certainly, granting patents for foundational scientific principles prevents use of these “building blocks” of human ingenuity. In that sense, the Court appears to be using the preemption policy to foster cumulative invention. By excluding the “building blocks of human ingenuity,” the doctrine might be read to allow a rich source of information to fall into the public domain in a manner that would permit others to experiment, to make mistakes, to create, and to build on what has been done before.

The Supreme Court’s reliance on pre-emption as a policy goal suggests that the requirement can be used as an important mechanism to foster scientific creativity. The Court’s recent abstract subject matter opinions can be read to prioritize access to information as a creative input. This reflects the judicial

239. Alice Corp. v. CLS Bank Int’l, 134 S. Ct. 2347, 2354 (2014) (“We have described the concern that drives this exclusionary principle as one of pre-emption.”).

240. Id. (quoting Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1294 (2012)); see also Mayo Collaborative, 132 S. Ct. at 1294 (“[U]pholding the patents would risk disproportionately tying up the use of the underlying natural laws, inhibiting their use in the making of further discoveries.”).

241. Alice Corp., 134 S. Ct. at 2354; see also Frischmann & McKenna, supra note 220 (identifying the need for patent policy to limit protection to account for the need for later generations to use such information).

242. Mark A. Lemley et al., Life After Bilski, 63 Stan. L. Rev. 1315, 1329 (2011) (acknowledging that the abstract ideas exception “is about encouraging cumulative innovation and furthering societal norms regarding access to knowledge by preventing patentees from claiming broad ownership over fields of exploration rather than specific applications of those fields”).

243. Alice Corp., 134 S. Ct. at 2354; see also Frischmann & McKenna, supra note 220 (identifying the need for patent policy to limit protection to account for the need for later generations to use such information).

244. Alice Corp., 134 S. Ct. at 2354 (“We have described the concern that drives this exclusionary principle as one of pre-emption.”).

245. See Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1293 (2012) (observing the monopolization of research and abstract ideas in a patent would not promote innovation); Alice Corp. Pty. v. CLS Bank Int’l, 134 S. Ct. 2347, 2354 (2014) (placing patents between basic science and innovation); Gottschalk v. Benson, 409 U.S. 63, 67 (1972) (“Phenomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific
recognition of the need to keep some information in the public
domain to provide breathing space for new invention. Knowledge
accretes, and therefore a vibrant system of invention depends on
the availability of core concepts that must be preserved to allow
follow-on invention.\textsuperscript{246} By invalidating patents under section 101,
decision-makers eliminate patents that stray too close to the laws
of nature, scientific principles, and abstract ideas.\textsuperscript{247} In theory,
this practice allows a wider range of inventors to engage in
research without undertaking the significant transaction costs
and remedies to fight patent infringement claims.

Without more guidance, pre-emption is incapable of drawing
clear lines because all patent claims are inherently pre-emptive.
That is, the nature of the patent right inevitably preempts the
use of the claimed technology by others.\textsuperscript{248} The Court offers scant
guidance on determining the line between the unpatentable
preemptive claim and the patently sufficient one. For example,
when invalidating the claims at issue, the \textit{Mayo} Court undertook a
micro-level pre-emption analysis that seemed at odds with the
broad question that is answerable by the patentable subject
matter test.\textsuperscript{249} In \textit{Mayo}, Justice Breyer did not consider claim
breadth as determinative, observing, “even a narrow law of
nature (such as the one before us) can inhibit future research.”\textsuperscript{250}
Breyer further explained, “[c]ourts and judges are not
institutionally well suited to making [those] kinds of
judgments . . . .”\textsuperscript{251}

Another difficulty presented by the current exclusions from
patentable subject matter is that they carry assumptions about
scientific creativity from centuries ago.\textsuperscript{252} Many legal conceptions
of invention draw on a model of invention that rests on the

(recognizing the need to balance the incentive to invest in invention with the reality that
“imitation and refinement through imitation are both necessary to invention itself and the
very lifeblood of a competitive economy”).

