Aug. 5, 2014 — This essay is being prepared for the Meaning of Myriad Symposium at UC Irvine, and it remains a work in progress. Please contact ouellette@law.stanford.edu with suggestions or for the latest version.

Patentable Subject Matter and Non-Patent Innovation Incentives

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In four patentable subject matter cases in the past five Terms, the Supreme Court has repeatedly reaffirmed the judicially created prohibitions on patenting "abstract ideas" or "nature." But since the Court has failed to give much guidance beyond its specific holdings, the boundaries of these exceptions remain highly contested. The dominant justification for patentable subject matter limitations is utilitarian, so debates often focus on whether patents are needed to provide adequate innovation incentives in disputed subject matter areas such as software or genetic research, and whether their costs outweigh these benefits. Yet many participants in these debates ignore the fact that the absence of patents does not imply that there would be only private incentives such as reputational gains or first-mover advantage. Rather, federal and state governments facilitate transfers to researchers through a host of mechanisms—including tax incentives, direct grants and contracts, prizes, and regulatory exclusivity—which already provide substantial research support in the fields where patents are the most controversial.

Paying attention to non-patent incentives is particularly important in patentable subject matter cases, as it could prevent courts from being misled by the concern that a lack of patents for a certain type of invention would remove all incentives for nonobvious and valuable research in that field. Non-patent innovation incentives could also help ease the tension between utilitarian and moral considerations in the current patentable subject matter debates: if many people find patents on certain inventions (such as "human genes") morally objectionable, utilitarian goals can still be served by using other transfer mechanisms to substitute for the incentive provided by patents. Indeed, non-patent incentives may be more effective than patents in contested areas, where inventors who share moral objections find little incentive in patents, and those who don't still find the patent incentive to be dulled by the persistent uncertainty that has plagued patentable subject matter doctrine in recent years. Wider appreciation of the range of innovation incentives would help bring patentable subject matter discussions in line with the realities of scientific research, and might even make this doctrinal morass more tractable.

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Introduction

Over the past five Terms, the Supreme Court has struggled to place coherent limits on what kinds of inventions can be rewarded through the patent system.¹ This effort to elaborate the judicially created prohibitions on patenting "abstract ideas" or "nature"² has been influenced by the Court's concern that without patents for certain inventions, there would be no incentive for companies to invest in those fields. For example, at the oral argument in *AMP v. Myriad*, Justice Scalia asked: "Why would a company incur massive investment ... if it cannot patent?"³ In *Mayo v. Prometheus*, Justice Breyer worried that "discovering natural laws is often a very expensive process" with "lots of investment to be protected."⁴ And in *Bilski v. Kappos*, Justice Sotomayor expressed concern that she had "no idea what the limits of" a broad ruling that "patent law doesn't cover business methods" would be "in the computer world or the biomedical world," and she noted that "[a]ll of the amici were talking about how it will destroy industries."⁵

The Court ultimately held that most of the patent claims at issue were not directed to patentable subject matter in all four of its recent cases—but in so doing, it has seemed comfortable with the idea that no incentive was needed for those particular inventions. For example, Justice Kennedy thought the invention in *Alice v. CLS Bank* would be "fairly easy to program" for someone in "a second-year college class in engineering,"⁶ and those favoring invalidation argued that many "successful software companies ... grew strong without incentives from patents."⁷ Similarly, the plaintiffs seeking invalidation in *Myriad* argued that "[p]atent protection at the level of the gene ... is simply unnecessary to spur innovation in diagnostics,"⁸ and the Justices seemed reassured by the continuing availability of patents on other aspects of genetic research.⁹ But in all four cases, the Court was hesitant to reach any further than necessary; rather than establishing clear rules to guide future investment decisions, it explicitly reserved questions for future cases,¹⁰ leaving the boundaries of patentable subject matter far from settled.

¹ See Alice Corp. Pty. Ltd. v. CLS Bank Int'l, 134 S. Ct. 2347 (2014); Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107 (2013)); Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289 (2012); Bilski v. Kappos, 130 S. Ct. 3218 (2010).

² I use "nature" as a shorthand for the Court's unpatentable categories of "laws of nature," "natural phenomena," and "products of nature." *See Myriad*, 133 S. Ct. at 2116.

³ Transcript of Oral Argument at 12, Myriad, 133 S. Ct. 2107 (No. 12-398).

⁴ Transcript of Oral Argument at 17, Mayo, 132 S. Ct. 1289 (No. 10-1150).

⁵ Transcript of Oral Argument at 29, *Bilski*, 130 S. Ct. 3218 (No. 08-964).

⁶ Transcript of Oral Argument at 5, Alice, 134 S. Ct. -- (No. 13-298).

⁷ Br. of Amicus Curiae Red Hat, Inc., in Support of Resp'ts, Alice, 2014 WL 931833, at *17.

⁸ Reply Br. for Pet'rs, Myriad, 2013 WL 1850746, at *21-22.

⁹ Transcript of Oral Argument at 13-16, Myriad, 133 S. Ct. 2107.

¹⁰ See Alice, 134 S. Ct. at 2357 ("[W]e need not labor to delimit the precise contours of the 'abstract ideas' category in this case."); *Myriad*, 133 S. Ct. at 2120 ("[W]e express no opinion about the application of § 101 [to altered DNA]."); *Mayo*, 132 S. Ct. at 1302 ("We need not, and do not,

The Court's cautiousness may stem from the starkness of the choice it has been offered: either there are patents, or innovators must rely solely on private incentives such as reputational gains or first-mover advantage.¹¹ This choice is reflected not only in the briefing before the Court, but also in the burgeoning literature on "IP without IP" (intellectual production without intellectual property), which has focused primarily on informal norms and market incentives that promote innovation in the absence of IP.¹²

The Justices are right to be concerned about eliminating statesupported financial incentives for innovation. There is often a gap between an invention's public benefit and the private benefit that can be appropriated by the inventor, and so many welfare-enhancing R&D projects will not be pursued absent state action.¹³ But as I have explained in earlier work with Daniel Hemel, patents are only one of numerous ways that the government facilitates transfers to innovators.¹⁴ U.S. federal and state governments also offer billions of dollars of support each year through direct grants and contracts, innovation prizes, regulatory exclusivity, and R&D tax incentives and no one of these mechanisms is strictly superior to the others.¹⁵

This Essay examines the range of incentives that the U.S. federal and state governments already provide in two of the most contested areas of patentable subject matter: (1) biomedical innovations at the molecular level that might fall under the "nature" exception to patentability, including the types of inventions at issue in *Mayo* and *Myriad*; and (2) computer-implemented inventions that might be "abstract ideas," which are impacted by the decisions in *Bilski* and *Alice*. For each field, I examine the full array of state-provided incentives, analyze which incentives are likely to be most effective, and discuss where additional incentives might be needed in light of the Supreme Court's recent curtailment of patententable subject matter.

Greater recognition of the array of non-patent innovation incentives in these fields could have significant payoffs for patentable subject matter

now decide whether were the steps at issue here less conventional [they would still be unpatentable]."); *Bilski*, 130 S. Ct. at 3231 ("The Court ... need not define further what constitutes a patentable 'process'....").

¹¹ See infra notes 28-38 and accompanying text.

¹² See, e.g., KAL RAUSTIALA & CHRISTOPHER SPRIGMAN, THE KNOCKOFF ECONOMY: HOW IMITATION SPARKS INNOVATION (2012); Rochelle Cooper Dreyfuss, *Does IP Need IP?* Accommodating Intellectual Production Outside the Intellectual Property Paradigm, 31 CARDOZO L. REV. 1437 (2010).

¹³ The need for government intervention is often attributed to information's similarity to a public good, and the related low marginal cost of production. For a recent synthesis of the literature on the properties of information that questions the universality of these properties, see Tim Wu, *Properties of Information & the Legal Implications of Same* (Columbia Law Sch. Working Paper No. 482, 2014), *available at* http://ssrn.com/abstract=2446577.

¹⁴ Daniel J. Hemel & Lisa Larrimore Ouellette, *Beyond the Patents–Prizes Debate*, 92 TEX. L. REV. 303 (2013).

¹⁵ *Id.* at 309, 316-25. For our taxonomical purposes in *Beyond the Patents–Debate*, we lumped regulatory exclusivity and patents together as ex post, market set, user pays mechanisms. *Id.* at 319 n.65, 379. But when focusing on the scope of patentable subject matter, it is important to tease these separate reward mechanisms apart.

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debates. Most importantly, it could prevent courts from being misled by the concern that a lack of patents for a certain type of invention would remove all incentives for nonobvious and valuable research in that field. It could also ease the tension between utilitarian and moral considerations in the current patentable subject matter debates. If many people find patents on certain inventions (such as "human genes") morally objectionable,¹⁶ utilitarian goals can still be served by using other transfer mechanisms to substitute for the incentive provided by patents. Indeed, non-patent incentives may be more effective than patents in contested areas, where inventors who share moral objections find little incentive in patents, and those who don't still find the patent incentive to be dulled by the persistent uncertainty that has plagued patentable subject matter doctrine in recent years.

