

Essay

PATENT VALIDITY ACROSS THE EXECUTIVE BRANCH: EX ANTE FOUNDATIONS FOR POLICY DEVELOPMENT

ARTI K. RAI†

INTRODUCTION

In patent law, as in most areas of law, Congress, courts, and administrative agencies are the key institutions with the potential to shape policy.¹ In practice, though, courts have generally been regarded as the dominant players in shaping patent policy. This perception of judicial dominance is grounded in several notable features of the patent system. Since 1790, when the first patent statute² was enacted, patent legislation has been remarkably general in its provisions. Even when Congress has passed legislation to update

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† Elvin R. Latty Professor of Law, Duke University School of Law and Duke Institute for Genome Sciences and Policy. From 2009 to 2010, I served as the administrator of the U.S. Patent and Trademark Office's (PTO's) Office of External Affairs (now titled the Office of Policy and External Affairs). Prior to assuming the role of administrator, I served as an expert adviser to the Department of Commerce's Office of General Counsel. This Essay, however, represents only my personal views.

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1. I use the term "patent policy" advisedly. I mean to distinguish it from the determinations of science-related adjudicative facts, such as the state of the scientific art at the time the patent applicant filed for her invention, which represent an important mechanism by which patent-validity standards implement the policy goal of innovation. See Stuart Minor Benjamin & Arti K. Rai, *Who's Afraid of the APA? What the Patent System Can Learn from Administrative Law*, 95 GEO. L.J. 269, 276–77 (2007) (discussing the requirement that a patentable invention be scientifically "nonobvious" and noting that this requirement is premised on the view that if the invention were obvious, it could have arisen without a patent incentive). Policy is also distinct from questions of pure law, to which the patent statute provides clear answers.

2. Act of Apr. 10, 1790, ch. 7, 1 Stat. 109.

the Patent Act of 1952 (Patent Act),³ the amendments have typically left significant room for interpretation. Rather than passing more detailed provisions, Congress has instead delegated responsibility for interpreting the statute to the U.S. Patent and Trademark Office (PTO) and the courts—with a historical emphasis on the courts. The judicial nature of patent law has been particularly evident since 1982, when Congress created a single specialized court, the U.S. Court of Appeals for the Federal Circuit, to hear all appeals in patent cases.⁴ These appeals include direct challenges to the PTO's denial of patent applications. They also include challenges to the decisions of regional trial courts regarding patent validity and infringement with respect to previously granted patents.

Perhaps not surprisingly, then, the institutional debate has often focused on the Federal Circuit. Many patent scholars have written about the Federal Circuit, and some law reviews have devoted entire issues to analysis of the Federal Circuit as an institution.⁵

But other institutions are also beginning to compete for institutional primacy. The Supreme Court's increasingly assertive review of the Federal Circuit has prompted many articles discussing the Court's institutional role.⁶ Even the PTO, long considered a weak agency because of its limited rulemaking power, has begun to flex its muscle. In recent years, the PTO has repeatedly challenged Federal

3. The most recent fully codified version of the patent statute is found at 35 U.S.C. §§ 1–376 (2006 & Supp. IV 2010). This version does not include, however, significant amendments made in 2011.

4. Federal Courts Improvement Act of 1982, Pub. L. No. 97-164, 96 Stat. 25 (codified as amended in scattered sections of 28 U.S.C.). For a discussion comparing and contrasting the Federal Circuit's jurisdiction with that of its predecessor court, the Court of Customs and Patent Appeals, see generally Jeffrey Lefstin, *The Constitution of Patent Law: The Court of Customs and Patent Appeals and the Shape of the Federal Circuit's Jurisprudence*, 43 LOY. L.A. L. REV. 843 (2010).

5. E.g., Symposium, *The Federal Circuit as an Institution*, 43 LOY. L.A. L. REV. 749 (2010); Symposium, *The Federal Circuit: The National Appellate Court Celebration and Introspective Symposium*, 78 GEO. WASH. L. REV. 513 (2010).