\textsuperscript{247} \textit{Alice Corp.}, 134 S. Ct. at 2354 (“[W]e tread carefully in construing this
exclusionary principle lest it swallow all of patent law.”).

\textsuperscript{248} Specifically, \textit{Mayo}'s analysis justified invalidation reference its preemptive
reach, explaining that the claims at issue threatened to “tie up the doctor's subsequent
treatment decision . . . [and] inhibit the development of more refined treatment
1289, 1302 (2012).

\textsuperscript{249} \textit{Id.} at 1303.

\textsuperscript{250} \textit{Id.}.

\textsuperscript{251} \textit{Id.}

\textsuperscript{252} Michel, \textit{supra} note 101, at 1757 (stating that the exclusions from patentable
subject matter “were created by the Supreme Court ages ago kind of out of the air”).
existence of an inventive act of the human mind. The legal definition of conception—the starting point for an inventive act—is pegged to the moment when the invention is fully formed in “the mind of the inventor.” The U.S. Supreme Court has characterized the inventive act as the product of “intuitive genius,” and that the patent system’s goal is “the encouragement of the inventive genius of others . . .” Human intervention has been cited as a favorable factor to meet the patentable subject matter determination. As another example, the Federal Circuit has stated the biological modifications that occur as the result of interactions with environmental factors exist “quite independently of any effort of the patentee” and therefore were considered unpatentable works of nature. At some level, this finding is indicative of the line drawing that courts routinely perform to separate the patentable from the unpatentable. At another, the legal test places an individual as the key player in the inventive drama.

Since the time that the patent system was formed, other conceptions of invention have emerged which demonstrate that sociocultural influences are important to scientific advancement. One theory holds that scientific creativity is part of a “disorderly, unpredictable, and chaotic” process where ideas are generated from the raw material of information, and then sifted through a process of testing until success is achieved. In other words, the most fruitful creative processes consider the inappropriate and the impossible within this chaos, and thereby achieve “breakouts from the limits of available wisdom.”

254. Brand v. Miller, 487 F.3d 862, 869 n.4 (Fed. Cir. 2007).
259. DEAN KEITH SIMONTON, CREATIVITY IN SCIENCE 8 (2004); Dean Keith Simonton, Creativity As Blind Variation and Selective Retention: Is the Creative Process Darwinian?, 10 PSYCHOL. INQUIRY 309, 313 (1999); see also Mark A. Lemley, The Myth of the Sole Inventor, 110 MICH. L. REV. 709, 735 (2012).
260. Donald T. Campbell, Blind Variation and Selective Retention in Creative Thought As in Other Knowledge Processes, 67 PSYCHOL. REV. 380, 380 (1960) (internal quotation marks omitted).
some of these possibilities are selected to survive while others are rejected and die out. Mark Lemley has concluded that many inventions are likely to have been created slightly later in time regardless of the creative genius of any particular individual, and “[t]he few cases that don’t involve simultaneous work are mostly the result not of deliberate invention but of accident.”

Sources uniformly confirm that one of the vital inputs into any creative endeavor—including invention—requires knowledge as a critical input. Without exception, all invention derives from pre-existing information. The ability to create anything, including new inventions, depends on the capacity to access knowledge as a raw material. To some degree, the Court’s use of pre-emption as the touchstone of the subject matter exclusion implicitly recognizes this circumstance. Nonetheless, the Bilski/Mayo/Alice test is not well tailored to effectuate this purpose. Rather, the test rewards a claim with “something more” which does not weigh the preemptive potential within the larger context of follow-on invention in the field. A patent system that is intended to foster scientific creativity should place greater emphasis on whether the type of information that is the subject of the claim interferes with cumulative invention because it ties up an essential building block. Further, such an inquiry might consider the next two factors that are discussed in this piece—that is, the type of financial infrastructure needed to support the research in question and the potential social benefits of patentability.