While non-patent incentives may be relevant to patent policy in general, they are particularly significant in the patentable subject matter context. Doctrines such as novelty and nonobviousness have a clearer theoretical grounding: they exist to bar patents (and their associated costs) where the patent incentive is not needed for innovation to occur. Similarly, the disclosure requirements help limit the patent reward to the inventor's actual technical contribution. But the judicially created patentable subject matter exceptions can limit patents even where there is valuable, nonobvious innovation to be done—and where there is thus a clear need for effective non-patent incentives.

This Essay proceeds in three Parts. First, Part I illustrates the patentfocused internalism of the current patentable subject matter debates, in which the state's role in offering financial incentives is typically presented as "patents or nothing." Part II then discusses non-patent financial incentives offered by the government in particular contested areas. Finally, Part III describes the payoffs for patentable subject matter disputes from adopting an external perspective on innovation law.¹⁷

I. Patent Internalism in Patentable Subject Matter Debates

Although Section 101 of the Patent Act broadly defines patentable subject matter as "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof,"¹⁸ the Supreme Court has held repeatedly that "this provision contains an

¹⁶ See generally Tun-Jen Chiang, Competing Visions of Patentable Subject Matter, 82 GEO. WASH. L. REV. (forthcoming 2014) (contending that patentable subject matter "is often about non-economic moral values"), available at http://ssrn.com/abstract=2469415.

¹⁷ I borrow the internal-vs.-external framing from Amy Kapczynski, who has called on IP scholars to adopt an external approach to the innovation policy choice, Amy Kapczynski, *The Cost of Price: Why and How to Get Beyond Intellectual Property Internalism*, 59 UCLA L. REV. 970 (2012), although she has not argued that this perspective might also be valuable for approaching questions internal to IP law.

^{18 35} U.S.C. § 101.

important implicit exception."¹⁹ This judicial carve-out from patentable subject matter includes "abstract ideas," such as the computer-based method of using an intermediary to reduce settlement risk at issue in Alice,²⁰ or the method of hedging risk in the energy market at issue in Bilski.²¹ The implicit exception also includes "nature," such as the isolated genomic DNA sequences (but not cDNA sequences) in *Myriad*,²² and the method of calibrating drug dosage using a natural correlation in *Mayo*.²³ But in each of these four recent cases, the Court explicitly declined to provide much guidance beyond its specific holding,²⁴ leaving the boundaries of patentable subject matter far from settled.

As the Supreme Court has repeatedly explained in recent cases, its current justification for this exception is utilitarian:

[T]he concern that drives this exclusionary principle [is] one of pre-emption. Laws of nature, natural phenomena, and abstract ideas are the basic tools of scientific and technological work. [M]onopolization 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.²⁵

Commentators generally concur that patentable subject matter doctrine is (or should be) based on the utilitarian question of whether patents on certain kinds of inventions provide a net benefit to society.²⁶ In other words, under

- ²² Myriad, 133 S. Ct. at 2116-19.
- ²³ Mayo, 132 S. Ct. at 1305.
- ²⁴ See supra note 10.

²⁵ Alice, 134 S. Ct. at 2354 (citations omitted) (internal quotation marks omitted). The Court has not always focused so explicitly on this economic cost-benefit analysis; in earlier cases, the justification seems more deontological. *See, e.g.*, Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948) ("The qualities of these bacteria, like the heat of the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge of all men. They are manifestations of laws of nature, free to all men and reserved exclusively to none.").

²⁶ See, e.g., John F. Duffy, Rules and Standards on the Forefront of Patentability, 51 WM. & MARY L. REV. 609, 618 (2009) ("[T]he patentable subject matter doctrines are based not on a moral or ethical decision about the desirability of patents as an end in themselves, but on empirical estimation of the usefulness of patents in achieving other ends (progress)."); Mark A. Lemley et. al., Life After Bilski, 63 STAN. L. REV. 1315, 1317, 1329 (2011) (arguing that the subject matter exceptions are "best understood as an effort to prevent inventors from claiming their ideas too broadly"); Arti K. Rai, Diagnostic Patents at the Supreme Court, 18 MARQ, INTELL. PROP. L. REV. 1, 2 (2014) (agreeing with the "conventional frame" that "interpretation of patentable subject matter ... should be guided by innovation goals"). But see Chiang, supra note 16 (arguing that this "surface consensus" of utilitarianism masks underlying moral concerns); Adam Mossoff, Why History Matters in the Patentable Subject Matter Debate, 64 FLA. L. REV. F. 23, 25-26 (2012) (arguing that historically "courts treated patents liberally and expansively" because patents were seen "as

¹⁹ Alice, 134 S. Ct. at 2354 (quoting *Myriad*, 133 S. Ct. at 2116). This Essay takes these exceptions as a given, but it is worth noting that there are plausible arguments against any non-statutory carve-outs. *See, e.g.*, CLS Bank Int'l v. Alice Corp. Pty. Ltd., 717 F.3d 1269, 1333-35 (Fed. Cir. 2013) (Rader, C.J., additional reflections); Michael Risch, *Everything Is Patentable*, 75 TENN. L. REV. 591 (2008).

²⁰ Alice, 134 S. Ct. at 2356.

²¹ Bilski, 130 S. Ct. at 3231.

to help define the

this approach, economic efficiency can be used to help define the vague categories of "nature" and "abstract ideas." Patentable subject matter debates have thus focused on this empirical question, even though the lack of clear empirical data leads to "the instability of rules in the area."²⁷

Thus, the arguments in *Myriad* focused heavily on the economic effect of including gene patents within the "nature" exception to patentability. Those in favor of upholding the claims at issue argued that without patents, there would be no financial incentive to do the kind of research that had led to the patents at issue, without acknowledging even the non-patent incentives that already provide significant transfers to innovators.²⁸ Those in favor of invalidating the claims countered that these worries were unfounded because "the majority of geneticists are willing to undertake the research to discover genes and develop genetic tests without the possibility of a patent."²⁹ But the briefs contained little discussion of what was incentivizing those geneticists, if not patents. In other words, the innovation policy choice was presented to the Court from the internal perspective of patents vs. no patents, without analysis of the many non-patent mechanisms through which the state facilitates transfers to genetic researchers.³⁰

²⁹ Br. of Amici Curiae Am. Med. Ass'n et al. in Support of Pet'rs, *Myriad*, 2013 WL 390998, at *16; *see also* Reply Br. for Pet'rs, *Myriad*, 2013 WL 1850746, at *21-22 ("To the extent Myriad or its amici are arguing that the patents in this case were necessary to create an incentive to search for ... or to commercialize a test for the genes, the record is clear that they were not. Other scientists, including those who did not want patent exclusivity, were looking equally vigorously for the genes ... Patent protection at the level of the gene (versus on actual tests, recombinant DNA, etc.) is simply unnecessary to spur innovation in diagnostics.").

³⁰ The exception is an amicus brief from Knowledge Ecology International ("KEI"), which noted the "growing proliferation of alternative, non-patent mechanisms used to stimulate research and development," although its discussion focused on patent-like market exclusivity mechanisms and proposed prize systems. Br. of Amicus Curiae Knowledge Ecology Int'l in Support of Pet'rs, *Myriad*, 2013 WL 476050, at *10. KEI also filed a similar brief in *Bilski*. Br. of Amicus Curiae Knowledge Ecology Int'l in Support of Resp't, *Bilski*, 2009 WL 3199633, at *8-15.

fundamental civil rights securing property rights in inventions"); Sapna Kumar, *Life, Liberty, and the Pursuit of Genetic Information*, 65 ALA. L. REV. 625 (2014) (arguing that patents on bodily information such as genetic mutations can violate individual liberty interests).

²⁷ Duffy, *supra* note 26, at 618.

²⁸ See, e.g., Br. of Amici Curiae Animal Health Inst. & Merial Ltd. in Support of Resp'ts, *Myriad*, 2013 WL 1098263, at *5 ("If the statutory incentives for invention with regard to created genetic molecules are eradicated, innovation in that field will cease or, at the very least, be substantially diminished."); Br. of the Coalition for 21st Century Med. as Amicus Curiae in Support of Resp'ts, *Myriad*, 2013 WL 1098259, at *12 ("Gene Patents Are Necessary To Ensure Financial Incentives To Undertake Research and Development In Emerging Fields."); Br. for Amici Curiae Genentech, Inc. et al. in Support of Resp'ts, *Myriad*, 2013 WL 1098262, at *3 ("The development of both diagnostic and therapeutic applications of recombinant DNA technologies is capital intensive and time consuming. Success in these fields could not be achieved without the protections and incentives provided by the patent system."); Br. of MPEG LA, LLC as Amicus Curiae in Support of Resp'ts, *Myriad*, 2013 WL 1099167, at *7 ("[D]enial of patent protection ..., would provide an insufficient incentive for invention."); Br. for the Pharm. Research & Mfrs. of Am. as Amicus Curiae Supporting Resp'ts, *Myriad*, 2013 WL 1122811, at *19 ("Without Strong Patent Protection, Innovation in the Area of Biotechnology Will Decline.").

This debate clearly influenced the Court. At oral argument, Justices Kagan, Scalia, Kennedy, and Sotomayor worried that if genes could not be patented, there would no longer be incentives for companies like Myriad:

JUSTICE KAGAN: Mr. Hansen, could you tell me what you think the incentives are for a company to do what Myriad did? Why shouldn't we worry that Myriad or companies like it will just say, ... we're not going to do this work anymore?