6. See, e.g., Rochelle Cooper Dreyfuss, *What the Federal Circuit Can Learn from the Supreme Court—And Vice Versa*, 59 AM. U. L. REV. 787, 793 (2010) (“Supreme Court involvement in Federal Circuit decisions should be regarded as highly salutary, for these two tribunals have a great deal to learn from one another.”); John Golden, *The Supreme Court as “Prime Percolator”: A Prescription for Appellate Review of Questions in Patent Law*, 56 UCLA L. REV. 657, 662 (2009) (arguing that Supreme Court review of patent decisions is important but that it should be relatively circumscribed); Peter Lee, *Patent Law and the Two Cultures*, 120 YALE L.J. 2, 42–62 (2010) (discussing and critiquing the “holistic” approach taken by the Supreme Court in its patent jurisprudence).

Circuit decisions before the Court.⁷ The PTO also succeeded in securing passage of the 2011 America Invents Act (AIA).⁸ Although the AIA did not give the agency the expansive rulemaking authority over questions of substantive patent law that had been proposed in earlier versions of the legislation, the AIA did confer upon the PTO the ability to conduct postgrant review proceedings that resemble formal adjudications.⁹ Under standard administrative law, formal adjudication is a salient mechanism through which agencies make policy. Based on these developments, patent-law scholars are beginning to treat the PTO as a full-fledged participant in the institutional debate.

To some extent, patent-law scholars have also begun to recognize the policymaking role of agency actors beyond the PTO. For the most part, the literature has focused on the International Trade Commission (ITC) and the Federal Trade Commission (FTC). Scholars note that the ITC—which issues injunctions barring the entry of goods that infringe valid U.S. patents—affects patent policy, particularly policy related to remedies for infringement.¹⁰ The literature on the FTC emphasizes the agency’s prominent role in investigating the antitrust implications of patent-litigation settlements between brand-name- and generic-pharmaceutical firms.¹¹

7. See *infra* notes 29–31.

8. Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) (to be codified in scattered sections of 15, 28, 35, 42, and 51 U.S.C.).

9. Prior to the AIA, the American Inventors Protection Act of 1999, Pub. L. No. 106-113, tit. IV, 113 Stat. 1501A-552, had given the PTO some ability to conduct inter partes adjudicatory proceedings, as well as additional authority over internal managerial matters. See generally Clarisa Long, *The PTO and the Market for Influence in Patent Law*, 157 U. PA. L. REV. 1965, 1972–75 (2009) (discussing these developments).

10. See, e.g., Colleen V. Chien, *Patently Protectionist? An Empirical Analysis of Patent Cases at the International Trade Commission*, 50 WM. & MARY L. REV. 63, 73–80 (2008) (discussing various aspects of the ITC’s role in the patent system); Sapna Kumar, *Expert Court, Expert Agency*, 44 U.C. DAVIS L. REV. 1547, 1551 (2011) (“[T]he ITC can grant broad exclusion orders to companies whose patents have been infringed by imported goods.”); Sapna Kumar, *The Other Patent Agency: Congressional Regulation of the ITC*, 61 FLA. L. REV. 529, 533 (2009) (“[T]he ITC makes patent policy that is sometimes in tension with the purpose of the patent system.”); David Schwartz, *Courting Specialization: An Empirical Study of Claim Construction Comparing Patent Litigation Before Federal District Courts and the International Trade Commission*, 50 WM. & MARY L. REV. 1699, 1728 (2009) (“Counterbalancing the lack of damages, injunctions are awarded under a more liberal standard in the ITC.”).

11. See Daniel Crane, *Technocracy and Antitrust*, 86 TEX. L. REV. 1159, 1200–01, 1206–11 (2008) (detailing the FTC’s extensive involvement in the issue of reverse payments and arguing that the FTC’s adjudicatory position in settlements essentially adopts a rule that should be given deference under *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984)); C. Scott Hemphill, *An Aggregate View of Antitrust: Using New Data and Rulemaking*

