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Patentable Subject Matter and Nonpatent Innovation Incentives

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Patentable Subject Matter and Nonpatent Innovation Incentives

Lisa Larrimore Ouellette*

In four patentable-subject-matter cases in five recent Terms, the Supreme Court has reaffirmed the judicially created prohibitions on patenting “abstract ideas” and “nature,” but the boundaries of these exceptions remain highly contested. The dominant justification for these limitations is utilitarian: courts create exemptions in areas where patents are more likely to thwart innovation than to promote it. The resulting debates thus focus on whether patents are needed to provide adequate innovation incentives in disputed fields such as software or genetic research, or whether private incentives such as reputational gains, first-mover advantages, or competitive pressures are sufficient. But because they are framed by patent blinders, these debates frequently overlook a significant fact: the absence of patents does not imply that there would be only private incentives. Rather, federal and state governments facilitate financial 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.

What do these nonpatent incentives mean for patentable-subject-matter doctrine? For those who argue that patentable subject matter should be based on an economic cost-benefit analysis, the answer is that this balancing must include a much broader array of factors—which might militate against tasking courts with this analysis at all. But patentable-subject-matter debates are not just about economics, and nonpatent incentives might help ease the tension between utilitarian and moral considerations. 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, nonpatent incentives may be more effective than patents in

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contested areas, where inventors who share moral objections find little incentive in patents, and those who do not still find the patent incentive to be dulled by the persistent uncertainty that has plagued patentable-subject-matter doctrine in recent years. In short, if courts continue to enforce robust subject matter exceptions, they should worry less about the lack of patents removing all incentives for nonobvious and valuable research, and more about creating stable doctrine.

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INTRODUCTION

In four cases over five recent 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

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*, 561 U.S. 593 (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 16, *Mayo*, 132 S. Ct. 1289 (No. 10-1150).

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 seemed to take comfort in 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 explicitly reserved questions for future cases,¹⁰ leaving the boundaries of patentable subject matter far from settled.

This cautiousness in setting clear boundaries makes it difficult for researchers and investors to act with confidence in the patent system. The Court’s timidity 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 state-supported financial incentives for innovation. There is often a gap between an invention’s

5. Transcript of Oral Argument at 29, *Bilski*, 561 U.S. 593 (No. 08-964).

6. Transcript of Oral Argument at 5, *Alice*, 134 S. Ct. 2347 (No. 13-298).

7. Brief of Amicus Curiae Red Hat, Inc. in Support of Respondents, *Alice*, 134 S. Ct. 2347 (No. 13-298), 2014 WL 931833, at *17.

8. Reply Brief for Petitioners at 21–22, *Myriad*, 133 S. Ct. 2107 (No. 12-398), 2013 WL 1850746, at *21–22.

9. Transcript of Oral Argument at 13–16, *Myriad*, 133 S. Ct. 2107 (No. 12-398).

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 Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1302 (2012) (“We need not, and do not, now decide whether were the steps at issue here less conventional [they would still be unpatentable.]”); *Bilski*, 561 U.S. at 612 (“The Court . . . need not define further what constitutes a patentable ‘process’ . . .”).

11. See *infra* notes 30–40 and accompanying text.

12. For some of the most prominent recent works in this area, see KAL RAUSTIALA & CHRISTOPHER SPRIGMAN, *THE KNOCKOFF ECONOMY: HOW IMITATION SPARKS INNOVATION* (2012); and Rochelle Cooper Dreyfuss, *Does IP Need IP? Accommodating Intellectual Production Outside the Intellectual Property Paradigm*, 31 *CARDOZO L. REV.* 1437 (2010). For a rare example of innovation without IP in a more capital-intensive field, see Amy Kapczynski, *Order Without Intellectual Property Law: The Flu Network as a Case Study in Open Science* (Mar. 12, 2015) (unpublished manuscript) (on file with author).

public benefit and the private benefit that can be appropriated by the inventor through mechanisms such as first-mover advantage, and so many welfare-enhancing research and development (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 many 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 Article 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 *Myo* and *Myriad*; and (2) computer-implemented software inventions that might be “abstract ideas,” which are impacted by the decisions in *Bilski* and *Alive*. For each field, I examine the full array of public 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 patentable subject matter.

Greater recognition of the array of nonpatent innovation incentives in these fields could have significant payoffs for patentable-subject-matter debates. Most importantly, it could prevent courts from viewing cases with patent blinders—that is, assuming that all innovation problems must be solved through the patent system—and thus 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, nonpatent incentives may be more effective than patents in

13. The need for government intervention is often attributed to information’s similarity to a public good, and the related low marginal cost of reproduction. See generally Daniel J. Hemel & Lisa Larrimore Ouellette, Knowledge Goods and Nation-States (Dec. 2, 2015) (unpublished manuscript) (on file with author) (reviewing the literature on the extent to which information is in fact a public good).

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–Prizes 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.

16. See generally Tun-Jen Chiang, *Competing Visions of Patentable Subject Matter*, 82 GEO. WASH. L. REV. 1858, 1860 (2014) (contending that patentable subject matter “is often about non-economic moral values”).

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. Furthermore, these contested areas are ones in which scholars have raised particular concerns about the patent system,¹⁷ so nonpatent incentives may be more effective at spurring valuable innovations in these fields. The participants who object most vigorously to the Supreme Court's recent curtailment of patentable subject matter (such as the biotech industry¹⁸) thus may have more success lobbying for increased nonpatent incentives such as tax credits or regulatory exclusivity than for recapturing lost ground in the subject matter wars.

While nonpatent 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 nonpatent incentives.

To be clear, my argument is *not* that courts must empirically study the most effective form of incentives for each field of technology and then grant subject-matter exclusions for technologies where nonpatent incentives exist (or are likely to be supplied) and are more effective than patents. For those who think courts *should* draw patentable-subject-matter boundaries based on an explicit economic balancing of incentives, the implications of my analysis are that this balancing must look beyond patents and that subject-matter boundaries will vary as the state adds or removes other incentives. I am not convinced that courts are institutionally equipped for this detailed, context-specific analysis, although it is possible that they are better equipped than the various innovation-related agencies or Congress, even with fewer policy levers at their disposal. Rather, I think the complexity of the necessary analysis is a strong argument against judicial tailoring of subject matter exceptions based on economic balancing.

Instead, my argument is simply that courts deciding patentable-subject-matter cases should not allow their concerns about eliminating innovation incentives for certain valuable inventions to trump competing values. Courts need not unduly worry that a bright-line patent exception will remove incentives for valuable inventions because the many other existing and potential public innovation incentives provide a backstop. Thus, courts should feel comfortable

17. See *infra* notes 158–59 and accompanying text.

18. See, e.g., Donald Zuhn, *Examination of Myriad-Mayo Guidance Comments—International Bioindustry Associations*, PATENT DOCS (Aug. 11, 2014, 11:59 PM), <http://www.patentdocs.org/2014/08/examination-of-myriad-mayo-guidance-comments-international-bioindustry-associations.html> [<http://perma.cc/3QCJ-NMSY>].

drawing clearer subject matter boundaries based on their interpretation of the statute—which might be informed by economic analysis, but which may also involve text, precedent, moral rights, or the value of stable and predictable doctrine. Just because our patent system is primarily justified by economic utilitarianism does not mean that it cannot accommodate competing concerns, or that every patent doctrine is best approached from the perspective of optimizing the welfare effect of the particular claims at issue.

This Article proceeds in three parts. First, Part I illustrates the patent-focused 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 nonpatent 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.¹⁹ One might disagree about the payoffs of this spotlight on nonpatent incentives, but I hope to at least convince readers that these incentives are important, that they have mostly been ignored in the subject matter wars, and that patentable-subject-matter doctrine would benefit from considering innovation policy without patent blinders.

I. PATENT INTERNALISM IN PATENTABLE-SUBJECT-MATTER DEBATES

Although § 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,”²⁰ the Supreme Court has held repeatedly that “this provision contains an important implicit exception.”²¹ 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*,²² or the method of hedging risk in the energy market at issue in *Bilski*.²³ The implicit exception also includes “nature,” such as the isolated genomic DNA sequences (but not cDNA sequences) in *Myriad*,²⁴ and the method

19. I borrow the internal-versus-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.

20. 35 U.S.C. § 101 (2012).