B. Scientific and Technical Infrastructure

Currently, patent jurisprudence maintains a deliberate distance from discussions of funding research and development in determining patentability. The time and expense involved in

---

261. See Schot, supra note 220, at 38.
262. Lemley, supra note 259, at 735.
263. See id. at 713 (defining invention as an incremental step in an ongoing process).
264. Id. at 715.
265. As the Court explains, “monopolization of those tools through the grant of a patent might tend to impede innovation more than it would tend to promote it’, thereby thwarting the primary object of the patent laws.” Alice, 134 S. Ct. at 2354 (quoting Ass’n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2116 (2013)); see also Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1294 (2012) (“[U]pholding the patents would risk disproportionately tying up the use of the underlying natural laws, inhibiting their use in the making of further discoveries.”).
266. See Frischmann & McKenna, supra note 220, at 128; See Schot, supra note 220, at 40.
267. [placeholder]
268. See generally Laakmann, supra note 53 (discussing the factors that courts
creating an invention is assumed to be irrelevant. Rather, the law considers that the patent system’s ability to secure economic rewards for invention through innovation is not assured. In theory, a successful invention can be used to foster investment in research and development. Through operation of the patent system, the rewards from the subsequent commercialization of a patented invention are preserved to the rights holder, preventing the dissipation of profits that would otherwise occur if copyists were permitted to compete with the inventor.

Theory differs from reality. There is no assurance that those who invest heavily in research and development and obtain a treasure-trove of patents will flourish or act in a manner consistent with the public interest. Some assert that companies will continue to invent regardless of the existence of patents to preserve their competitive positions. Examples, including prominent innovators Cisco and Microsoft, demonstrate that some companies continue to innovate successfully for years with only minimal patent protection. It is evident that the ability to create economic success, create jobs, repay funders and shareholders, and continue a cycle of invention and innovation is a part of a large and complicated picture.

Certain conditions foster technical advance. Some of these include foundational scientific knowledge, the development and availability of adequate tools, sufficient antecedent information, conventions that permit interactions with others that allow the flow of knowledge, cultural influences and trends, and financial support. Scientists, engineers, and other types of inventors operate within this circumstantial framework. One important

consider in patentability decisions, and noting that policy is rarely considered).

274. See Edwin G. Boring, The Dual Role of the Zeitgeist in Scientific Creativity in THE VALIDATION OF SCIENTIFIC THEORIES 204–06 (Philipp G. Frank ed. 1956) (describing how scientific thinking is affected by the total sum of social interaction as is common to a particular period and particular locale and noting that “[o]ne can say it is thought being affected by culture”).
piece of that framework is the infrastructure that supports research and development. For some types of invention, that infrastructure is resource-intensive and requires significant funding support. The question of whether the patent system should consider funding in the patentability determination has never been incorporated into its substantive standards. This is true, despite the fact that it is widely recognized that some types of inventions require higher levels of infrastructure funding compared to others. This statement from innovator Novartis is emblematic of the manner that the pharmaceutical and health care industries rely on the patent system. According to the company, because innovation “requires substantial investment, . . . [r]emoving these incentives for any type of innovation makes it much more difficult, and in many cases impossible, to continue to invest in that research direction—which is why so much is indeed at stake in defining the bounds of what is, and what is not, patent-eligible.”

This question is independent from the level of predictability within an art, which is a central consideration of the nonobviousness doctrine. Despite this circumstance, the patentability determination’s connection with the considerable financial investment needed to accomplish certain types of inventions is absent from the legal analysis.

This analysis must be performed on a more refined basis than on an industry specific basis. In that sense, this consideration can account for patenting problems that manifest in the pharmaceutical industry, including the problem of evergreening, can become part of the patentability consideration.

Systems Perspective for the Study of Creativity, in HANDBOOK OF CREATIVITY 313 (Robert J. Sternberg ed., 1999) (“[I]t has become increasingly clear that variables external to the individual must be taken into account if one wishes to explain why, when, and where new ideas or products arise from and become established . . . .”).


See generally id. at 3.

See generally Laakmann, supra note 53.


Email from Corey Salsberg, supra note 48.


In addition, this factor can become part of an integrated analysis that considers creativity as well as the social benefit of the invention.