That non-PTO agency actors play a significant role in specific areas of patent policy *beyond* patent validity is unsurprising. After all, under the Patent Act, the PTO's decisionmaking authority is largely confined to the adjudication of questions of patent validity.¹² More notable is the manner in which the Supreme Court's renewed interest in patent law has transformed the executive branch's Supreme Court litigator, the Department of Justice's (DOJ's) Office of the Solicitor General (SG), into a significant player in patent policy across the board, *including* on core issues of patent validity.¹³

In many respects, however, the SG is a generalist actor that refines and arbitrates among the views of underlying agencies that have more specialized expertise in the legal questions at issue. These underlying agencies themselves play a powerful role in shaping the litigation positions taken by the SG and by the DOJ more generally. Yet scholars have generally failed to explore the influence exercised by these underlying agencies, whether before the Supreme Court or in other contexts.

A striking and candid acknowledgment of these agencies' influence emerged in *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office (Myriad II)*,¹⁴ a 2011 case involving a challenge to breast-cancer-gene-related patents held by the diagnostic firm Myriad on the ground that the patents covered subject matter that should not have been eligible for patenting.¹⁵ The amicus brief filed by the U.S. government in that case observed:

The extent to which basic discoveries in genetics may be patented is a question of great importance to the national economy, to medical science, and to the public health. This appeal consequently implicates the expertise and responsibilities of a wide array of

To Preserve Drug Competition, 109 COLUM. L. REV. 629, 639–40 (2009) (discussing both adjudicatory actions by the FTC and the possibility of the FTC's engaging in rulemaking with respect to reverse payments in settlements of patent disputes between brand-name- and generic-pharmaceutical firms).

12. See Patent Act of 1952, 35 U.S.C. § 2(a)(1) (2006) (providing that the PTO "shall be responsible for the granting and issuing of patents").

13. See John F. Duffy, *The Federal Circuit in the Shadow of the Solicitor General*, 78 GEO. WASH. L. REV. 518, 519 (2010) ("The innovative jurisdictional structure of the new appellate court has fostered a unique relationship between the Federal Circuit and the Solicitor General's Office and has, in a subtle but meaningful way, shifted power over the development of patent law from the judicial to the executive branch of government.").

14. *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office (Myriad II)*, 653 F.3d 1329 (Fed. Cir. 2011).

15. *Id.* at 1339–40, 1355.

federal agencies and components, including the [PTO], the National Institutes of Health . . . , the Antitrust Division of the Department of Justice, the Centers for Disease Control and Prevention, the Office of Science and Technology Policy, and the National Economic Council, among others.¹⁶

That the government saw the need specifically to identify the interests of agencies other than the PTO that were interested in the *Myriad* litigation is unsurprising, given that its amicus brief urged the court to reject a decades-old PTO practice of treating almost all DNA as patentable subject matter.¹⁷

Viewed on its own, the *Myriad* litigation might be seen as *sui generis*—a case in which many agencies got involved only because of the emotional resonance of the plaintiffs' allegations that Myriad was using its patents to deny access to breast-cancer testing. But the involvement of agencies other than the PTO in core questions of DNA-patent validity is not an isolated event. To the contrary, the National Institutes of Health (NIH) has, since the early 1990s, substantially influenced the evolution of DNA-patent jurisprudence. Indeed, the available empirical evidence indicates that NIH influence, primarily manifested in two sets of PTO guidelines issued in 2001, has been an important factor in mitigating the development of a patent thicket in the area of DNA-related research.¹⁸ NIH's persistent interest in the issue of DNA patenting is hardly surprising. NIH is by far the biggest funder of biomedical research in the world. It funds over \$30 billion of academic biomedical research annually, a significant percentage of which leads to patents, including patents that relate to, or encompass, nucleic acids.¹⁹

As a normative matter, investigating the policymaking role of agency actors other than the PTO in patent law contributes to the

16. Brief for the United States as Amicus Curiae in Support of Neither Party at 1, *Myriad II*, 653 F.3d 1329 (No. 2010-1406).

17. The government's brief did not address Myriad's DNA-related process/method claims. For this reason, I focus in this Essay on the product claims. *See infra* Part I.B.2.

18. *See infra* Part I.B.2.