21. *Alice Corp. Pty. Ltd. v. CLS Bank Int’l*, 134 S. Ct. 2347, 2354 (2014) (quoting *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2116 (2013)). This Article takes these exceptions as a given, but it is worth noting that there are plausible arguments against any nonstatutory carve-outs, including the expansive language of the statutory text and the difficulty of drawing coherent and predictable boundaries around any exception. *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).

22. *Alice*, 134 S. Ct. at 2356.

23. *Bilski v. Kappos*, 561 U.S. 593, 611–12 (2010).

24. *Myriad*, 133 S. Ct. at 2116–19.

of calibrating drug dosage using a natural correlation in *Mayo*.²⁵ But in each of these four recent cases, the Court explicitly declined to provide much guidance beyond its specific holding.²⁶ The boundaries of patentable subject matter thus remain 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 [i]s 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.²⁷

Many commentators agree 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.²⁸ In other words, under 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.”²⁹

Thus, the arguments in *Myriad* focused heavily on the economic effect of including gene patents within the “nature” exception to patentability. Those in

25. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1294 (2012).

26. See cases cited *supra* note 10.

27. *Alice*, 134 S. Ct. at 2354 (citations 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.”).

28. See, e.g., Kevin Emerson Collins, *The Knowledge/Embodiment Dichotomy*, 47 U.C. DAVIS L. REV. 1279, 1287 n.14 (2014) (arguing that exclusion of “knowledge-advances” from patentable subject matter is normatively justified because such claims “are unusually costly and that the loss of incentives at the margin forgoes only a small social benefit”); 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, at 1860 (arguing that this “surface consensus” of utilitarianism masks underlying moral concerns); 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); Adam Mossoff, *Why History Matters in the Patentable Subject Matter Debate*, 64 FLA. L. REV. 23, 25–26 (2012) (arguing that historically “courts treated patents liberally and expansively” because patents were seen “as fundamental civil rights securing property rights in inventions”).

29. Duffy, *supra* note 28, at 618.

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 nonpatent incentives that already provide significant transfers to innovators, much less the possibility of additional incentives.³⁰ 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.”³¹ But the briefs contained little discussion of what was incentivizing those geneticists if not patents—or what incentives existed to validate and commercialize the discoveries. In other words, the innovation policy choice was presented to the Court from the internal perspective of patents versus no patents, with little analysis of the nonpatent mechanisms through which the state facilitates transfers to genetic researchers.³²

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

30. See, e.g., Brief of Amici Curiae Animal Health Inst. & Merial Ltd. in Support of Respondents, Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2116 (2013) (No. 12-398), 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.”); Brief of the Coalition for 21st Century Med. as Amicus Curiae in Support of Respondents, *Myriad*, 133 S. Ct. 2107 (No. 12-398), 2013 WL 1098259, at *12 (“Gene Patents Are Necessary To Ensure Financial Incentives To Undertake Research and Development In Emerging Fields.”); Brief for Amici Curiae Genentech, Inc. et al. in Support of Respondents, *Myriad*, 133 S. Ct. 2107 (No. 12-398), 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.”); Brief of MPEG LA, LLC as Amicus Curiae in Support of Respondents, *Myriad*, 133 S. Ct. 2107 (No. 12-398), 2013 WL 1099167, at *7 (“[D]enial of patent protection . . . would provide an insufficient incentive for invention. . . .”); Brief for the Pharm. Research & Mfrs. of Am. as Amicus Curiae Supporting Respondents, *Myriad*, 133 S. Ct. 2107 (No. 12-398), 2013 WL 1122811, at *19 (“Without Strong Patent Protection, Innovation in the Area of Biotechnology Will Decline.”).

31. Brief of Amici Curiae Am. Med. Ass'n et al. in Support of Petitioners, *Myriad*, 133 S. Ct. 2107 (No. 12-398), 2013 WL 390998, at *16; see also Reply Brief for Petitioners, *Myriad*, 133 S. Ct. 2107 (No. 12-398), 2013 WL 1850746, at *21–22 (citations omitted) (“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.”).

32. The exception is an amicus brief from Knowledge Ecology International (“KEI”), which noted the “growing proliferation of alternative, nonpatent mechanisms used to stimulate research and development,” although its discussion focused on patent-like market exclusivity mechanisms and proposed prize systems. Brief of Amicus Curiae Knowledge Ecology Int'l in Support of Petitioners, *Myriad*, 133 S. Ct. 2107 (No. 12-398), 2013 WL 476050, at *10. KEI also filed a similar brief in *Bilski*. Brief of Amicus Curiae Knowledge Ecology Int'l in Support of Respondent, *Bilski*, 561 U.S. 593 (No. 08-964), 2009 WL 3199633, at *8–15.

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.

. . . .

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.

. . . .

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

. . . .

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.³³

As this exchange indicates, even when the lawyer for the plaintiffs seeking invalidation attempted to mention some nonpatent 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.

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

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,³⁴ and that “patent protection today provides *the* incentive for . . . research and development of other diagnostic tests.”³⁵ 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,”³⁶ 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 to investment in innovation”³⁷ and that “[i]nability to patent software innovation [would] cripple[] the ability of small- and mid-size entrepreneurial software businesses to compete”³⁸ And the parties favoring an expansive “abstract ideas” exception

34. Brief of Genomic Health, Inc. et al. as Amici Curiae in Support of Respondent, *Mayo*, Collaborative Servs. v. Prometheus Labs. Inc., 132 S. Ct. 1289 (2012) (No. 10-1150), 2011 WL 5439047, at *17.

35. Brief for Amicus Curiae Novartis Corp. Supporting Respondent, *Mayo*, 132 S. Ct. 1289 (No. 10-1150), 2011 WL 5373697, at *21 (emphasis added); *see also* Brief of Amicus Curiae Am. Intellectual Prop. Law Ass’n in Support of Respondent, *Mayo*, 132 S. Ct. 1289 (No. 10-1150), 2011 WL 5373692, at *23 (arguing that patents are “necessary to ensure that the companies investing in medical research are adequately compensated”); Brief of Amicus Curiae Intellectual Prop. Owners Ass’n in Support of Respondent, *Mayo*, 132 S. Ct. 1289 (No. 10-1150), 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”); Brief for Myriad Genetics, Inc., as Amicus Curiae Supporting Respondent, *Mayo*, 132 S. Ct. 1289 (No. 10-1150), 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.”); Brief for Amici Curiae Roche Molecular Sys., Inc. et al. in Support of Neither Party, *Mayo*, 132 S. Ct. 1289 (No. 10-1150), 2011 WL 4071920, at *21 (“Absent patent protection, there would be little or no incentive[s] for diagnostics companies”).

36. Brief of Amici Curiae the Am. Coll. of Med. Genetics et al. in Support of Petitioners, *Mayo*, 132 S. Ct. 1289 (No. 10-1150), 2011 WL 4071917, at *15; *see also* Brief for Petitioners, *Mayo*, 132 S. Ct. 1289 (No. 10-1150), 2011 WL 3919717, at *50 n.9 (“Time and first mover-advantage often provide greater or more predictable returns to innovation than patenting does.”); *id.* at *51 (“[I]n the area of genetic research, [t]he prospect of patent protection does’ not play a significant role in motivating scientists to conduct medical research.”); Brief for ARUP Labs., Inc. & Lab. Corp. of Am. (d/b/a/ LabCorp) as Amici Curiae in Support of Petitioners, *Mayo*, 132 S. Ct. 1289 (No. 10-1150), 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.”); Brief of Amici Curiae Cato Inst. et al. in Support of Petitioners, *Mayo*, 132 S. Ct. 1289 (No. 10-1150), 2011 WL 4071914, at *23 (“[M]ost innovations would be developed even if patent protection were unavailable.”).

37. Brief of Amicus Curiae IEEE-USA in Support of Neither Party, *Alice Corp. Pty. Ltd. v. CLS Banks Int’l*, 134 S. Ct. 2347 (No. 13-298), 2014 WL 411287, at *25; *see also* Brief of BSA | The Software Alliance as Amicus Curiae in Support of Respondent, *Alice*, 134 S. Ct. 2347 (No. 13-298), 2014 WL 828032, at *8 (“[P]atent protection is a critical incentive to expenditures for software research and development”).