C. The Impact of the Patent System on Competition

At various points in time over the past centuries, courts have subjected the patent system through cycles of favor, followed by disfavor. Generally, these trends have affected patents as a class, primarily reasoning that patents were contrary to the principles that support anti-competition laws. For example, the 1883 decision *Atlantic Works v. Brady* typifies the Court’s anti-monopoly sentiment with respect to patent protection:

Such an indiscriminate creation of exclusive privileges tends rather to obstruct than to stimulate invention. It creates a class of speculative schemers who make it their business to watch the advancing wave of improvement, and gather its foam in the form of patented monopolies, which enable them to lay a heavy tax upon the industry of the country, without contributing anything to the real advancement of the arts.

After a brief period of pro-patent decisions, another anti-patent trend began around 1935. According to one source, in part this was attributable to concerns about perceived abuses of the patent system and concerns about monopoly power. The 1952 Patent Act legislatively sought to restore balance. When the Federal Circuit was established in 1982, another pro-patent era began to gain strength. *Bilski, Alice and Myriad* may herald a pendulum swing back to an anti-patent era.

There are circumstances that may warrant tipping the balance in favor of patent protection for certain types of development, and others that favor competition. As one example,

---

287. *Id.* at 775; C. H. Boehringer Sohn v. Watson, 256 F.2d 713, 714 (D.C. Cir.1958) (Burger, J., concurring) (observing the then-current trend that was “the inhospitable attitude toward patents, stemming in part from our natural aversion to monopolies”).
289. See, e.g., AT&T Corp. v. Excel Commc’ns, Inc., 172 F.3d 1352, 1361 (Fed. Cir. 1999); Al-Site Corp. v. VSI Int’l, Inc., 174 F.3d 1308, 1332 (Fed. Cir. 1999); State St. Bank & Trust Co. v. Signature Fin. Grp., Inc., 149 F.3d 1368, 1377 (Fed. Cir. 1998); *In re Deuel*, 51 F.3d 1552, 1560 (Fed. Cir. 1995).
curbing patent protection for particular types of inventions might be expected to increase price competition. If so, existing solutions will become more readily available to those with few financial resources. Under these circumstances, small firms may be formed to capture the spillovers created by larger, research-intensive organizations. These entrants might be expected to exploit avenues of research that the knowledge-originating firm has not yet brought to market. Further, decreasing patent protection might encourage the development of improvements and follow-on research by others who wish to create variations of existing solutions. However, for areas where patents are important to investment decisions, weakening patent protection may decrease available financial resources and lessen research and development in those fields.

These circumstances suggest that indiscriminate weakening or strengthening of patents in all sectors misses opportunities to fine tune preferences. Moreover, economists have begun to identify that the relation between competition, research and development, and innovation is complex. Fritz Machlup’s statement, “no firm could hope to maintain its position in the industry if it did not constantly strive to keep ahead of its competitors by developing and using new technologies” is overly broad to stand as a truism in isolation. Indeed, one source theorizes that competition does not drive increased research and development, but rather does so primarily when rivalry is comparatively flat and firms are competing “neck and neck.”

Increased research and development depends on additional

290. Hubbard, supra note 279, at 1929.
291. Id. at 1929–30.
296. SUBCOMM. ON PATENTS, TRADEMARKS, AND COPYRIGHTS OF THE S. COMM. ON THE JUDICIARY, 85TH CONG. AN ECONOMIC REVIEW OF THE PATENT SYSTEM 78 (Comm. Print 1958) ; see also William J. Baumol, The Free-Market Innovation Machine: Analyzing the Growth Miracle of Capitalism 50 (2002) (“It is competitive pressures that force firms to run as fast as they can in the innovation race just to keep up with the others.”).
297. See Aghion, supra note 295, at 3.
factors that include the ability to rely on spillover information, firm size, the availability of human and financial capital, and a host of other variables.\textsuperscript{298}

Patent law’s incentive structure was established during the era when the closed model of innovation was prevalent.\textsuperscript{299} Under this framework, individual firms commercialize products based on their own research and development.\textsuperscript{300} More recently, numerous firms have been creating value through more open innovation methods.\textsuperscript{301} There may be instances that do not require patents to incentivize and support research for new creations, and indeed some types of systems may be impeded by stringent protection.\textsuperscript{302} If so, the patentable subject matter inquiry can carve out such areas from protection. By allowing a confluence of factors to guide the patentability inquiry, patent protection can be more finely tuned to increase new knowledge creation in the aggregate.