19. For example, analysis of the leading public database of DNA patents shows that the University of California system is the third-largest holder of DNA patents. *See* Robert Cook-Deegan & Christopher Heaney, *Patents in Genomics and Human Genetics*, 11 ANN. REV. GENOMICS & HUM. GENETICS 383, 388 fig.3 (2010) (indicating that the University of California system holds approximately 1200 patents). Not only do academic institutions such as the University of California hold DNA patents that stem from NIH funding, but NIH's intramural research program also yields many DNA patents: the same DNA-patent database shows that NIH is the fifth-largest holder of U.S. DNA patents. *Id.*

debate over institutional choice in patent policy. Critics of a policymaking role for the PTO, even a role limited to the context of patent validity, have expressed concern about agency capture.²⁰ The capture issue, however, is not only more complex than has been conventionally understood but is also mitigated by the reality that, at least in significant DNA-related cases, PTO decisionmaking is embedded in the larger institutional apparatus of the executive branch. Although debate among knowledgeable agencies with different perspectives may not always yield the right conclusion, it is at least likely to produce conclusions that are plausible. The existence of this interagency debate should be a factor that counsels in favor of judicial deference to determinations of patent policy by the executive branch.

Moreover, although interagency debate has, to date, generally been limited to the DNA context, one can imagine the creation of institutional structures that would allow agency actors with perspectives differing from those of the PTO to play a more systematic role. Agencies such as the FTC and the DOJ Antitrust Division, which have missions that emphasize innovation through competition, are obvious candidates. To ensure the requisite White House coordination, a core executive-branch agency such as DOJ Antitrust may be more suitable than an independent agency such as the FTC.²¹

Systematic interagency debate would be particularly useful if begun *ex ante*. Although *ex ante* action should be subject to revision, policymaking that is conducted entirely *ex post* has considerable associated liabilities. Most obviously, *ex post* approaches produce delay and uncertainty. Moreover, as this Essay's discussion of the

20. See, e.g., DAN L. BURK & MARK A. LEMLEY, *THE PATENT CRISIS AND HOW COURTS CAN SOLVE IT* 106–07 (2009) (“The Patent and Trademark Office interacts regularly with those seeking patents, but very little with third parties affected by the patents they grant.”); Craig Allen Nard, *Legal Forms and the Common Law of Patents*, 90 B.U. L. REV. 51, 57 (2010) (discussing “capture-prone administrative rulemaking”).

21. The administrative-law literature on whether (and to what extent) independent agencies should be subject to White House control is voluminous. For purposes of this Essay, I do not take a position on this literature, except to note the practical point that both scholars and policymakers consider White House coordination of executive-branch agencies less controversial than White House coordination of independent agencies. Cf. Elena Kagan, *Presidential Administration*, 114 HARV. L. REV. 2245, 2320 (2001) (“[M]ost statutes granting discretion to executive branch—but not independent—agency officials should be read as leaving ultimate decisionmaking authority in the hands of the President.”).

Myriad litigation illustrates,²² the passage of time can significantly constrain available policy options. Appellate courts that adjudicate disputes *ex post* will justifiably be concerned about the retroactive effects of their decisionmaking on large numbers of existing patents. Additionally, as discussed in this Essay, to the extent that concerns about retroactive effects are more salient to courts when they contract patent rights than when they expand such rights, *ex post* adjudicatory approaches may yield a one-way ratchet in favor of expansion.

A larger role for *ex ante* decisionmaking would not necessarily require the PTO, or the executive branch more generally, to have rulemaking authority over patent validity. Although such authority would produce controlling law more quickly, reasonably expeditious and deferential review of guidelines would achieve many of the benefits of such authority. Indeed, to the extent that guidelines were to be implemented in a postgrant review proceeding that resembled a formal adjudication, the strong form of deference enunciated by the Court in *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*²³ and its progeny would be applicable. Importantly, a guideline-focused approach would also be more politically feasible than a wholesale shift to PTO rulemaking.