38. Brief of Amici Curiae Entrepreneurial Software Cos. in Support of Petitioner, *Bilski v. Doll*, 129 S. Ct. 2735 (2009) (No. 08-964), 2009 WL 2418474, at *9; *see also* Brief for the Business

argued that many successful software companies “grew strong without incentives from patents. Instead, these successes arose from the dynamics of the competitive market place.”³⁹ Most discussion of nonpatent incentives focused on private incentives such as “[f]irst-mover advantages,” “[n]etwork effects,” “personal satisfaction,” and “reputation,”⁴⁰ not the other forms of state support for software innovation or new business methods.⁴¹

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. And while the Justices are surely aware at some level of the existence of other public innovation incentives, they appear to have viewed patentable-subject-matter cases through patent blinders. I think Dan Burk and Mark Lemley summed up the view of many patent scholars and judges when they wrote at the beginning of one of their articles: “Patent law is our primary policy tool to promote innovation, encourage the development of new technologies, and increase the fund of human knowledge.”⁴² 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

Software Alliance as Amicus Curiae in Support of Affirmance, *Bilski v. Kappos*, 561 U.S. 593 (2010) (No. 08-964), 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.”); Brief of Amicus Curiae Eagle Forum Educ. & Legal Defense in Support of Petitioners, *Bilski v. Doll*, 129 S. Ct. 2735 (No. 08-964), 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.”).

39. Brief of Amicus Curiae Red Hat, Inc., in Support of Respondents, *Alice Corp. Pty. Ltd. v. CLS Bank Int’l*, 134 S. Ct. 2347 (No. 13-298), 2014 WL 931833, at *17.

40. Brief of Amici Curiae Checkpoint Software, Inc. et al. in Support of Respondents, *Alice*, 2014 WL 828039, at *4; see Brief of Amicus Curiae Red Hat, Inc. in Support of Respondents, *Alice*, 134 S. Ct. 2347 (No. 13-298), 2014 WL 931833, at *3 n.4 (“Open source software developers often contribute to open source projects on a voluntary basis.”); see also Brief for Amicus Curiae Computer & Comm’n’s Indus. Ass’n in Support of Respondent, *Bilski v. Kappos*, 561 U.S. 593, 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.”); Brief of Entrepreneurial and Consumer Advocates Amici Curiae in Support of Respondent, *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.”).

41. As noted, the KEI brief is an exception. See *supra* note 32. 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.” Brief Amici Curiae of Professors Peter S. Menell & Michael J. Meurer in Support of Respondent, *Bilski*, 2009 WL 3199629, at *36–37.

42. Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1576 (2003).

role of patents—the ongoing patents-versus-prizes debate dates back to at least the nineteenth century,⁴³ and there have been numerous thoughtful analyses of the merits of different innovation policies from both lawyers and economists.⁴⁴ More 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.⁴⁵

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.⁴⁶ 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, R&D tax incentives, regulatory exclusivity, and other forms of intellectual property.

In theory, all of these incentives can accomplish the same goal: intellectual property and regulatory exclusivity transfer rewards to innovators through supracompetitive prices on protected products or services, and they impose as much of a cost on society as policies that transfer the same amount through more traditional taxing and spending.⁴⁷ In practice, there are important differences in the efficacy of these different transfer mechanisms. In *Beyond the Patents–Prizes Debate*, Daniel Hemel and I developed a new framework for comparing these policies.⁴⁸ We argued 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.⁴⁹

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

44. See, e.g., Brett Frischmann, *Innovation and Institutions: Rethinking the Economics of U.S. Science and Technology Policy*, 24 VT. L. REV. 347 (2000); Nancy Gallini & Suzanne Scotchmer, *Intellectual Property: When Is It the Best Incentive System?*, in 2 INNOVATION POLICY AND THE ECONOMY 51 (Adam B. Jaffe et al. eds., 2002); Brian D. Wright, *The Economics of Invention Incentives: Patents, Prizes, and Research Contracts*, 73 AM. ECON. REV. 691, 691 (1983).

45. See, e.g., John M. Golden & Hannah J. Wiseman, *The Fracking Revolution: Shale Gas as a Case Study in Innovation Policy*, 64 EMORY L.J. 955, (2015); Hemel & Ouellette, *supra* note 14; Kapczynski, *supra* note 19.

46. See KAUFFMAN TASK FORCE ON LAW, INNOVATION, AND GROWTH, RULES FOR GROWTH: PROMOTING INNOVATION AND GROWTH THROUGH LEGAL REFORM (2011), http://www.kauffman.org/~media/kauffman_org/research%20reports%20and%20covers/2011/02/rulesforgrowth.pdf [<http://perma.cc/A3PS-4G4Z>].

47. See Hemel & Ouellette, *supra* note 14, at 371 (discussing how patents act as a “shadow tax”).

48. *Id.*

49. *Id.* at 327–33.

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 market exclusivity 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 one dollar tax credit or grant today than to a one-in-ten chance of a ten dollar 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 ten dollars in the future more than the innovator does).⁵⁰
3. *Who pays*: all taxpayers, or only users of the resulting technology? Here, patents (and similar exclusivity mechanisms) look different in that they are generally paid for by users of the resulting technology (through supracompetitive prices), rather than by all taxpayers. We argue that whether this “user pays” feature is normatively attractive will vary with the technology, and that in theory, “user pays” could be incorporated into other reward mechanisms.⁵¹

The third dimension—who pays—largely raises distributive concerns that are not the focus of this Article, although it is important to remember that any innovation policy could be moved to a different place along this axis.⁵² (Indeed, patents themselves are shifted away from “user pays” in the medical context due to insurance markets.) The other two dimensions are illustrated below in Figure 1.⁵³

50. *Id.* at 333–45. In contrast, optimism bias can make ex post rewards appear more cost effective, though it can also cause inventors to inefficiently invest in projects with negative net present value. And optimism bias cannot offset the combined effects of capital constraints and risk aversion because the private rate of return on R&D spending is greater than the rate of return on ordinary capital investment. *Id.* at 340–42.

51. *Id.* at 345–52.

52. *Id.* at 347.

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

Figure 1

		Reward Setting	
		government-set (government selects projects and reward sizes)	market-set (government creates technology-neutral rules)
Reward Timing	ex ante (reward before results)	direct spending: grants, contracts, national labs	R&D tax incentives
	ex post (only reward success)	fixed 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.⁵⁴ Many of my conclusions here are tentative, as much remains unknown about the effect of different incentives.⁵⁵ The important point, however, is that there *are* many nonpatent 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.⁵⁶ Such applications

54. See 1 DONALD S. CHISUM, CHISUM ON PATENTS § 1.02[7] (2014) (describing these areas as the “two most controversial areas of patentable subject matter”).

55. A new congressionally mandated report from the National Academies offers suggestions about metrics for the impact of research on society. NAT’L RESEARCH COUNCIL OF NAT’L ACADEMIES, FURTHERING AMERICA’S RESEARCH ENTERPRISE (Richard F. Celeste et al. eds., 2014), http://www.nap.edu/openbook.php?record_id=18804 [<http://perma.cc/7PN9-SM57>]. The report also encourages more evaluation through randomized experimentation, *id.* ch. 5, at 18, an approach I have also advocated, Lisa Larrimore Ouellette, *Patent Experimentalism*, 101 VA. L. REV. 65 (2015).

56. 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 blood of a pregnant woman. *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, No. C 11-06391 SI, 2013 WL 5863022, at *9 (N.D. Cal. Oct. 30, 2013). Another district court concluded that there were “substantial questions” about whether any of Myriad’s remaining BRCA-related claims were directed

typically stem from basic research on likely unpatentable “laws of nature,”⁵⁷ such as the connection between gene variants and diseases⁵⁸ or novel approaches for inhibiting disease effects.⁵⁹ The resulting commercial applications include not only diagnostic methods and genetic tests like those at issue in *Mayo* and *Myriad*, which currently have minimal regulatory barriers,⁶⁰ but also products requiring clinical trials. The Food and Drug Administration (FDA) regulates trials for both small molecule drugs and more complex “biologics,”⁶¹ and many new therapeutics in both categories are natural products or are derived from them.⁶² These natural compounds may not be patentable subject matter under the United States Patent and Trademark Office’s (PTO) post-*Myriad* guidelines for examiners⁶³ (although

to patentable subject matter. *In re BRCA1- and BRCA2-Based Hereditary Cancer Test Patent Litig.*, 3 F. Supp. 3d 1213, 1219 (D. Utah 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).