D. Social Benefit

Just as the European Patent Directive favors patentability for gene fragments to foster the development of that industry for public health and environmental reasons, the patentable subject matter doctrine could be used in the U.S. to allow (or discourage) patenting in particular subject matters based on the social desirability of the solution involved.\textsuperscript{303} To some degree, the social benefit of the invention can be integrated with the other two factors—that is, a balance of creativity, infrastructure, and the social consideration can become touchstones of the ultimate patentable subject matter inquiry.


\textsuperscript{300} See \textit{Jennifer Brant & Sebastian Lohse, ICC Innovation & Intell. Prop. Series, The Open Innovation Model} (2014) (describing that closed innovation “entails the complete integration of research and development (R&D) within the boundaries of a firm”).


\textsuperscript{302} Landers, \textit{supra} note 273, at 970.

\textsuperscript{303} See text accompanying footnote 181.
There may be instances in which certain patentable subject matters become part of a social exigency. For example, claims to inventions relating to the mitigation of climate change impacts, alternative energy, and potential solutions to the problem should be carefully weighed to determine whether patents in those areas might meet social goals. Further, some assert that the patent system can be used to achieve social justice concerns, including making vital medicines available at low cost. As one example, economist Joseph Stiglitz argues that “our intellectual property regime . . . contributes needlessly to the gravest form of inequality. The right to life should not be contingent on the ability to pay.” To date, decision makers have not engaged in this discussion.

Decision-makers must confront with these difficult questions, keeping in mind the need for appropriate incentives to engage in research and development into new solutions. Some representing pharmaceutical makers have expressed concern that the current standards do not encompass certain products derived from nature that include antibiotics and certain types of vaccines that are structurally similar to substances that exist in the body. For example, it has been reported that certain types of bacteria are becoming resistant to antibiotics, while larger drug companies are cutting back on the development of new antibiotics. A cutback in research has been attributed to lower returns on investment for antibiotics. According to one antibiotic research company, a broad reading of the Supreme Court’s Myriad case would be entirely unable to protect the $1 billion investment made. Although as a legal matter decision makers might conclude that, despite such evidence, antibiotics should not be protectable under the patent laws, that should be the result of a conscious decision to do so, based on a

304. [placeholder]
306. Id.
307. [placeholder]
310. Id.
consideration of the research infrastructure and impact on social and health care policy. Decisions based on patentable subject matter can provide guidance to industry as the appropriateness of investment, and the likelihood that exclusivity will be forthcoming so long as the remaining requirements of the right are met.

VI. IMPLEMENTATION: A CONFLUENCE OF CONSIDERATIONS

This piece proposes using the patentable subject matter requirement as a means to align protection decisions with the purpose and consequences of the patent system. Other governments have considered patent law as part of a larger picture that includes economic and social goals.\textsuperscript{312} Rather than using patentable subject matter as a way to carry forward past precedent, formed during very different economic and social circumstances, the requirement must be re-cast as a dynamic means to effectuate large-scale policy decisions. By considering creative, economic, and social factors in making the patentability determination, decision makers can endeavor to use the patent system as a more effective means to achieve its policy ends.

Certainly, there are numerous problems of process and implementation. There may be, as Justice Breyer recognized, competency concerns.\textsuperscript{313} The difficulty in making informed decisions, including the consideration of public input, cannot be underestimated. There are legitimate concerns about the extent to which government intervention into innovation should extend.\textsuperscript{314} One important question is whether these concerns overwhelm any of this proposal’s efficacies. At present, the courts are making patentable subject matter determinations without expressly considering some of the system’s core concerns.\textsuperscript{315} The consequences of these decisions are occurring and will continue. Although perfection cannot be expected, the goals of transparency and more meaningful guidance can be implemented for the betterment of the system.