MR. HANSEN: [I]n this particular case, ... [w]e know that there were other labs looking for the BRCA genes and they had announced that they would not patent ... [and] prior to the patent actually being issued, there were other labs doing BRCA testing

JUSTICE SCALIA: But you still haven't answered her question. Why? Why would a company incur massive investment . . . if it cannot patent?

MR. HANSEN: Well, taxpayers paid for much of the investment in Myriad's work, but—

JUSTICE SCALIA: You're still not answering the question.

MR. HANSEN: I think scientists look for things for a whole variety of reasons, sometimes because they're curious about the world as a whole, sometimes because—

JUSTICE SCALIA: Curiosity is your answer.

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MR. HANSEN: Sometimes because they want a Nobel Prize.

JUSTICE KAGAN: I hoped you were going to say something else, which is that, notwithstanding that you can't get a patent on this gene, ... there are still ... things that you could get a patent on that would make this kind of investment worthwhile [But] I want to know what those things are rather than you're just saying, you know, we're supposed to leave it to scientists who want Nobel Prizes....

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JUSTICE KENNEDY: [T]here are substantial arguments in the amicus brief that this investment is necessary ... and that makes sense. To say, oh, well, the taxpayers will do it, don't worry, is, I think, an insufficient answer. As Justice Kagan's follow-up questions indicated, I thought you might say, well, there are process patents that they can have

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MR. HANSEN: [I]t is certainly true, as Your Honor suggests, that one of the incentives here is a process patent

JUSTICE SOTOMAYOR: That's the whole point, isn't it? The isolation itself is not valuable, it's the use you put the isolation to....

MR. HANSEN: That's exactly correct. Thank you.³¹

As this exchange indicates, even when the lawyer for the plaintiffs seeking invalidation attempted to mention some non-patent incentives, such as funding from taxpayers (through government grants) and reputational gains, the Justices were uninterested. The answer they were seeking was that even if they invalidated some of the claims at issue, other patent claims would still be available.

The arguments about the medical diagnostic claims at issue in *Mayo* were in many ways similar to those in *Myriad*. Those favoring a narrow "nature" exception argued that patents are "absolutely necessary" for new medical innovations,³² and that "patent protection today provides *the* incentive for . . . research and development of other diagnostic tests."³³ And those favoring a broader "nature" exception argued that researchers are instead motivated by "curiosity, career ambitions, and desire to advance understanding of health and disease," as well as "clinical need and demand,"³⁴ with little analysis of other state-provided financial incentives for this research.

This patent internalism is not limited to medical innovation cases. The parties opposing an expansive "abstract ideas" exception in *Alice* and *Bilski* argued that "[p]atents on computer-implemented inventions are crucial

³¹ Transcript of Oral Argument at 11-16, Myriad, 133 S. Ct. 2107 (No. 12-398).

³² Br. of Genomic Health, Inc. et al. as Amici Curiae in Support of Resp't, *Mayo*, 2011 WL 5439047, at *18.

³³ Br. for Amicus Curiae Novartis Corp. Supporting Resp't, *Mayo*, 2011 WL 5373697, at *21 (emphasis added); *see also* Br. of Amicus Curiae Am. Intellectual Prop. Law Ass'n in Support of Resp't, *Mayo*, 2011 WL 5373692, at *23 (arguing that patents are "necessary to ensure that the companies investing in medical research are adequately compensated"); Br. of Amicus Curiae Intellectual Prop. Owners Ass'n in Support of Resp't, *Mayo*, 2011 WL 5317315, at *11-12 ("Only if scientists, doctors, and investors can rely on broad access to patent protection will we continue to benefit from the incredible innovation in this field"); Br. for Myriad Genetics, Inc., as Amicus Curiae Supporting Resp't, *Mayo*, 2011 WL 5373694, at *4-5 ("Claims like those at issue in this case, therefore, are particularly important because they will be the only vehicle for introducing (and incentivizing) new and pathbreaking personalized medicine products for the public good."); Br. for Amici Curiae Roche Molecular Sys., Inc. et al. in Support of Neither Party, *Mayo*, 2011 WL 4071920, at *21 ("Absent patent protection, there would be little or no incentive[s] for diagnostics companies").

³⁴ Br. of Amici Curiae the Am. Coll. of Med. Genetics et al. in Support of Pet'rs, *Mayo*, 2011 WL 4071917, at *15; *see also* Br. for ARUP Labs., Inc. & Lab. Corp. of Am. (d/b/a/ LabCorp) as Amici Curiae in Support of Pet'rs, *Mayo*, 2011 WL 4071919, at *18 ("There is little danger that [invalidating the patents] will harm genetic or other biomedical research by reducing incentives for making discoveries."); Br. of Amici Curiae Cato Inst. et al. in Support of Pet'rs, *Mayo*, 2011 WL 4071914, at *23 ("[M]ost innovations would be developed even if patent protection were unavailable."); Br. for Pet'rs, *Mayo*, 2011 WL 3919717, at *50-51 & n.9 (arguing that "[t]he prospect of patent protection does not play a significant role in motivating scientists to conduct medical research" and that "[t]ime and first mover-advantage often provide greater or more predictable returns to innovation than patenting does").

to investment in innovation³⁵ and that "[i]nability to patent software innovation [would] cripple[] the ability of small- and mid-size entrepreneurial software businesses to compete.³⁶ And the parties favoring an expansive "abstract ideas" exception argued that many successful software companies "grew strong without incentives from patents. Instead, these successes arose from the dynamics of the competitive market place.³⁷ Most discussion of non-patent incentives focused on private incentives such as "[f]irst-mover advantages," "[n]etwork effects," "personal satisfaction," and "reputation,"³⁸ not the other forms of state support for software innovation or new business methods.³⁹

In sum, the arguments before the Supreme Court in recent patentable subject matter cases have tended to describe the innovation policy choice as patents versus purely private incentives. But as discussed in the following Part, the reality of government innovation policy is far richer.

II. Innovation Incentives Beyond Patents

Although patentable subject matter debates have tended to frame the choice of innovation laws as "patents or nothing," patent law is only one tool in the state's innovation policy toolkit. Of course, not all commentators have ignored the role of patents—the ongoing patents-versus-prizes debate dates back to at least the nineteenth century,⁴⁰ and there have been numerous

³⁵ Br. of Amicus Curiae IEEE-USA in Support of Neither Party, *Alice*, 2014 WL 411287, at *25; *see also* Br. of BSA | The Software Alliance as Amicus Curiae in Support of Resp't, *Alice*, 2014 WL 828032, at *8 ("[P]atent protection is a critical incentive to expenditures for software research and development").

³⁶ Br. of Amici Curiae Entrepreneurial Software Cos. in Support of Pet'r, *Bilski*, 2009 WL 2418474, at *9; *see also* Br. for the Business Software Alliance as Amicus Curiae in Support of Affirmance, *Bilski*, 2009 WL 2418485, at *2 ("If innovation is the engine of the American economy, then intellectual property is its fuel. From the time of the Founding, it has been understood that ... economic incentives must be provided to those who develop new inventions."); Br. of Amicus Curiae Eagle Forum Educ. & Legal Defense in Support of Pet'rs, *Bilski*, 2009 WL 2445760, at *13 ("Without the full and robust protections of patent law, ingenuity by the small inventor is diminished and the American economy suffers from a lack of incentives for valuable inventions.").

³⁷ Br. of Amicus Curiae Red Hat, Inc., in Support of Resp'ts, Alice, 2014 WL 931833, at *17.

³⁸ Br. of Amici Curiae Checkpoint Software, Inc. et al. in Support of Resp'ts, *Alice*, 2014 WL 828039, at *4; *see id.* *3 n.4 ("Open source software developers often contribute to open source projects on a voluntary basis."); *see also* Brief for Amicus Curiae Computer & Commc'ns Indus. Ass'n in Support of Resp't, *Bilski*, 2009 WL 3199624, at *3 ("Internet-based business models enjoy first-mover advantages that do not, as an economic matter, need bolstering from patent exclusivity."); Br. of Entrepreneurial and Consumer Advocates Amici Curiae in Support of Resp't, *Bilski*, 2009 WL 3199630 at *18 ("[T]he innovation and quality required to maintain [business advantages] are based on loyalty and reputation, not patent incentives.").

³⁹ As noted, the KEI brief is an exception. *See supra* note 30. A brief from Peter Menell and Michael Meurer mentioned "tax incentives, research contracts, [and] government grants," but it contained no further discussion of these policies and stated that "[s]taying ahead of competitors is the most basic and most important incentive." Br. Amici Curiae of Professors Peter S. Menell & Michael J. Meurer in Support of Resp't, *Bilski*, 2009 WL 3199629, at *36-37.

⁴⁰ See generally Steven Shavell & Tanguy van Ypersele, Rewards Versus Intellectual Property Rights, 44 J.L. & ECON. 525, 526-27 (2001).

thoughtful analyses of the merits of different innovation policies from both lawyers and economists.⁴¹ But recently, a growing literature has emphasized the importance of considering patent policy in the context of the array of policies through which the state influences knowledge production.⁴²

The full set of such policy levers is vast, encompassing laws and legal institutions related to immigration, education, contracts, land use, financial regulation, and tort law.⁴³ But here I focus on the laws that most directly facilitate monetary transfers from the public to innovators: direct R&D spending through grants and contracts (including spending on national laboratories), prizes, regulatory exclusivity, and R&D tax incentives.