57. 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”).

58. 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.

59. E.g., Hyung Jin Ahn et al., *A Novel A β -Fibrinogen Interaction Inhibitor Rescues Altered Thrombosis and Cognitive Decline in Alzheimer’s Disease Mice*, 211 J. EXPERIMENTAL 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.

60. For an overview of the FDA regulatory process for in vitro diagnostics, see *Overview of IVD Regulation*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/IVDRegulatoryAssistance/ucm123682.htm> [<http://perma.cc/9XT4-S3Y9>] (last updated Mar. 19, 2015). The FDA is planning to regulate certain diagnostic tests more extensively. See Press Release, U.S. Food & Drug Admin., *FDA Takes Steps to Help Ensure the Reliability of Certain Diagnostic Tests* (July 31, 2014), www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm407321.htm [<http://perma.cc/KC8E-ZSHB>].

It is unclear whether any diagnostic tests remain patentable. See *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015) (invalidating patents on diagnostic tests based on cell-free fetal DNA as not patentable subject matter); Rebecca S. Eisenberg, *Diagnostics Need Not Apply*, 21 B.U. J. SCI. & TECH. L. 256 (2015).

61. See 21 U.S.C. § 355 (2012) (small molecule drugs); 42 U.S.C. § 262 (biologics).

62. 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 the 1355 therapeutics approved by the FDA between 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)).

63. See *2014 Interim Guidance on Subject Matter Eligibility*, U.S. PATENT & TRADEMARK OFFICE, <http://www.uspto.gov/patent/laws-and-regulations/examination-policy/2014-interim-guidance-subject-matter-eligibility-0> [<https://perma.cc/5FAY-6Y9N>] (last visited Jan. 3, 2016).

method of treatment claims are allowed, and most drugs are in fact protected by more than one patent⁶⁴).

Even though the “nature” exception may preclude patents on both basic and applied research results, many other public innovation incentives are available in this area. As discussed below, these incentives include (1) patent-like tools such 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 has explained, pharmaceutical firms rely most heavily on trade secrecy protection for manufacturing innovations.⁶⁵ Additionally, trademarks enable firms to charge supracompetitive prices even after their patents have expired.⁶⁶ (Of course, an absence of patent protection likely would make it more difficult for a brand to establish itself in the market, but first-mover advantage or a period of regulatory exclusivity, as discussed below, may accomplish the same goal.)

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 ingredient⁶⁷ and three years for other drugs that require new clinical trials,⁶⁸ the Biologics Price Competition and Innovation Act provides twelve years of exclusivity for new biologics,⁶⁹ and the Orphan Drug Act provides seven years of exclusivity for new drugs that treat rare diseases.⁷⁰ An additional six months of exclusivity is available for drugs or biologics that undergo certain pediatric studies.⁷¹ These exclusivity periods are typically shorter than those provided by patents: the effective market

64. See 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, 314–15 & fig.2 (2010) (showing that sixty-seven percent of the 938 drugs approved by the FDA from 1988 to 2005 are protected by more than one patent).

65. See W. Nicholson Price II, *Black-Box Medicine*, 28 HARV. J. L. & TECH. 419 (2015); W. Nicholson Price II, *Making Do in Making Drugs: Innovation Policy and Pharmaceutical Manufacturing*, 55 B.C. L. REV. 491 (2014) [hereinafter, Price, *Making Do in Making Drugs*].

66. See Dipak C. Jain & James G. Conley, *Patent Expiry and Pharmaceutical Market Opportunities at the Nexus of Pricing and Innovation Policy*, in INNOVATION AND MARKETING IN THE PHARMACEUTICAL INDUSTRY 255 (Min Ding et al. eds., 2014).

67. 21 U.S.C. §§ 355(c)(3)(E)(ii), (j)(5)(F)(ii) (2012).

68. *Id.* §§ 355(c)(3)(E)(iii)–(iv), (j)(5)(F)(iii)–(iv).

69. 42 U.S.C. § 262(k)(7)(A).

70. 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).

71. *Id.* § 355a; 42 U.S.C. § 262(m)(3).

life of brand-name drugs (i.e., the period before generic entry) is twelve years.⁷² 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.”⁷³ But there are numerous proposals for relying more heavily on regulatory exclusivity for pharmaceutical innovations.⁷⁴

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 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).⁷⁵ Another study looked at Internal Revenue Service (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.⁷⁶

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 National Institutes of Health (NIH), which “grew into the world’s largest funder of biomedical research.”⁷⁷ Today, the NIH has a budget of approximately \$30 billion, of which over eighty percent is used to fund almost 50,000 competitive grants to more than 300,000 researchers, and about ten percent is used to support nearly 6000 scientists in the NIH’s own laboratories.⁷⁸

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

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

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

74. See, e.g., Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMM. & TECH. L. REV. 345 (2007); Price, *Making Do in Making Drugs*, *supra* note 65, at 555–58; Roin, *supra* note 73, at 564–68.

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

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

77. 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).

78. *Budget*, NAT’L INSTS. HEALTH, <http://www.nih.gov/about/budget.htm> [<http://perma.cc/F5GX-53A3>] (last visited Nov. 15, 2015).

in fiscal year 2011.⁷⁹ Additional direct support for basic research comes from public-spirited nonprofit institutions, including universities and private foundations (such as the Gates Foundation and the Howard Hughes Medical Institute).⁸⁰ In fiscal year 2011, U.S. universities spent \$3.2 billion of institutional funds on R&D in the medical sciences and another \$1.9 billion in the biological sciences,⁸¹ and the largest U.S. foundations distributed about \$1.6 billion in health-related research grants.⁸²

3. Tax Incentives

R&D tax incentives are another significant source of support for biomedical research. The largest general R&D incentives in the 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.⁸³ Together, these provisions are estimated to cost U.S. taxpayers \$11 billion in 2014 for all technologies,⁸⁴ with the portion going to pharmaceutical R&D likely around \$2 billion.⁸⁵

79. NAT'L CTR. FOR SCI. & ENG'G STATS., NAT'L SCI. FOUND., SURVEY OF STATE GOVERNMENT RESEARCH AND DEVELOPMENT: FYS 2010 AND 2011, at 17 tbl.8 (2014), <http://www.nsf.gov/statistics/nsf14311/pdf/nsf14311.pdf> [<http://perma.cc/YN52-2YTZ>].

80. 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.

81. 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, Arlington, VA), Nov. 2012, at 3 tbl.2, <http://www.nsf.gov/statistics/infbrief/nsf13305/nsf13305.pdf> [<http://perma.cc/6EE3-8PB7>].

82. *Aggregate Fiscal Data of Grants from FC 1000 Foundations, for Health, 2011*, FOUND. CTR., <http://data.foundationcenter.org/#/fc1000/subject:health/all/total/list/2011> [<http://perma.cc/FNL3-F4HV>] (last updated Oct. 2014). For a list of non-NIH funding opportunities, primarily from private foundations, see *Finding Foundations and Other Funding Sources*, NAT'L INSTS. HEALTH, <http://www.niaid.nih.gov/researchfunding/ann/pages/found.aspx> [<http://perma.cc/45E7-XQWV>] (last updated Nov. 6, 2015).

83. I.R.C. §§ 41, 174 (2012). For IRS guidance about these provisions, see *Pharmaceutical Industry Research Credit Audit Guidelines – Revised – 4/30/04*, IRS, <http://www.irs.gov/Businesses/Pharmaceutical-Industry-Research-Credit-Audit-Guidelines---Revised---4-30-04> [<http://perma.cc/9BHK-5M8K>] (last updated Jan. 14, 2015).

84. 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), <http://www.taxpayer.net/images/uploads/JCT%20Tax%20Expenditure%20report%202013.pdf> [<http://perma.cc/6XCM-U3DK>].