Patentable subject matter is the optimal vehicle for consideration of these questions. Unlike patent doctrines that

\begin{footnotesize}
\textsuperscript{312}. [placeholder]
\textsuperscript{315}. As with footnote 151 and 282, we have an absence of authority because the courts are not discussing this.
\end{footnotesize}
focus on the novelty or usefulness of claims, patentable subject matter accommodates policy considerations.\textsuperscript{316} The purpose of the doctrine addresses whether categories of inventions are appropriate for patent protection.\textsuperscript{317} As discussed earlier, the British insight that, “whoever controls the meaning of ‘invention’ controls what can be patented and hence an important aspect of industrial policy,” can be utilized in the U.S. system in an analogous manner.\textsuperscript{318} As other systems have relied on patentable subject matter to facilitate policy, this portion of the patentability requirements can be used for meaningful consideration of the patent system’s goals.\textsuperscript{319}

Implementing this solution within patentable subject matter presents the optimal opportunity for certainty. As courts begin to shift toward consideration of the important underlying policies, it can be expected that a doctrine that operates at a categorical level will allow inventions that implicate similar policies to be treated in the same manner. Thus, those with similar claims can use precedent to some degree to guide decision-making. Because these considerations are multi-factorial, the categorization of particular types of claims may not break down across industry lines.\textsuperscript{320} As one example, it is conceivable that foundational claims to particular types of software might be viewed similarly to those that involve complex molecules.\textsuperscript{321} Depending on the specific claims, both might have a similar potential to impede future scientific creativity, or to become catalysts to the anti-commons problem.

Integrating policy into patentable subject matter is preferable to doing so within the application of the nonobviousness doctrine, which considers claims on a singular basis.\textsuperscript{322} Moreover, the nonobviousness requirement is currently used to accomplish a multiplicity of goals, including ensuring that economically trivial patents are not granted, preventing

320. [placeholder]
321. [placeholder]
322. [placeholder]}
privatization of exogenous technological development, and limiting the scope of rights that an individual inventor can obtain.\textsuperscript{323} Placing more weight on this requirement by increasing its complexity threatens to entirely overwhelm it.\textsuperscript{324}

This proposed infusion of meaningful policy considerations does not contemplate replacing the existing exclusions of patentable subject matter as such. As this Article demonstrates, the existing limitations act as legal conclusions rather than immutable truths.\textsuperscript{325} Rather, these policy considerations should be used to guide the application of the existing exclusions. In other words, decision-makers should refrain from the recitation of precedent unguided by the consequences of their decisions. To implement the full potential of the patent system, the policies should be expressly integrated into this substantive requirement.

\section*{VII. Conclusion}

The open-ended framework of section 101 of the Patent Act permits judicial interpretation to effectuate its purpose on a large scale.\textsuperscript{326} Indeed, some international patent systems suggest that this direction is fully implementable.\textsuperscript{327} Of the patentability requirements, patentable subject matter is perhaps best suited to address large-scale policy concerns. This requirement serves a gatekeeping function—that is, as “a means of excluding certain types of inventions entirely from the scope of patent protection.”\textsuperscript{328} This reading allows decision makers to broadly define the types of information that warrant patent protection, and those that do not. Ideally, these determinations should rest on articulated, transparent reasoning so that, under a common law system, those policies can serve as touchstones to ensure that the relevant precedents are implementable.

\begin{footnotes}
\item[325] [placeholder]
\item[326] Peter S. Menell, \textit{The Mixed Heritage of Federal Intellectual Property Law and Ramifications for Statutory Interpretation} in \textit{INTELLECTUAL PROPERTY AND THE COMMON LAW} 63, 78 (Shyamkrishna Balganesh ed., 2011) (arguing that Congress did not crystalize the meanings of portions of the intellectual property statutes, including section 101 of the Patent Act, but “rather envisioned that courts would continue to evolve aspects of these doctrines”).
\item[327] See text accompanying footnotes 133-34; 181-182.
\item[328] Lemley, \textit{supra} note 242, at 1326.
\end{footnotes}