In *Beyond the Patents–Prizes Debate*, Daniel Hemel and I develop a new framework for comparing these policies.⁴⁴ We argue that every government transfer to spur innovation embodies the answers to three distinct questions:

- (1) Who decides the size of the transfer? Does the government tailor the reward on a project-by-project basis, or does it simply establish technology-neutral ground rules? Grants and fixed prizes are effective when the government can foresee a potential invention and evaluate its costs and benefits. In contrast, patents (and the patent-like reward of regulatory exclusivity) and tax incentives leverage private information about potential projects.⁴⁵
- (2) When is the reward transferred: before the R&D results are known, or only ex post to successful projects? Ex post rewards such as patents and prizes provide a strong incentive for success, but in some cases that incentive might be dulled because ex post rewards are both delayed and speculative, and innovators might be more responsive to a \$1 tax credit or grant today than to a 1-in-10 chance of a \$10 patent or prize in the future. Ex ante rewards may also be more efficient because the social discount rate is less than the private discount rate (i.e., society values \$10 in the future more than the innovator does).⁴⁶
- (3) *Who pays*: all taxpayers, or only users of the resulting technology? Here, patents look different in that they are generally paid for by users of the resulting technology (through supracompetitive prices on patented products), rather than by all taxpayers. We argue that

⁴⁵ *Id.* at 327-33.

⁴¹ See, e.g., Brett Frischmann, Innovation and Institutions: Rethinking the Economics of U.S. Science and Technology Policy, 24 VT. L. REV. 347 (2000); Brian D. Wright, The Economics of Invention Incentives: Patents, Prizes, and Research Contracts, 73 AM. ECON. REV. 691, 691 (1983).

⁴² See, e.g., John M. Golden & Hannah J. Wiseman, *The Fracking Revolution: A Case Study in Policy Levers To Promote Innovation*, 64 EMORY L.J. (forthcoming 2014); Hemel & Ouellette, *supra* note 14; Kapczynski, *supra* note 17.

⁴³ See THE KAUFFMAN TASK FORCE ON LAW, INNOVATION, AND GROWTH, RULES FOR GROWTH: PROMOTING INNOVATION AND GROWTH THROUGH LEGAL REFORM (2011), available at http://perma.cc/A3PS-4G4Z.

⁴⁴ Hemel & Ouellette, *supra* note 14.

⁴⁶ *Id.* at 333-45.

whether the "user pays" aspect of patents is normatively attractive will vary with the technology, and that in theory, "user pays" could be incorporated into other reward mechanisms.⁴⁷

The third dimension—who pays—largely raises distributive concerns that are not the focus of this Essay, although it is important to remember that any innovation policy could be moved to a different place along this axis. The other two dimensions are illustrated below in Figure 1.⁴⁸

Figure 1

		Reward Setting	
		government-set (government selects projects and reward sizes)	market-set (government creates technology-neutral rules)
Reward	ex ante (reward before results)	direct spending: grants, contracts, national labs	R&D tax incentives
Timing	ex post (only reward success)	fixed Longitude-type prizes	patents, trade secrets, market-based prizes, regulatory exclusivity

Each dimension is a spectrum rather than a binary choice: the middle of the first dimension includes incentives like technology-specific tax credits and proposed medical prize schemes that tie rewards to both government assessments of health impact and market performance; along the second dimension, transfers can be scheduled at various times in the R&D process.

Here, I apply our framework to the most controversial areas of patentable subject matter: medical biotechnology and computer-implemented inventions.⁴⁹ Many of my conclusions here are tentative, as much remains unknown about the effect of different incentives. The important point, however, is that there *are* many non-patent incentives through which the state facilitates transfers to innovators in these contexts, and optimal incentives likely vary for different types of inventions.

A. "Nature" and Medical Biotechnology

The "nature" exception to patentability—newly broadened in *Mayo* and *Myriad*—has the potential to affect a vast range of research, but most litigation has involved biomedical applications at the molecular level.⁵⁰ Such

⁴⁷ Id. at 345-52.

⁴⁸ Figure 1 is closely based on *id.* at 333 fig.1.

⁴⁹ See 1 DONALD S. CHISUM, CHISUM ON PATENTS § 1.02[7] (2014) (describing these areas as the "two most controversial areas o[f] patentable subject matter").

⁵⁰ For example, after *Mayo* and *Myriad*, one district court struck down claims on prenatal testing methods because they only added "conventional techniques of DNA detection" to the unpatentable natural phenomenon of paternally inherited fetal DNA circulating freely in the

applications typically stem from basic research on likely unpatentable "laws of nature,"⁵¹ such as the connection between gene variants and diseases⁵² or novel approaches for inhibiting disease effects.⁵³ The resulting commercial applications include not only diagnostic methods and genetic tests like those at issue in *Mayo* and *Myriad*, which have minimal regulatory barriers,⁵⁴ but also products requiring clinical trials. The FDA regulates trials for both small molecule drugs and more complex "biologics,"⁵⁵ and many new therapeutics in both categories are natural products or are derived from them.⁵⁶ These natural compounds may not be patentable subject matter under the PTO's post-*Myriad* guidelines for examiners⁵⁷ (although method of treatment claims are allowed, and most drugs are in fact protected by more than one patent⁵⁸).

Even though the "nature" exception to patentability may preclude patents on both basic and applied biomedical research results, many other state-sponsored non-patent innovation incentives are available in this area. As discussed below, these non-patent incentives include (1) patent-like tools such

⁵¹ See Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1296 (2012) (stating that "relationships between concentrations of certain metabolites in the blood and the likelihood that a dosage of a thiopurine drug will prove ineffective or cause harm" are unpatentable "laws of nature").

 52 E.g., Scott Smemo et al., Obesity-Associated Variants Within FTO form Long-Range Functional Connections with IRX3, 507 NATURE 371 (2014) (showing that obesity-linked variations in introns of the FTO gene alter the expression of not FTO (as previously thought) but rather a different protein, IRX3). This research was funded by the NIH and overseas counterparts. Id. at 375.

⁵³ E.g., Hyung Jin Ahn et al., A Novel $A\beta$ -Fibrinogen Interaction Inhibitor Rescues Altered Thrombrosis and Cognitive Decline in Alzheimer's Disease Mice, 211 J. EXP. MED. 1049 (2014) (showing that a small molecule (RU-505) that inhibits interactions between the Alzheimer's-linked peptide amyloid- β (A β) and the blood-clotting protein fibrinogen can improve Alzheimer's disease in mice). This work was funded by grants from the NIH and various foundations. *Id.* at 1061.

⁵⁴ For an overview of the FDA regulatory process for in vitro diagnostics, see *Overview of IVD Regulation*, FOOD & DRUG ADMIN., http://perma.cc/9XT4-S3Y9 (last updated Feb. 21, 2014).

⁵⁵ See 21 U.S.C. § 355 (small molecule drugs); 42 U.S.C. § 262 (biologics).

⁵⁶ See David J. Newman & Gordon M. Cragg, *Natural Products as Sources of New Drugs over the 30 Years from 1981 to 2010*, 75 J. NAT. PRODUCTS 311, 312 fig.1 (2012) (reporting that of 1355 FDAapproved therapeutics 1981 to 2010, 15% were biological (usually a large peptide or peptide or protein), 4% were unmodified natural products, 22% were derived from a natural product, and 6% were vaccines (usually made from natural products)).

⁵⁷ See ANDREW H. HIRSHFELD, DEPUTY COMM'R, U.S. PATENT & TRADEMARK OFFICE, 2014 PROCEDURE FOR SUBJECT MATTER ELIGIBILITY ANALYSIS OF CLAIMS RECITING OR INVOLVING LAWS OF NATURE/NATURAL PRINCIPLES, NATURAL PHENOMENA, AND/OR NATURAL PRODUCTS (Mar. 4, 2014), *available at* http://perma.cc/QQ2P-PUFS.

⁵⁸ See Ouellette, *supra* note 104, at 314-15 & fig.2 (showing that 67% of the 938 drugs approved by the FDA from 1988 to 2005 are protected by more than one patent).

blood of a pregnant woman. Ariosa Diagnostics, Inc. v. Sequenom, Inc., No. C 11-06391, 2013 WL 5863022, at *9 (N.D. Cal. Oct. 30, 2013). Another district court concluded that there are "substantial questions" about whether any of Myriad's remaining BRCA-related claims are directed to patentable subject matter. *In re* BRCA1-, BRCA2-Based Hereditary Cancer Test Patent Litig., MDL 2:14-MD-2510, 2014 WL 931057, at *2 (D. Utah Mar. 10, 2014). And a court rejected a 12(b)(6) challenge to claims directed to the natural law of "correlations between genomic variation in non-coding and coding regions of DNA" because there was insufficient evidence (at least so far) that claimed method of amplifying and analyzing the DNA to look for these correlations lacked sufficient "inventive concept" to be patentable. Genetic Techs. Ltd. v. Agilent Techs., Inc., No. CV 12-01616, 2014 WL 941354, at *3, 8 (N.D. Cal. Mar. 7, 2014).

as regulatory exclusivity and other forms of IP protection, (2) direct spending through grants and national labs, (3) R&D tax incentives, and, though not yet widely used, (4) prizes.