85. In 2005, the pharmaceutical industry claimed \$915 million under section 174, or fourteen percent of the amount claimed under this provision by all industries. NAT'L SCI. FOUND., SCIENCE AND ENGINEERING INDICATORS 2010, app. tbl.4-25 (2010), <http://www.nsf.gov/statistics/scind10/append/c4/at04-25.pdf> [<http://perma.cc/GEM7-JQ5G>]. And in 2011, pharmaceutical firms spent \$41 billion on R&D, which is seventeen percent of all industrial R&D spending. Raymond M. Wolfe, *Business R&D Performance in the United States Increased in 2011*, INFOBRIEF (Nat'l Ctr. for Sci. & Eng'g Statistics, Nat'l Sci. Foundation, Arlington, VA), Sept. 2013, at 2 tbl.2, <http://www.nsf.gov/statistics/infbrief/nsf13335/nsf13335.pdf> [<http://perma.cc/PD44-BJ9V>]. It thus

In addition to these technology-neutral incentives, pharmaceutical firms can also claim the federal tax credit for fifty percent of the cost of clinical trials for rare diseases,⁸⁶ through which they receive about \$800 million a year,⁸⁷ and the qualifying therapeutic discovery project credit,⁸⁸ through which they receive about \$200 million per year.⁸⁹ And firms can also take advantage of R&D tax incentives at the state level;⁹⁰ for example, pharmaceutical firms received \$57 million in 2001 (\$77 million today) through California's R&D tax credit.⁹¹

4. Prizes

Eighteenth- and nineteenth-century governments often used technology inducement prizes such as the British Longitude Prize.⁹² After a 1999 National Academies report urged the U.S. government to make greater use of such prizes,⁹³ Congress and the President have encouraged agencies to use their budgets for this purpose.⁹⁴ The NIH has been slow to use this authority,⁹⁵ although it has offered small prizes for novel biomedical designs from undergraduates,⁹⁶ and it recently announced a staged \$100,000 prize for better methods of single-cell analysis.⁹⁷ Other agencies use prizes more often; for example, the Defense Advanced

seems plausible that roughly fifteen percent of total R&D tax expenditures go toward the pharmaceutical industry.

86. I.R.C. § 45C (2012).

87. STAFF OF THE JOINT COMM. ON TAXATION, *supra* note 84, at 39 tbl.1.

88. I.R.C. § 48D. This provision falls more toward the "government-set" side of the spectrum than most other tax incentives because the Department of Health and Human Services reviews applications, and the credit was initially limited to \$5 million per applicant.

89. STAFF OF THE JOINT COMM. ON TAXATION, *supra* note 84, at 30 tbl.1.

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

91. LEGISLATIVE ANALYST'S OFFICE, AN OVERVIEW OF CALIFORNIA'S RESEARCH AND DEVELOPMENT TAX CREDIT (2003), http://www.lao.ca.gov/2003/randd_credit/113003_research_development.html [<http://perma.cc/HDG4-G3PT>].

92. *See* SUZANNE SCOTCHMER, INNOVATION AND INCENTIVES 32–34, 43–44 (2004).

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

94. *See* 15 U.S.C. § 3719 (2012); NAT'L ECON. COUNCIL ET AL., A STRATEGY FOR AMERICAN INNOVATION: SECURING OUR ECONOMIC GROWTH AND PROSPERITY 12 (2011), <https://www.whitehouse.gov/sites/default/files/uploads/InnovationStrategy.pdf> [<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").

95. Michael Price, *Will NIH Embrace Biomedical Research Prizes?*, SCI. INSIDER (July 19, 2011, 4:53 PM), <http://news.sciencemag.org/health/2011/07/will-nih-embrace-biomedical-research-prizes> [<http://perma.cc/Y9R9-FBFC>] ("NIH has so far sat on the sidelines of the prize game").

96. *See Design by Biomedical Undergraduate Teams (DEBUT) Challenge*, NAT'L INST. BIOMEDICAL IMAGING & BIOENGINEERING, <http://www.nibib.nih.gov/training-careers/undergraduate-graduate/design-biomedical-undergraduate-teams-debut-challenge> [<http://perma.cc/GLB3-9BDL>] (last visited Nov. 15, 2015).

97. *NIH Single Cell Analysis Challenge: Follow That Cell*, INNOCENTIVE (Aug. 15, 2014), <https://www.innocentive.com/ar/challenge/9933618> [<http://perma.cc/G36A-73HU>].

Research Project Agency (DARPA) recently announced a \$150,000 prize for infectious disease forecasting.⁹⁸

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,⁹⁹ and the biopharmaceutical company AstraZeneca is offering \$100,000 for an improved method of delivering short DNA molecules to designated cells.¹⁰⁰ There are also many privately offered recognition prizes like the Nobel Prize in Medicine.¹⁰¹ The success of these private efforts may help the NIH determine whether and how to incorporate prizes into its offerings.

In sum, there are already many nonpatent incentives for biomedical research at the 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 two¹⁰²).

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.¹⁰³ 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,¹⁰⁴ 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.¹⁰⁵

98. See Rachel Sachs, *DARPA Announces Disease Forecasting Prize*, BILL HEALTH (Aug. 19, 2014), <http://blogs.law.harvard.edu/billofhealth/2014/08/19/darpa-announces-disease-forecasting-prize/> [<http://perma.cc/EM4F-J95V>].

99. *Intestinal Carcinoid and Pancreatic Neuroendocrine Tumor Cell Lines Needed*, INNOCENTIVE (Apr. 2, 2014), <https://www.innocentive.com/ar/challenge/9933510> [<http://perma.cc/AXT9-EE5E>].

100. *AstraZeneca Challenge: Targeted Delivery of Oligonucleotides*, INNOCENTIVE (Apr. 4, 2014), <https://www.innocentive.com/ar/challenge/9933013> [<http://perma.cc/XR42-PJ76>].

101. See, e.g., *About the Wiley Foundation*, WILEY FOUND., <http://www.wiley.com/WileyCDA/Section/id-390059.html> [<http://perma.cc/F597-SPZH>] (last visited Nov. 15, 2015); *The Lurie Prize in the Biomedical Sciences*, FOUND. NAT'L INSTS. HEALTH, <http://www.fnih.org/what-we-do/current-lectures-awards-and-events/lurie-prize> [<http://perma.cc/PNE8-EYR8>] (last visited Nov. 15, 2015).

102. See OFFICE OF TECH. ASSESSMENT, U.S. CONG., *INNOVATION AND COMMERCIALIZATION OF EMERGING TECHNOLOGIES* 31–60 (1995) (describing models of the innovative process).

103. See Hemel & Ouellette, *supra* note 14, at 333–45.

104. See Bhaven N. Sampat, *Serendipity* (Jan. 5, 2015) (unpublished manuscript), <http://ssrn.com/abstract=2545515> (showing that many NIH grants lead to publications or drugs in different areas than intended).

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

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 Stanley Cohen at Stanford and Herbert Boyer at University of California, San Francisco, supported by both the NIH and the National Science Foundation (NSF).¹⁰⁶ Stanford later patented their inventions,¹⁰⁷ although both Cohen and Boyer were surprised by the idea, and Cohen initially renounced his share of the royalties.¹⁰⁸ These patents did have the benefit of bringing in \$255 million in licensing fees for Stanford,¹⁰⁹ although the patent system is far less efficient than direct taxing and spending at generating revenue for universities.¹¹⁰

The other innovation policy tools discussed above are more effective for research projects when the commercial application is less remote and speculative. Because many biomedical inventions can be cheaply imitated,¹¹¹ firms will have little incentive to commercialize inventions unless they have some way to recoup the cost of this commercialization.

For therapeutics requiring clinical trials to obtain FDA approval, the commercialization cost is quite high.¹¹² If *Myriad's* curtailment of patentable

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

107. 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).

108. 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).

109. 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).

110. Indeed, many university technology transfer offices do not turn a profit. See 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. 285 (2014) (reviewing this literature); see also 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).

111. 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. 672, 733 (2014) (citing Steven A. Berkowitz et al., *Analytical Tools for Characterizing Biopharmaceuticals and the Implications for Biosimilars*, 11 NATURE REVS. DRUG DISCOVERY 527, 527 (2012); and Savanna Steele et al., *Better Development of Biosimilars*, DRUG DISCOVERY & DEV. (June 11, 2013, 12:03 PM), <http://www.dddmag.com/articles/2013/06/better-development-biosimilars> [http://perma.cc/5FHR-BVL5] (“[T]echniques for characterizing the structural composition of biologic agents are advancing rapidly with the molecular structural characterization of these agents anticipated to approach 100% in the next five to 10 years.”)).

112. 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 Ouellette, *supra* note 64, at 302 (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

subject matter in fact restricts firms' ability to obtain meaningful patent protection for new "natural" therapeutics,¹¹³ it will likely deter firms from pursuing these products.¹¹⁴ 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,¹¹⁵ and its combination of grants, regulatory exclusivity, and tax credits appears to be quite effective.¹¹⁶ (Ironically, those supporting expansive patentable subject matter rules have cited the Orphan Drug Act as evidence of the success of patents.¹¹⁷) An alternative reward system might also be more effective than patents: many commentators argue that the current patent-based system provides insufficient incentives for investment in the most promising, cost-effective treatments, such as new uses of existing medicines or methods to reduce infections through hand washing that are not easily excludable.¹¹⁸ There are many proposals for nonpatent rewards for biotech and pharmaceutical companies based on the health impact of the new drugs they develop,¹¹⁹ 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 has been significantly lower. Patents thus have been 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—

conservative." F.M. Scherer, *R&D Costs and Productivity in Biopharmaceuticals* (Regulatory Policy Program Working Paper RPP-2011-10, 2011), http://www.hks.harvard.edu/m-rcbg/rpp/Working%20papers/RPP_2011_10_Scherer.pdf [<http://perma.cc/RJ5F-CLR6>].

113. Although patents on the products themselves may be unavailable, *see* Newman & Cragg, *supra* note 62, at 312, firms can still obtain method-of-treatment patents.

114. *See* Roin, *supra* note 73, at 566–67.

115. Orphan Drug Act of 1983, Pub. L. No. 97-414, 96 Stat. 2049 (codified as amended in scattered sections of 15 U.S.C., 21 U.S.C., 26 U.S.C., 35 U.S.C. & 42 U.S.C.).

116. Hemel & Ouellette, *supra* note 14, at 379–80 (reviewing studies).

117. *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. . ."); Brief for Amicus Curiae Lynch Syndrome Int'l in Support of Respondents, Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107 (2013) (No. 12-398), 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.'").

118. *See, e.g.*, Rebecca S. Eisenberg, *The Problem of New Uses*, 5 YALE J. HEALTH POLY 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 73; *see also* Eric Budish, Benjamin N. Roin & Heidi Williams, *Do Firms Underinvest in Long-Term Research? Evidence from Cancer Clinical Trials*, 105 AM. ECON. REV. 2044 (2015) (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).

119. *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, INCENTIVES FOR GLOBAL HEALTH, 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).

including the breast cancer genes at issue in *Myriad*—found that “[i]n none of the case studies was the test developed by the exclusive rights holder the first to market.”¹²⁰ This result suggests that exclusivity may not be necessary for commercialization of genetic tests, though it of course may spur discovery of the genetic correlation in the first place.

However, the FDA is taking steps to regulate diagnostic tests more heavily.¹²¹ And other work suggests that the line between therapeutics and diagnostics is blurring, and that both require a significant government incentive.¹²² But if it becomes evident post-*Myriad* that the expanded “nature” exception to patentability is leading to undercommercialization of genetic diagnostics, then additional nonpatent incentives could be added to this problem as well.

To be sure, it may be politically challenging to replace lost patent incentives with incentives that are reflected in government budgets because, as noted above, the costs of patents is hidden in the “shadow tax” of supracompetitive prices on patented products.¹²³ This apparent advantage of patents to taxpayers and politicians is illusory, and an important goal of innovation policy reform should be to increase the political salience of the patent system’s costs. But the political hurdles should not be overstated. As discussed above, researchers (and their lobbyists) have already convinced policymakers to devote significant tax revenues to other transfer mechanisms, and these on-budget transfers appear to be greater than the transfers through the patent system. And if the political costs of increasing these on-budget transfers are indeed insurmountable, the advantages of patents can be fairly directly replicated through increased regulatory exclusivity provisions.

B. “Abstract Ideas” and Software

Although the claims at issue in *Bilski* and *Alice* were not for software inventions per se,¹²⁴ the “abstract ideas” exception to patentability has significant

120. SEC’Y’S ADVISORY COMM. ON GENETICS, HEALTH, AND SOC’Y, U.S. DEP’T HEALTH & HUMAN SERVS., GENE PATENTS AND LICENSING PRACTICES AND THEIR IMPACT ON PATIENT ACCESS TO GENETIC TESTS 31 n.82 (2010), http://osp.od.nih.gov/sites/default/files/SACGHS_patents_report_2010.pdf [<http://perma.cc/4EXL-HCK4>]; see also Heidi L. Williams, *Intellectual Property Rights and Innovation: Evidence from the Human Genome*, 121 J. POL. ECON. 1, 1 (2013) (demonstrating that IP-like restrictions on human genes led to a 20–30% decrease in subsequent innovation).

121. See *supra* note 60 and accompanying text.

122. 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).

123. See Hemel & Ouellette, *supra* note 14, at 371, and accompanying text.

124. The claims in *Bilski* could but did not have to be performed on a computer. See *Bilski v. Kappos*, 561 U.S. 593, 596–99 (2010). In *Alice*, the patentee argued that “the claims are patent eligible because these steps ‘require a substantial and meaningful role for the computer,’” although the patent did not claim any particular software algorithm. *Alice Corp. Pty. v. CLS Bank Int’l*, 134 S. Ct. 2347, 2359 (2014). But as noted above, much of the briefing in these cases discussed a broader rule of software patent ineligibility. A precise definition of “software” is unimportant for this Article; in

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; Mark Lemley expects the *Alice* rule "to invalidate the majority of all software patents in force today."¹²⁵ (*Alice* may also have a significant impact on certain algorithm-based medical innovations,¹²⁶ but this Section focuses on more traditional algorithms.) Because this symposium is focused on the effects of *Myriad*, I review incentives for software in less detail. My goal in this Section is simply to illustrate that as in the case of biomedical research, many other public innovation incentives are available for software R&D, although the optimal mix of incentives will likely differ from the biomedical context.

1. Patent-like Incentives

There is no equivalent to FDA-administered regulatory exclusivity for software. However, nonpatent 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, trade secrets, and trademark protection.¹²⁷ Trademarks are not typically thought of as innovation incentives in the U.S. legal literature, but a growing body of economic scholarship emphasizes their role as an appropriation mechanism for innovators, particularly in the high-tech sector.¹²⁸ These other IP incentives may be more effective for software than patents, which often take longer to issue than the lifecycle of the corresponding software.¹²⁹

general, I am focusing on new algorithms and computer programs. Cf. Adam Mossoff, *A Brief History of Software Patents (and Why They're Valid)*, 56 ARIZ. L. REV. SYLLABUS 65 (2014) (discussing the many possible definitions for "software patent").

125. Scott Graham, *CLS Bank Ruling a Big Deal for Valley Software Patents*, RECORDER, June 19, 2014.

126. See, e.g., Guy Haskin Fernald et al., *Bioinformatics Challenges for Personalized Medicine*, 27 BIOINFORMATICS 1741 (2011); Marc Maegele et al., *Predictive Models and Algorithms for the Need of Transfusion Including Massive Transfusion in Severely Injured Patients*, 39 TRANSFUSION MED. & HEMOTHERAPY 85 (2012).

127. See Derek E. Bambauer & Oliver Day, *The Hacker's Aegis*, 60 EMORY L.J. 1051, 1068 (2011) (discussing how software vendors use all of these forms of IP protection); Michael Risch, *Trade Secret Law and Information Development Incentives*, in THE LAW AND THEORY OF TRADE SECRECY: A HANDBOOK OF CONTEMPORARY RESEARCH 152, 153 (Rochelle C. Dreyfuss & Katherine J. Strandburg eds., 2011) ("[A] computer software program may be simultaneously protected by copyright, patent and trade secret law."); see also Pamela Samuelson, *The Uneasy Case for Software Copyrights Revisited*, 79 GEO. WASH. L. REV. 1746 (2011).