1. Patent-like incentives. Patents are not the only ex post, market-set, user-pays reward for new biomedical innovations. As Nicholson Price as explained, pharmaceutical firms rely most heavily on trade secrecy protection for manufacturing innovations.⁵⁹ Additionally, trademarks enable firms to charge supracompetitive prices even after their patents have expired.⁶⁰

Congress has also created a separate system of regulatory exclusivity for many products requiring FDA approval before marketing. The Hatch-Waxman Act provides five years of exclusivity for any drug with a new active ingredient⁶¹ and three years for other drugs that require new clinical trials,⁶² the Biologics Price Competition and Innovation Act provides twelve years of exclusivity for new biologics,⁶³ and the Orphan Drug Act provides seven years of exclusivity for new drugs that treat rare diseases.⁶⁴ An additional six months of exclusivity is available for drugs or biologics that undergo certain pediatric studies.⁶⁵ These exclusivity periods are typically shorter than those provided by patents: the effective market life of brand-name drugs (i.e., the period before generic entry) is twelve years.⁶⁶ As Ben Roin has explained, "there is compelling evidence that the current periods of FDA-administered exclusivity are inadequate because pharmaceutical companies continue to screen drugs with weak patent protection out of their pipelines."⁶⁷ But there are numerous proposals for relying more heavily on regulatory exclusivity for pharmaceutical innovations.⁶⁸

Determining the current value of these patent-like incentives is hard: separating the value of patents from the value of the underlying technology is difficult, and separating the value of patent-like incentives from patents themselves is even more challenging. One study estimated worldwide patent

⁶⁵ 21 U.S.C. § 355a; 42 U.S.C. § 262(m)(3).

⁵⁹ See W. Nicholson Price II, Making Do in Making Drugs: Innovation Policy and Pharmaceutical Manufacturing, 55 B.C. L. REV. 491 (2014).

⁶⁰ See Dipak C. Jain & James G. Conley, Patent Expiry and Pharmaceutical Market Opportunities at the Nexus of Pricing and Innovation Policy (INSEAD Working Paper No. 2012/89/MKT, 2012), available at http://ssrn.com/abstract=2156237.

 $^{^{61}}$ 21 U.S.C. §§ 355(c)(3)(E)(ii), (j)(5)(F)(ii).

⁶² Id. §§ 355(c)(3)(E)(iii)-(iv), (j)(5)(F)(iii)-(iv).

^{63 42} U.S.C. § 262(k)(7)(A).

⁶⁴ 21 U.S.C. § 360cc. Whereas the "data exclusivity" periods under Hatch-Waxman and the Biologics Price Competition and Innovation Act simply prevent a generic company from relying on clinical trial data from a brand-name drug, the Orphan Drug Act exclusivity period precludes any company from obtaining approval for the same therapeutic (small-molecule drug or biologic).

⁶⁶ C. Scott Hemphill & Bhaven N. Sampat, *Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals*, 31 J. HEALTH ECON. 327, 336 (2012).

⁶⁷ Benjamin N. Roin, Unpatentable Drugs and the Standards of Patentability, 87 TEX. L. REV. 503, 566-67 (2009) (footnote omitted).

⁶⁸ See, e.g., Rebecca S Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMM. TECH. L. REV. 345 (2007); Price, *supra* note 59, at 555-58; Roin, *supra* note 67, at 564-58.

rents earned in 1999 by U.S. public firms in the chemical and pharmaceutical industries to be \$15.2 billion in 1992 dollars (\$25.8 billion today).⁶⁹ Another study looked at IRS tax returns and found that pharmaceutical firms reported \$20 billion in IP-related royalties in 2002 (\$27 billion today), which also includes foreign income.⁷⁰

2. Direct spending. Perhaps the largest source of state support for biomedical research is direct public investment through grants and national labs, including in research infrastructure. As Robert Cook-Deegan notes, "[b]iotechnology companies were founded to exploit a technological base that grew from substantial and sustained public investment" over the twentieth century, particularly from the NIH, which "grew into the world's largest funder of biomedical research."⁷¹ Today, the NIH has a budget of approximately \$30 billion, of which over 80% is used to fund almost 50,000 competitive grants to more than 300,000 researchers, and about 10% is used to support nearly 6,000 scientists in the NIH's own laboratories.⁷²

U.S. state governments also provide direct R&D support, albeit at more modest levels: total state spending on health-related R&D was about \$314 million in fiscal year 2011.⁷³ Additional direct support for basic research comes public-spirited nonprofit institutions, including universities and private foundations (such as the Gates Foundation and the Howard Hughes Medical Institute).⁷⁴ In fiscal year 2011, U.S. universities spent \$20 million on R&D in the medical sciences and another \$12 million on R&D in the biological sciences,⁷⁵ and the largest U.S. foundations distributed about \$1.6 billion in health-related research grants.⁷⁶

3. Tax incentives. R&D tax incentives are another significant source of support for biomedical research. The largest general R&D incentives in the

⁶⁹ JAMES BESSEN & MICHAEL J. MEURER, PATENT FAILURE: HOW JUDGES, BUREAUCRATS, AND LAWYERS PUT INNOVATORS AT RISK 114 (2008).

⁷⁰ Carol A. Robbins, *Measuring Payments for the Supply and Use of Intellectual Property, in* INTERNATIONAL TRADE IN SERVICES AND INTANGIBLES IN THE ERA OF GLOBALIZATION 139, 159 tbl.4.8 (Marshall Reinsdorf & Matthew J. Slaughter eds., 2009).

⁷¹ Robert Mullan Cook-Deegan, *National Policies Influencing Innovation Based on Human Genetics, in* THE COMMERCIALIZATION OF GENETIC RESEARCH: ETHICAL, LEGAL, AND POLICY ISSUES 13, 15, 17 (Timothy A. Caulfield & Bryn Williams-Jones eds., 1999).

⁷² *NIH Budget*, NAT'L INSTS. HEALTH, http://perma.cc/T22F-VQJY (last visited July 30, 2014).

⁷³ NAT'L SCI. FOUND., SURVEY OF STATE GOVERNMENT RESEARCH AND DEVELOPMENT: FYS 2010 AND 2011, at 17 tbl.8 (2014), *available at* http://perma.cc/YN52-2YTZ.

⁷⁴ Although this support does not represent a direct transfer from taxpayers to researchers, these nonprofits supplement state provision of public goods and can serve as models or tests of how governments might most effectively use tax revenues to spur innovation.

⁷⁵ Ronda Britt, Universities Report Highest-Ever R&D Spending of \$65 Billion in FY 2011, INFOBRIEF (Nat'l Ctr. for Sci. & Eng'g Statistics, Nat'l Sci. Foundation, 13-305), Nov. 2012, at 2, available at http://perma.cc/6EE3-8PB7.

⁷⁶ Aggregate Fiscal Data of Grants from FC 1000 Foundations, for Health, 2011, FOUNDATION CENTER, http://perma.cc/FNL3-F4HV (last updated Oct. 2013). For a list of non-NIH funding opportunities, primarily from private foundations, see *NIAID's List of Foundations and Other Funding Sources*, NAT'L INSTS. HEALTH, http://perma.cc/45E7-XQWV (last updated June 25, 2014).

current federal Tax Code are section 174, which allows companies to deduct research expenses immediately rather than over a period of future years, and section 41, which provides a tax credit for companies that increase their R&D spending.⁷⁷ Together, these provisions are estimated to cost U.S. taxpayers \$11 billion in 2014 for all technologies,⁷⁸ with the portion going to pharmaceutical R&D likely around \$2 billion.⁷⁹

In addition to these technology-neutral incentives, pharmaceutical firms can also claim the federal tax credit for 50% of the cost of clinical trials for rare diseases,⁸⁰ through which they receive about \$800 million a year,⁸¹ and the qualifying therapeutic discovery project credit,⁸² through which they receive about \$200 million per year.⁸³ And firms can also take advantage of R&D tax incentives at the state level;⁸⁴ for example, pharmaceutical firms received \$57 million in 2001 (\$77 million today) through California's R&D tax credit.⁸⁵

4. Prizes. Eighteenth- and nineteenth-century governments often used technology inducement prizes such as the British Longitude Prize,⁸⁶ and after a 1999 National Academies report urged the U.S. government to make greater use of such prizes,⁸⁷ Congress and the President have encouraged agencies to use their budgets for this purpose.⁸⁸ The NIH has been slow to use this authority,⁸⁹ although it has offered small prizes for novel biomedical

⁸⁰ 26 U.S.C. § 45C.

⁸¹ STAFF OF THE JOINT COMM. ON TAXATION, *supra* note 78, at 39 tbl.1.

⁸² 26 U.S.C. § 48D.

⁸³ STAFF OF THE JOINT COMM. ON TAXATION, *supra* note 78, at 30 tbl.1.

⁸⁴ See generally Hemel & Ouellette, supra note 14, at 325 & n.112.

⁸⁵ An Overview of California's Research and Development Tax Credit, LEGISLATIVE ANALYST'S OFFICE (Nov. 2003), http://perma.cc/HDG4-G3PT.

⁸⁶ See SUZANNE SCOTCHMER, INNOVATION AND INCENTIVES 32-34, 43-44 (2004).

⁸⁷ NAT'L ACAD. OF ENG'G, CONCERNING FEDERALLY SPONSORED INDUCEMENT PRIZES IN ENGINEERING AND SCIENCE (1999).