128. See, e.g., Patrick Llerena & Valentine Millot, *Are Trade Marks and Patents Complementary or Substitute Protections for Innovation* (Bureau d'Économie Théorique et Appliquée Working Paper No. 2013-01, 2013) (finding that trademarks are a substitute for patents in the high-tech business sector). See generally Philipp Schautschick & Christine Greenhalgh, *Empirical Studies of Trade Marks: The Existing Economics Literature* (Melbourne Inst. Working Paper No. 25/13, 2013) (reviewing this literature).

129. See Eric Goldman, *The Problems with Software Patents (Part 1 of 3)*, FORBES (Nov. 28, 2012, 2:53 PM), <http://www.forbes.com/sites/ericgoldman/2012/11/28/the-problems-with-software-patents/> [<http://perma.cc/3ZLA-2SQK>].

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,¹³⁰ and additional grants are available at the state level.¹³¹ (In fiscal year 2011, U.S. universities expended an additional \$240 million of institutional funds on computer science R&D.¹³²) Many local governments have also directly supported software innovation by investing in broadband infrastructure.¹³³

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.¹³⁴ As noted above, these provisions together cost about \$11 billion per year,¹³⁵ with the portion going to software R&D likely around \$500 million to \$1 billion.¹³⁶ The federal government also supports the infrastructure necessary for many types of software innovation through the broadband sales tax exemption.¹³⁷ Additional R&D tax incentives are available at the state level.¹³⁸

4. Prizes

The federal government has offered numerous prizes for new software. For

130. NAT'L SCI. FOUND., NSF 14-213, FEDERAL FUNDS FOR RESEARCH AND DEVELOPMENT: FISCAL YEARS 2011–13, at 53 tbl.19 (2014), <http://www.nsf.gov/statistics/nsf14312/pdf/nsf14312.pdf> [<http://perma.cc/ZH35-BDDD>].

131. 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 CTR. FOR SCI. & ENG'G STATS., *supra* note 79, at 17 tbl.8.

132. Britt, *supra* note 81, at 2.

133. 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> [<http://perma.cc/Q6T7-A6AU>].

134. See, e.g., Ryan R. Coleman & Trevor Salzmann, *Cloud Computing and the Credit for Increasing Research Activities*, TAX ADVISER (Jan. 31, 2014), <http://www.thetaxadviser.com/issues/2014/feb/clinic-story-04.html> [<http://perma.cc/BS5X-MQZM>].

135. See STAFF OF THE JOINT COMM. ON TAXATION, *supra* note 84 and accompanying text.

136. Software firms spent \$27 billion on R&D in 2011, which was eleven percent of all industrial R&D spending, see Wolfe, *supra* note 85, at 2 tbl.2, and software firms claimed \$274 million under section 174 in 2005, which was four percent of the total claimed by all industries, see NAT'L SCI. FOUND., *supra* note 85, 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 four to nine percent of the total. Eleven percent of the \$11 billion spent on all R&D tax incentives is \$1.2 billion.

137. Internet Tax Freedom Act of 1998, Pub. L. No. 105-277, §§ 1100–1104, 112 Stat. 2681-719, 2681-719 to -28 (codified as amended at 47 U.S.C. § 151 (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).

138. See Hemel & Ouellette, *supra* note 14, at 325 n.112.

example, the Department of Veterans Affairs (VA) awarded over \$3 million for better patient scheduling software,¹³⁹ the Department of Defense awarded \$1 million for an algorithm that identifies organisms from a stream of DNA sequences,¹⁴⁰ and over 100 completed or ongoing government-prize competitions are listed on Challenge.gov.¹⁴¹ 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 $P=NP$,¹⁴² to the \$1 million prize Netflix awarded for an improved algorithm for predicting how much someone will enjoy a movie.¹⁴³

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 technologically risky because it is more predictable: software is less prone to unexpected failure or unwanted side effects than biomedical research. (Though there is still significant commercial risk in new software ventures.) Software also moves faster between the initial idea and the first sale as a commercialized product: the typical time to market for software products is five to fourteen months, compared with twelve to sixteen years for pharmaceuticals and one to ten years for in vitro diagnostics.¹⁴⁴

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.

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

139. See *Help Veterans Make Appointments for VA Outpatient and Ambulatory Care by Creating Systems that are Compatible with Open Source VistA and Help to Lead Health IT Transformation*, DEVPOST, <http://vascheduling.devpost.com/> [<http://perma.cc/7K4D-QTMG>] (last visited Nov. 15, 2015).

140. 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://media.ntu.edu.sg/Pages/newsdetail.aspx?news=a445a300-9a52-4b91-bc31-a9fb6ffc38a> [<http://perma.cc/6PWH-3YUG>].

141. CHALLENGE.GOV, <http://challenge.gov/list/?type=SoftwareApps> [<http://web.archive.org/web/20150706225540/https://www.challenge.gov/list/?type=SoftwareApps>] (last visited July 6, 2015).

142. *P vs NP Problem*, CLAY MATHEMATICS INST., <http://www.claymath.org/millennium-problems/p-vs-np-problem> [<http://perma.cc/MUV2-Z7HZ>] (last updated Nov. 19, 2015). See generally Lance Fortnow, *The Status of the P Versus NP Problem*, 52 COMM. ACM 78 (2009).

143. *Netflix Prize*, NETFLIX, <http://netflixprize.com> [<http://perma.cc/WU09-7SUL>] (last visited Nov. 15, 2015).

144. See Roin, *supra* note 111, 719 tbl.1.

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 nonpatent IP and R&D tax incentives—thus appear to be more effective at promoting software innovation. And these nonpatent financial transfers to innovators may be sufficient to lead to an efficient amount of research in this field.¹⁴⁵

Before turning to how these nonpatent 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.¹⁴⁶ This disclosure may be ineffective in many software patents,¹⁴⁷ and it is also unclear how well disclosure works in biotech patenting where physical materials and know-how are often critical.¹⁴⁸ 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 public reward could (and perhaps should) be conditioned on some level of disclosure.

III. PATENTABLE SUBJECT MATTER: AN EXTERNAL PERSPECTIVE

More widespread understanding of nonpatent 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.

First, greater emphasis on nonpatent 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. As discussed above, the dominant rationale for subject matter exceptions is

145. See Goldman, *supra* note 129 (arguing that software will be produced without any patent incentive because (1) it has significant first-mover advantages, (2) copyrights and trade secrets provide adequate incentives, and (3) software vendors can restrict competition without patents).

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

147. See Mark A. Lemley, *Software Patents and the Return of Functional Claiming*, 2013 WIS. L. REV. 905 (2013) (arguing that many software patents broadly claim functions that they do not disclose).

148. See Lisa Larrimore Ouellette, Note, *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.

utilitarian.¹⁴⁹ Yet many parties arguing for robust exceptions are motivated more by noneconomic moral concerns.¹⁵⁰ For example, amicus parties argued that the gene patent claims in *Myriad* “commodify[] human life” and “impinge[] on . . . rights of privacy,”¹⁵¹ that the diagnostic method claims in *Mayo* “should be invalidated as unconscionable violations of the freedom of thought,”¹⁵² and that software claims should be invalidated in *Bilski* because “the freedom to use a computer as one sees fit . . . is a fundamental form of expression”¹⁵³

Recognizing a broader range of solutions may help some of these different actors find more common ground for consensus. For example, those who are morally opposed to granting a property interest in human genes through the patent system and those who think genetic research will be undersupplied absent significant and predictable transfers to innovators might both be satisfied with an expanded package of tax incentives, prizes, grants, or regulatory exclusivity for genetic R&D. Of course, such a consensus would require those who are morally opposed to gene patents to agree that the private market will not produce sufficient R&D absent state incentives, and it would require those who want additional public support for innovators to recognize that their goals can be met through nonpatent incentives. And this solution would not satisfy all participants in these debates, including those who think patents are morally required,¹⁵⁴ or utilitarians who view patents as strictly superior to nonpatent incentives (despite the lack of empirical support for this position¹⁵⁵). 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.

In addition to resolving some conflicts between utilitarians and those with competing concerns, nonpatent incentives may also be more effective in disputed subject matter areas from a purely utilitarian perspective. There are at least three distinct reasons why this seems likely to be so. First, the patent incentive is strongest when patent law is clear and predictable so that it can guide long-term investment decisions, so patents’ effectiveness is certainly reduced by the

149. See *supra* notes 27–28 and accompanying text. *But see* ROBERT P. MERGES, JUSTIFYING INTELLECTUAL PROPERTY 4–9 (2011) (developing a deontic theory of IP rights, with economic efficiency as a “midlevel principle”).

150. See Chiang, *supra* note 16, at 1873–85; Jorge L. Contreras, Narratives of Gene Patenting (July 21, 2014) (unpublished manuscript), https://www.law.berkeley.edu/files/Contreras_Jorge_IPSC_paper_2014.pdf.

151. Brief for Canavan Found. et al. as Amici Curiae in Support of Petitioners, Ass’n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. 2107 (2012) (No. 12-398), 2012 WL 5398891, at *14.

152. Brief of Amici Curiae Cato Inst. et al. in Support of Petitioners, Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289 (2012) (No. 10-1150), 2011 WL 4071914, at *31.

153. Brief for Free Software Found. as Amicus Curiae in Support of Respondents, *Bilski v. Kappos*, 561 U.S. 593 (2010) (No. 08-964), 2009 WL 3199627, at *24.

154. 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).

155. However, I do not think this position is supported by existing empirical evidence. See Ouellette, *supra* note 55, at 75–83.

profound uncertainty about their long-term availability in contested areas such as software or genetic research. While the optimal balance between patents and other innovation policies is empirically uncertain, we can at least be confident that nonpatent incentives are comparatively more valuable in areas where patents are less effective.

Second, patents are most effective at spurring innovation when most researchers actually view them as an incentive. Innovators who share moral concerns about patenting—programmers who “believe that software is thought, and math, and that no one can own it,”¹⁵⁶ or researchers who think that “[p]atents on human genes . . . violate ethical tenets”¹⁵⁷—naturally find little incentive from patents. Since these innovators’ moral concerns with patents seem to focus on the *properization* of certain kinds of knowledge, they may be more incentivized by mechanisms that do not rely on exclusivity as a financing mechanism. Nonpatent incentives may thus provide stronger incentives to a broader range of researchers in contested areas.

Third, the patentable-subject-matter debates have arisen in areas in which many scholars are concerned that the patent system is failing due to factors like high transaction costs or difficulty screening out invalid patents. For example, scholars have long been concerned about the potential negative effects of property rights on “upstream” scientific discoveries such as DNA.¹⁵⁸ And leading academics gathered in 2012 at a conference devoted to “Solutions to the Software Patent Problem.”¹⁵⁹ Despite these concerns, some scholars have argued that patents on software or upstream innovations should not be barred because there is valuable, nonobvious work to be done in these areas, so at least *some* patents will be beneficial.¹⁶⁰ However, it may make more sense to use patentable subject matter as a coarse filter in these areas,¹⁶¹ and to use nonpatent incentives to reward the valuable inventions that fall through this filter.

To be clear, I am not necessarily arguing for more field-specific tailoring of substantive patent law based on economic balancing.¹⁶² For those who think that

156. Michael Risch, *Two Worlds of Software Patents*, PRAWFSBLAWG (Nov. 27, 2012, 10:28 PM), <http://prawfsblawg.blogs.com/prawfsblawg/2012/11/two-worlds-of-software-patents.html> [<http://perma.cc/M6SK-V2AA>].

157. Brief of Amici Curiae Am. Med. Ass’n et al. in Support of Petitioners, Ass’n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107 (2013) (No. 12-398), 2013 WL 390998, at *4.

158. See Ouellette, *supra* note 148 (reviewing this literature).

159. See *Solutions to the Software Patent Problem*, SANTA CLARA L., <http://law.scu.edu/hightech/2012-solutions-to-the-software-patent-problem/> [<http://perma.cc/3BPW-WE6P>] (last visited Nov. 15, 2015).

160. See, e.g., Dmitry Karshedt, *The Completeness Requirement in Patent Law*, 56 B.C. L. REV. 949 (2015); Risch, *supra* note 156.

161. See John M. Golden, *Patentable Subject Matter and Institutional Choice*, 89 TEX. L. REV. 1041, 1066 (2011) (developing a simple model to illustrate how such a coarse filter can be welfare enhancing, assuming that the PTO makes mistakes in its more particularized determinations).

162. On the prevalence of industry-specific tailoring in patent law, see Burk & Lemley, *supra* note 42.

patentable-subject-matter doctrine should be based on judicial balancing of incentives for each type of invention, the prevalence of nonpatent incentives implies that courts must look beyond patents. Under this approach, the boundaries of patentable subject matter would necessarily change over time as Congress supplies or removes alternative incentives. But there is little reason to think that courts are particularly good at this kind of comprehensive economic analysis.¹⁶³ Of course, courts might be the least bad option: the PTO and other innovation-focused agencies lack coordination,¹⁶⁴ and Congress has been politically deadlocked. A full comparative institutional analysis is beyond the scope of this Article; my point is simply that judicial balancing of economic incentives is not the only approach.

Rather than dictating to courts how they should decide patentable-subject-matter cases, my argument is simply that courts should not allow concerns about eliminating innovation incentives to trump other concerns. Courts can focus on whatever analytical tools seem most appropriate, including textual analysis, historical exclusions for “nature,” moral concerns about propertizing certain kinds of information, or the need for stable and predictable doctrine. The latter seems particularly important in patent law, where rules are supposed to be guiding investment decisions made on multidecade timescales. Greater recognition of nonpatent incentives may prevent courts from worrying so much that a clear and predictable subject matter rule will allow many valuable inventions to fall through the cracks—those inventions can be caught by the safety net of other public incentives, and policymakers can step in to tailor innovation policy around whatever bright lines the courts set up. Recognition that insufficient patent incentives can be supplemented with other transfer mechanisms may give courts more confidence in drawing clearer patentable-subject-matter boundaries, improving this doctrinal morass.

163. See Stuart Minor Benjamin & Arti K. Rai, *Fixing Innovation Policy: A Structural Perspective*, 77 GEO. WASH. L. REV. 1, 33–40 (2008).

164. See generally *id.* (proposing such an agency). However, the PTO now has an Office of the Chief Economist, which was created in March 2010 with research goals including “[u]ncovering how IP relates to economic growth, performance and employment.” Press Release, U.S. Patent & Trademark Office, USPTO Chief Economist Unveils Agency’s New Economic Research Agenda During Conference on Intellectual Property and the Innovation Economy (Dec. 9, 2010), <http://www.uspto.gov/about-us/news-updates/uspto-chief-economist-unveils-agencys-new-economic-research-agenda-during> [<http://perma.cc/KN49-3FMC>]. Many other agencies also affect patent policy. See Tejas N. Narechania, *Patent Conflicts*, 103 GEO. L.J. 1483 (2015); Jacob S. Sherkow, *Administering Patent Litigation*, 90 WASH. L. REV. 205 (2015). During rulemaking, “[e]ach agency shall also seek to identify, as appropriate, means to achieve regulatory goals that are designed to promote innovation.” Exec. Order No. 13,563, 76 Fed. Reg. 3821 (Jan. 18, 2011). It thus seems plausible that the dialog among these agencies could lead to better innovation policy than courts deciding particular patent cases. See generally Arti K. Rai, *Patent Validity Across the Executive Branch: Ex Ante Foundations for Policy Development*, 61 DUKE L.J. 1237, 1242 (2012) (discussing the value of “[s]ystematic interagency debate” in setting innovation policy).

CONCLUSION

Although most commentators agree that the primary justification for the patent laws is economic utilitarianism, this does not mean that every patent doctrine is best approached from a utilitarian perspective. There are likely many welfare-enhancing inventions relating to genes and algorithms for which the expected cost to the innovator is greater than the private benefit that can be appropriated without state intervention, so state-facilitated transfers that help close this gap are socially valuable. And yet there may be good reasons—including noneconomic ones—to limit the extent to which patent law is the primary policy tool for closing this gap. It may thus make more sense to define these patentable-subject-matter exclusions in ways that are relatively easy to apply, and to leave the utilitarian tailoring to other innovation policies.

But my key point is simply that whatever courts do with patentable-subject-matter doctrine, they should not do it with patent blinders. The state provides financial transfers to innovators through a vast array of nonpatent incentives, and it could provide more. Ignoring these nonpatent incentives in patentable-subject-matter debates is a mistake.