⁸⁸ See 15 U.S.C. § 3719; NAT'L ECON. COUNCIL ET AL., A STRATEGY FOR AMERICAN INNOVATION: SECURING OUR ECONOMIC GROWTH AND PROSPERITY 12 (2011), available at http://perma.cc/4YCJ-F73W ("President Obama called on all agencies to increase their use of prizes In the months to come, the Obama Administration will work closely with key agencies to leverage the new authority for ambitious prizes ").

⁸⁹ Michael Price, *Will NIH Embrace Biomedical Research Prizes?*, SCI. INSIDER (July 19, 2011), http://perma.cc/YYR9-FBFC ("NIH has so far sat on the sidelines of the prize game").

⁷⁷ IRC §§ 41, 174. For IRS guidance about these provisions, see *Pharmaceutical Industry Research Credit Audit Guidelines*, IRS, http://perma.cc/YS5X-3MBP (last updated Jan. 27, 2014).

⁷⁸ STAFF OF THE JOINT COMM. ON TAXATION, 113TH CONG., ESTIMATES OF FEDERAL TAX EXPENDITURES FOR FISCAL YEARS 2012-2017, at 30 tbl.1 (Comm. Print 2013), *available at* http://perma.cc/6XCM-U3DK.

⁷⁹ In 2005, the pharmaceutical industry claimed \$915 million under section 174, or 14% of the amount claimed under this provision by all industries. NAT'L SCI. FOUND., SCIENCE AND ENGINEERING INDICATORS 2010, at 227 tbl.4-25 (2010), *available at* http://perma.cc/GEM7-JQ5G. And in 2011, pharmaceutical firms spent \$41 billion on R&D, which is 17% of all industrial R&D spending. Raymond M. Wolfe, *Business R&D Performance in the United States Increased in 2011*, INFOBRIEF 2 tbl.2 (Nat'l Ctr. for Sci. & Eng'g Statistics, Nat'l Sci. Foundation, 13-335), Sept. 2013, *available at* http://perma.cc/PD44-BJ9V. It thus seems plausible that roughly 15% of total R&D tax expenditures go toward the pharmaceutical industry.

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designs from undergraduates.⁹⁰ Prizes from foundations and private firms for new biomedical innovations are somewhat more common; for example, the Caring for Carcinoid Foundation is offering \$300,000 for new cell lines derived from certain tumors,⁹¹ and the biopharmaceutical company AstraZeneca is offering \$100,000 for an improved method of delivering short DNA molecules to designated cells.⁹² There are also many privately offered recognition prizes like the Nobel Prize.⁹³ The success of these private efforts may help the NIH determine how to incorporate prizes into its offerings.

In sum, there are already many non-patent incentives for biomedical research at molecular level, and there are a number of opportunities for the government to increase the transfers to innovators through these incentives. But if a policymaker wants to increase incentives for biomedical work, which incentives are most effective? As discussed below, the answer will depend somewhat on whether one is considering basic or applied biomedical work (though the innovation process does not always involve a clear distinction or a linear progression between the two⁹⁴).

Basic biomedical research is often capital-intensive and prone to failure, which may decrease the effectiveness of ex post rewards such as prizes and patents.⁹⁵ And when basic research does lead to significant results, these are often unexpected and serendipitous, making it difficult to target such work toward a particular market need. For example, many NIH grants lead to publications or drugs in different areas than intended,⁹⁶ and one study found that long-term grants that tolerated early failure and provided great freedom to experiment led to many more high-impact publications than grants with predefined deliverables.⁹⁷ Based on the framework above, one might thus expect ex ante, government-set transfers to be the most effective tool for producing basic biomedical research. And perhaps unsurprisingly, as noted above, this is what we already observe in practice.

As a prominent example, a breakthrough that led to the biotech revolution was the 1973 development of recombinant DNA technology by

⁹⁰ See Design by Biomedical Undergraduate Teams (DEBUT) Challenge, NAT'L INST. OF BIOMEDICAL IMAGING & BIOENGINEERING, http://perma.cc/GLB3-9BDL (last visited Aug. 3, 2014).

⁹¹ Intestinal Carcinoid and Pancreatic Neuroendocrine Tumor Cell Lines Needed, INNOCENTIVE (posted Apr. 2, 2014), http://perma.cc/AXT9-EE5E.

⁹² AstraZeneca Challenge: Targeted Delivery of Oligonucleotides, INNOCENTIVE (posted Apr. 4, 2014), http://perma.cc/XR42-PJ76.

⁹³ See, e.g., About the Wiley Foundation, WILEY FOUND., http://perma.cc/F597-SPZH (last visited Aug. 3, 2014); Questions and Answers about the Lurie Prize in the Biomedical Sciences, FOUND. FOR THE NAT'L INSTS. OF HEALTH, http://perma.cc/CP45-GFGN (last visited Aug. 3, 2014).

⁹⁴ See OFFICE OF TECH. ASSESSMENT, U.S. CONG., INNOVATION AND COMMERCIALIZATION OF EMERGING TECHNOLOGIES 31-60 (1995), *available at* http://perma.cc/H87T-CZ32 (describing models of the innovative process).

⁹⁵ See Hemel & Ouellette, supra note 14, at 333-45.

⁹⁶ See Bhaven N. Sampat, Serendipity (Mar. 8, 2014) (unpublished manuscript) (showing that many NIH grants lead to publications or drugs in different areas than intended).

⁹⁷ Pierre Azoulay et al., Incentives and Creativity: Evidence from the Academic Life Sciences, 42 RAND J. ECON. 527 (2011).

Stanley Cohen at Stanford and Herbert Boyer at UCSF, and this work was supported by both the NIH and the National Science Foundation (NSF).⁹⁸ Stanford later patented their inventions,⁹⁹ although both Cohen and Boyer were surprised by the idea, and Cohen renounced his share of the royalties.¹⁰⁰ These patents did have the benefit of bringing in \$255 million in licensing fees for Stanford,¹⁰¹ although in general the patent system is far less efficient than direct taxing and spending at generating revenue for universities.¹⁰²

The other innovation policy tools discussed above are more effective for research projects when the commercial application is less remote and speculative. Because the imitation cost for many biomedical inventions is much lower than the initial commercialization cost, the required size of the transfer to innovators is closely related to the cost of commercialization.¹⁰³

For therapeutics requiring clinical trials to obtain FDA approval, the commercialization cost is quite high.¹⁰⁴ If *Myriad*'s curtailment of patentable subject matter in fact restricts firms' ability to obtain meaningful patent protection for new "natural" therapeutics,¹⁰⁵ it will likely deter firms from

¹⁰² Indeed, many university technology transfer offices do not turn a profit. See generally Brian J Love, Do University Patents Pay Off? Evidence from a Survey of University Inventors in Computer Science and Electrical Engineering, 16 YALE J.L. & TECH. (forthcoming 2014) (manuscript at 11), available at http://ssrn.com/abstract=2448521 (reviewing this literature). See also Hemel & Ouellette, supra note 14, at 371 (explaining how patents operate as a "shadow tax"); Lisa Larrimore Ouellette, Comment, Addressing the Green Patent Global Deadlock Through Bayh-Dole Reform, 119 YALE L.J. 1727, 1731 (2010) (explaining that the most compelling justification for university patents is for those inventions that would not be commercialized without an exclusive right).

¹⁰³ Although biologics are much more difficult to imitate than small-molecule drugs, "the technology for reverse engineering complex biological compounds is advancing rapidly." Benjamin N. Roin, *The Case for Tailoring Patent Awards Based on the Time-to-Market of Inventions*, 61 UCLA L. REV. (forthcoming 2014), *available at* http://ssrn.com/abstract=2235354 (citing Savanna Steele et al., *Better Development of Biosimilars*, DRUG DISCOVERY & DEV., May/June 2013; Steven A. Berkowitz et al., *Analytical Tools for Characterizing Biopharmaceuticals and the Implications for Biosimilars*, 11 Nat. Rev. Drug Discovery 527, 527 (2012)).

¹⁰⁴ The pharmaceutical industry group, the Pharmaceutical Research and Manufacturers of America (PhRMA), claimed that the R&D cost per new drug was \$1.3 billion in 2005, although this industry-funded research has been highly contested. *See generally* Lisa Larrimore Ouellette, *How Many Patents Does It Take To Make A Drug? Follow-on Pharmaceutical Patents and University Licensing*, 17 MICH. TELECOMM. & TECH. L. REV. 299, 302 (2010) (reviewing this literature). F.M. Scherer reviewed these critiques and concluded from his own "broad-brush" estimation that the industry-funded estimates "are both credible and perhaps even conservative." F.M. Scherer, *R&D Costs and Productivity in Biopharmaceuticals* (Regulatory Policy Program Working Paper RPP-2011-10, 2011), *available at* http://perma.cc/RJ5F-CLR6.

¹⁰⁵ Although patents on the products themselves may be unavailable, *see supra* note 56 and accompanying text, firms can still obtain method-of-treatment patents.

⁹⁸ Stanley N. Cohen et al., *Construction of Biologically Functional Plasmids* In Vitro, 70 PROC. NAT'L ACAD. SCI. 3240 (1973).

⁹⁹ See U.S. Patent No. 4,237,224 (filed Jan. 4, 1979); U.S. Patent No. 4,468,464 (filed Nov. 9, 1978); U.S. Patent No. 4,740,470 (filed Apr. 20, 1984).

¹⁰⁰ See Sally Smith Hughes, Making Dollars out of DNA: The First Major Patent in Biotechnology and the Commercialization of Molecular Biology, 1974-1980, 92 ISIS 541, 548-51 (2001).

¹⁰¹ Kirsten Leute, Patenting and Licensing of University-Based Genetic Inventions—A View from Experience at Stanford University's Office of Technology Licensing, 8 COMMUNITY GENETICS 217, 221 (2005).

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pursuing these products.¹⁰⁶ Congress may thus need to address insufficient incentives for the development of new therapeutics. Congress has already increased rewards for a subset of pharmaceuticals through the Orphan Drug Act,¹⁰⁷ and its combination of grants, regulatory exclusivity, and tax credits appears to be quite effective.¹⁰⁸ (Ironically, those supporting expansive patentable subject matter rules have cited the Orphan Drug Act as evidence of the success of patents.¹⁰⁹) An alternative reward system might also be more effective than patents: many commentators argue that the current patentbased system discourages investment in the most promising, cost-effective treatments.¹¹⁰ There are thus many proposals for non-patent rewards for pharmaceutical companies based on the health impact of the new drugs they develop,¹¹¹ and these proposals might gain more traction if the need for congressional intervention becomes apparent.

For genetic diagnostics with fewer regulatory hurdles such as those at issue in *Myriad*, the commercialization cost is significantly lower. Patents are thus less important for this step, especially in light of the tax incentives that are already available. Indeed, a review of genetic tests for ten conditions—including the breast cancer genes at issue in *Myriad*—found that "[i]n none of the cases was a patent-protected test the first to market."¹¹² Other work suggests that the line between therapeutics and diagnostics is blurring, and that both require a significant government incentive.¹¹³ But if it becomes evident post-*Myriad* that the expanded "nature" exception to patentability is

¹¹¹ See, e.g., Prize Fund for HIV/AIDS Act, S. 1138, 112th Cong. (2011); Medical Innovation Prize Fund Act, S. 1137, 112th Cong. (2011); AIDAN HOLLIS & THOMAS POGGE, THE HEALTH IMPACT FUND: MAKING NEW MEDICINES ACCESSIBLE FOR ALL (2008); Shamnad Basheer, *The Invention of an Investment Incentive for Pharmaceutical Innovation*, 15 J. WORLD INTELL. PROP. 305 (2012).

¹¹² SEC'Y'S ADVISORY COMM. ON GENETICS, HEALTH, AND SOC'Y, HHS, GENE PATENTS AND LICENSING PRACTICES AND THEIR IMPACT ON PATIENT ACCESS TO GENETIC TESTS 2 (2010), available at http://perma.cc/4EXL-HCK4; see also Heidi Williams, Intellectual Property Rights and Innovation: Evidence from the Human Genome, 121 J. POL. ECON. 1 (2013) (demonstrating that IPlike restrictions on human genes led to a 20-30% decrease in subsequent innovation).

¹¹³ See Lori Pressman, DNA Patent Licensing Under Two Policy Frameworks: Implications for Patient Access to Clinical Diagnostic Genomic Tests and Licensing Practice in the Not-for-Profit Sector, 6 LIFE SCI. L. & INDUS. REP. 329 (2012).

¹⁰⁶ See supra note 67 and accompanying text.

¹⁰⁷ Orphan Drug Act, Pub. L. No. 97-414, 96 Stat. 2049 (1983).

¹⁰⁸ Hemel & Ouellette, *supra* note 14, at 379-80.

¹⁰⁹ See CLS Bank Int'l v. Alice Corp. Pty. Ltd., 717 F.3d 1269, 1326 & n.5 (Fed. Cir. 2013) (Newman, J., concurring-in-part and dissenting-in-part) ("No substitute has been devised for the incentive of profit opportunity through market exclusivity. . . . Illustration is seen in the Orphan Drug Act."); Br. for Amicus Curiae Lynch Syndrome Int'l in Support of Resp'ts, *Myriad*, 2013 WL 1099162, at *14 ("Absent patent protection . . . new [genetic diagnostic] assays [for small markets] will likely go the way of treatments and medicines for orphan diseases prior to the 1983 Orphan Drug Act.").

¹¹⁰ See, e.g., Rebecca S. Eisenberg, *The Problem of New Uses*, 5 YALE J. HEALTH POL'Y L. & ETHICS 717 (2005); Amy Kapczynski & Talha Syed, *The Continuum of Excludability and the Limits of Patents*, 122 YALE L.J. 1900 (2013); Roin, *supra* note 67; *see also* Eric Budish, Benjamin N. Roin & Heidi Williams, *Do Fixed Patent Terms Distort Innovation? Evidence from Cancer Clinical Trials* (NBER Working Paper No. 19430, 2013), *available at* http://www.nber.org/papers/w19430 (estimating \$89 billion per year in life-years lost to U.S. cancer patients due to the distortion caused by a fixed patent term, which biases R&D toward quick-acting cancers that can have shorter clinical trials).

leading to under-commercialization of genetic diagnostics, then additional non-patent incentives could be added to this problem as well.

B. "Abstract Ideas" and Software

Although the claims at issue in *Bilski* and *Alice* were not for software inventions, the "abstract ideas" exception to patentability has significant implications for software. As discussed in Part I, much of the briefing in these cases thus focused on this field. The Supreme Court's decision in *Alice* may have significantly limited the scope of software patentability, but as in the case of biomedical research, many other state-sponsored non-patent innovation incentives are available in this area.

1. Patent-like incentives. There is no equivalent to FDA-administered regulatory exclusivity for software. However, non-patent forms of intellectual property provide ex post, market-set financial incentives for software development. In particular, many forms of software innovation are rewarded through copyright,¹¹⁴ trade secrets, and trademark protection.

2. Direct spending. Federal and state governments also provide significant support for software innovation through direct spending. For each of the past three years, the federal government has spent between \$3 and \$4 billion per year on research grants in computer science and mathematics,¹¹⁵ and additional grants are available at the state level.¹¹⁶ (In fiscal year 2011, U.S. universities expended an additional \$2.4 billion on computer science and mathematics R&D.¹¹⁷) Many local governments have also directly supported software innovation by investing in broadband infrastructure.¹¹⁸

3. Tax incentives. The general federal R&D tax incentives described above, sections 41 and 174 of the Tax Code, are also available for software research.¹¹⁹ As noted above, these provisions together cost about \$11 billion per year,¹²⁰ with the portion going to software R&D likely around \$500 million to \$1 billion.¹²¹ The federal government also supports the

¹¹⁴ See generally Pamela Samuelson, The Uneasy Case for Software Copyrights Revisited, 79 GEO. WASH. L. REV. 1746 (2011).

¹¹⁵ NAT'L SCI. FOUND., FEDERAL FUNDS FOR RESEARCH AND DEVELOPMENT: FISCAL YEARS 2011-13, at 53 tbl.19 (2014), *available at* http://perma.cc/ZH35-BDDD.

¹¹⁶ NSF statistics on state R&D spending only list field-specific expenditures in agriculture, energy, environment, health, and transportation; the total amount of "other" expenditures was \$157 million in fiscal year 2011, a small fraction of which likely supports software-related research. NAT'L SCI. FOUND., *supra* note 73, at 17 tbl.8.

¹¹⁷ Britt, *supra* note 75, at 2.

¹¹⁸ See Brian Heaton, Local Governments Pursue Independent Broadband Despite Challenges, GOVERNING (Nov. 21, 2012), http://www.governing.com/blogs/view/gov-local-governments-pursue-independent-broadband.html.

¹¹⁹ See generally Ryan R. Coleman, Cloud Computing and the Credit for Increasing Research Activities, TAX ADVISOR (Feb. 1, 2014), http://www.aicpa.org/Publications/TaxAdviser/2014/february /Pages/clinic-story-04.aspx.

¹²⁰ See supra note 78 and accompanying text.

¹²¹ Software firms spent \$27 billion on R&D in 2011, which was 11% of all industrial R&D spending, *see* Wolfe, *supra* note 79, at 2 tbl.2, and software firms claimed \$274 million under

infrastructure necessary for software innovation through the broadband sales tax exemption.¹²² Additional R&D tax incentives are available at the state level.

4. Prizes. The federal government has offered numerous prizes for new software. For example, the VA awarded over \$3 million for better patient scheduling software,¹²³ the Department of Defense awarded \$1 million for an algorithm that identifies organisms from a stream of DNA sequences,¹²⁴ and over 100 completed or ongoing government prize competitions are listed on Challenge.gov.¹²⁵ Many software-related prizes have also been offered by private foundations or industries, ranging from the Clay Mathematics Institute's open \$1 million prize for proving whether or not P=NP,¹²⁶ to the \$1 million prize Netflix awarded for an improved algorithm for predicting how much someone will enjoy a movie.¹²⁷

The optimal package of innovation incentives for software likely looks very different from the biomedical context because of the differences between research in the two fields. Software R&D is generally less capital intensive than biomedical research. It is also less risky because it is more predictable: software is less prone to unexpected failure or unwanted side effects than biomedical research. And it moves faster between the initial idea and the first sale as a commercialized product: the typical time to market for software products is 5-14 months, compared with 12-16 years for pharmaceuticals and 1-10 years for in vitro diagnostics.¹²⁸

Because the incentive of ex post rewards is unlikely to be significantly dulled by capital constraints, risk aversion, or long commercialization times, these rewards are likely to be more effective in the software context. Thus, prizes are optimal when the government is able to set a clear goal, such as for a specific mathematical or algorithmic challenge—and it appears that the government is beginning to take advantage of this incentive.

¹²⁴ See Press Release, Nanyang Technological University, Singapore Research Centre Team Members Win US\$1 Million Prize in US Department of Defense's Bioterror Detection Competition (Sept. 24, 2013), http://perma.cc/QM96-27AD.

¹²⁵ CHALLENGE.GOV, http://challenge.gov (click "Advanced search" and then "Filter results by: Software").

section 174 in 2005, which was 4% of the total claimed by all industries, *see* NAT'L SCI. FOUND., *supra* note 79, at 227 tbl.4-25. It thus seems plausible that software firms receive roughly \$500 million to \$1 billion of total R&D tax expenditures, or 4-9% of the total.

¹²² Internet Tax Freedom Act, Pub. L. No. 105-277, §§ 1100–1104, 112 Stat. 2681-719, 2681-719 to -28 (1998) (codified as amended at 47 U.S.C. § 151 (2006 & Supp. V 2012)). See generally Austan Goolsbee, *The Value of Broadband and the Deadweight Loss of Taxing New Technology* (Nat'l Bureau of Econ. Research, Working Paper No. 11994, 2006).

¹²³ See VA Medical Appointment Scheduling Contest, CHALLENGEPOST, http://vascheduling. challengepost.com (last visited Aug. 1, 2014).

¹²⁶ P vs NP Problem, CLAY MATHEMATICS INST., http://perma.cc/D9U9-DT36 (last visited July 29, 2014); see generally Lance Fortnow, The Status of the P Versus NP Problem, 52 COMM. ACM 78 (2009).

¹²⁷ Netflix Prize, NETFLIX, http://www.netflixprize.com.

¹²⁸ See Roin, supra note 103, manuscript at 44-46 tbl.1.

But the government often fails to recognize the innovations that will have the greatest market demand, and market signals are often a good proxy for the social value of software, so market-set rewards seem likely to be efficient. One might thus expect patents to be very effective in the software field, but in practice they are plagued by significant administrative and transaction costs stemming from the large number of patents per product (contributing to problems such as hold-up), delays in examination (such that many products are obsolete by the time any corresponding patents are granted), and the existence of many vague or low-quality patents.

Other state-sponsored, market-set rewards—including non-patent IP and R&D tax incentives—thus appear to be more effective at promoting software innovation. And these non-patent financial transfers to innovators may be sufficient to lead to an efficient amount of research in this field.

* * *

Before turning to how these non-patent incentives might improve the debates over patentable subject matter, it is worth noting that patents do more than incentivizing invention and commercialization by facilitating transfers from consumers to patentees. Patents also encourage the disclosure of technical knowledge, which can benefit future innovators and prevent duplicative research.¹²⁹ This disclosure may be ineffective in many software patents, and it is also unclear how well disclosure works in biotech patenting where physical materials and know-how are often critical.¹³⁰ But to the extent that the government wants to encourage disclosure of technical developments, it is worth remembering that disclosure is an independent policy lever: any state-sponsored reward could be conditioned on some level of disclosure.

III. Patentable Subject Matter: An External Perspective

More widespread understanding of non-patent innovation incentives could have significant payoffs for patentable subject matter debates. Most obviously, it would ensure that such debates occur on a sound basis, without misleading arguments such as "no patents means no incentives." But it also might help substantively improve these debates in at least two ways.

First, recognition of non-patent incentives might ameliorate the persistent conflict over contested subject matter areas. This conflict arises in part from the disparate motivations of the various participants in these debates: although the dominant rationale for subject matter exceptions is

¹²⁹ See generally Lisa Larrimore Ouellette, Do Patents Disclose Useful Information?, 25 HARV. J.L. & TECH. 545 (2012).

¹³⁰ See Lisa Larrimore Ouellette, Access to Bio-Knowledge: From Gene Patents to Biomedical Materials, 2010 STAN. TECH. L. REV. N1, ¶¶ 106-13 (discussing Gregory N. Mandel, The Generic Biologics Debate: Industry's Unintended Admission that Biotech Patents Fail Enablement, 11 VA. J.L. & TECH. 8, ¶ 9 (2006)). But note that some of these problems could be addressed through increased use of material depositories. See id. ¶¶ 101-13.

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utilitarian,¹³¹ many parties arguing for robust exceptions are motivated more by non-economic moral concerns.¹³² Recognizing a broader range of solutions may help these different actors find more common ground for consensus.¹³³ For example, those who are morally opposed to gene patents and those who think research on genes will be undersupplied absent significant transfers to innovators might both be satisfied with an expanded package of tax incentives, prizes, grants, or regulatory exclusivity for genetic R&D.

Second, greater reliance on non-patent incentives may prove more effective than patents in disputed subject matter areas. Although empirical evidence on whether patents are more effective than other innovation policy mechanisms is often ambiguous,¹³⁴ patents' effectiveness is certainly reduced by the profound uncertainty about their long-term availability in contested areas such as software or genetic research. Additionally, innovators who share moral concerns about patenting—programmers who "believe that software is thought, and math, and that no one can own it,"¹³⁵ or researchers who think that "[p]atents on human genes . . . violate ethical tenets"¹³⁶—naturally find little incentive from patents. Recognition that insufficient patent incentives can be supplemented with other transfer mechanisms might even give courts more confidence in drawing clearer patentable subject matter boundaries, improving this doctrinal morass.

To be clear, I am not arguing for more field-specific tailoring of substantive patent law.¹³⁷ As our framework highlights, one of the benefits of

¹³⁴ See Ouellette, supra note 133.

¹³⁵ Michael Risch, *Two Worlds of Software Patents*, PRAWFSBLAWG (Nov. 27, 2012, 10:28 PM), http://perma.cc/M6SK-V2AA.

¹³¹ See Alice, 134 S. Ct. at 2354 (explaining that the subject matter exceptions exist because "'[m]onopolization of those [categories] . . . might tend to impede innovation more than it would tend to promote it,' thereby thwarting the primary object of the patent laws" (quoting *Mayo*, 132 S. Ct. at 1923)); see also supra notes 25-26 and accompanying text.

¹³² E.g., Br. for Canavan Found. et al. as Amici Curiae in Support of Pet'rs, *Myriad*, 2012 WL 5398891, at *14 (arguing that gene patents "commodify[] human life" and "impinge[] on ... rights of privacy"); Br. for Free Software Found. as Amicus Curiae in Support of Resp't, *Bilski*, 2009 WL 3199627, at *22-24 (arguing that software patents are "unjust" because "the freedom to use a computer as one sees fit . . . is a fundamental form of expression"); Br. of Amici Curiae Cato Inst. et al. in Support of Pet'rs, *Mayo*, 2011 WL 4071914, at *31 ("[T]he claimed patents should be invalidated as unconscionable violations of the freedom of thought."); *see* Chiang, *supra* note 16.

¹³³ To be sure, some utilitarians may view patents on contested areas as strictly superior to non-patent incentives, although I do not think this position is supported by existing empirical evidence. See Lisa Larrimore Ouellette, Patent Experimentalism, 101 VA. L. REV. (forthcoming 2015), available at http://ssrn.com/abstract=2294774. And the view that certain patents are morally suspect may be difficult to reconcile with the view of other commentators that patents are morally required. See, e.g., Adam Mossoff, Saving Locke from Marx: The Labor Theory of Value in Intellectual Property Theory, 29 SOC. PHIL. & POL'Y 283 (2012). I do not claim that recognition of the full innovation policy toolkit will resolve all conflicts; only that it may help some participants in these debates to find common ground.

¹³⁶ Br. of Amici Curiae Am. Med. Ass'n et al. in Support of Pet'rs, *Myriad*, 2013 WL 390998, at *4.

¹³⁷ On the prevalence of industry-specific tailoring in patent law, see Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575 (2003).

patents is their general technology neutrality, which is also required by the international TRIPS agreement.¹³⁸ But the Supreme Court has continued to reaffirm technology-neutral exceptions for "abstract ideas" and "nature." My argument is that the courts should worry less about the field-specific tailoring of these exceptions.

The American Bar Association's amicus brief in *Myriad* argued that courts should not consider the existence of other forms of public or private funding when making patentable subject matter determinations.¹³⁹ Although they intended this as an argument for expansive patentability, their premise can easily support the opposite conclusion: the fact that there might not be sufficient incentives without patents in some field should not deter the Court from making a clear ruling. Even if utilitarianism is one of the primary goals of innovation law, that does not mean that all aspects of patents have to be focused on this single goal.

¹³⁸ Agreement on Trade-Related Aspects of Intellectual Property Rights art. 27, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 ("[P]atents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.").

¹³⁹ Br. of the Am. Bar Ass'n as Amicus Curiae in Support of Resp'ts, *Myriad*, 2013 WL 1099164, at *17a-18a (quoting American Bar Ass'n Resolution 111 (Feb. 14, 2011)).