Part I of this Essay discusses and adds to the existing literature on patent policymaking by agencies. It focuses on the particularly pervasive role that one executive-branch agency, NIH, has played in DNA-patenting debates. Part II sets out several criteria—including expertise, relative insulation from capture, and at least some ability to act prospectively—that are desirable for the patent-policymaking apparatus to have. It further argues that active involvement by other executive-branch agencies would diminish concerns about PTO capture, concerns that continue to represent the most important objection to establishing a significant PTO policymaking presence. As the DNA-patenting cases demonstrate, decisions on which knowledgeable agencies with different perspectives agree *ex ante* should be worthy of respect by reviewing courts. Part III considers how the executive branch could be more involved in setting patentability policy *ex ante*, not only in the area of DNA patenting but also more generally. It uses software patenting as an example of an arena in which *ex ante* approaches might have been useful. Part III

22. See *infra* Part I.B.2.

23. *Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984).

evaluates the role that an agency that emphasizes innovation through competition—such as the DOJ Antitrust Division—could play as an interlocutor for the PTO. Part IV asks whether the PTO should be given rulemaking authority over questions of substantive patent law, particularly if such authority were to require consultation with sister agencies. It concludes that although this step is probably not politically feasible, an approximation of that kind of authority could be achieved through swift and deferential review of PTO decisions that apply administrative guidelines.

I. THE POLICY ROLE OF AGENCY ACTORS OUTSIDE THE PTO

This Part addresses the role of agency actors other than the PTO. Section A reviews the existing literature with a particular focus on discussions of the role played by the SG. Section B relates in detail the extensive role played by NIH and other life-science agencies in determining executive-branch positions on such patent-validity requirements as utility, written-description, and patentable-subject-matter.

A. Existing Literature

Although the literature discussing the role of agency actors in making patent policy has historically focused on the PTO, scholars have begun to examine three other actors: the ITC, the FTC, and the SG.

The Supreme Court's 2006 decision in *eBay Inc. v. MercExchange, L.L.C.*,²⁴ significantly bolstered the influence of the ITC. That case held that under patent law's traditional equitable principles, it is inappropriate for a district court automatically to order injunctive relief upon a finding that a patent is valid and infringed.²⁵ The *eBay* case did not, however, affect the ITC's legislative authorization to exclude goods from the United States upon a finding that they infringe a valid patent; thus, the case made the ITC an attractive forum for patentees and a potentially important policy actor in the area of remedies.²⁶

24. *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006).

25. *See id.* at 393 (“To the extent that the District Court adopted such a categorical rule, then, its analysis cannot be squared with the principles of equity adopted by Congress.”); *see also supra* note 10 and accompanying text.

26. Additionally, the ITC has played a policymaking role in the narrow arena of what constitutes a valid defense against charges of infringement in the context of imported goods. It

Scholars have also discussed the FTC and the prominent role it has played in the debate about the antitrust concerns raised by settlements in patent disputes between brand-name- and generic-pharmaceutical firms. Several recent contributors to this debate argue that courts should give greater deference to FTC positions with respect to these settlements.²⁷

Most relevantly for this Essay's purposes, Professor John Duffy highlights the role of the SG in working with the PTO and other interested agencies to shape patent policy across the board, including policy on core questions of patent validity. The SG's increasing influence is largely a consequence of the Court's decision to begin taking significantly more patent cases than it has in the past.²⁸ Indeed, from 1996 through June 2011, the Court granted certiorari in almost as many patent cases as the Federal Circuit heard en banc—nineteen Supreme Court cases to twenty-three en banc Federal Circuit cases.²⁹

The data show that the executive branch participated either as a party or as an amicus in seventeen of the nineteen Supreme Court cases.³⁰ In ten of those seventeen cases, the executive branch

has played that role because the Federal Circuit has chosen to give the strong form of administrative deference enunciated by *Chevron* to certain ITC interpretations of the trade-related statutes the agency interprets. *See Kinik Co. v. Int'l Trade Comm'n*, 362 F.3d 1359, 1363 (Fed. Cir. 2004) (“To the extent that there is any uncertainty or ambiguity in the interpretation of [the statute], deference must be given to the view of the agency that is charged with its administration.”).

27. *See supra* note 11 and accompanying text.

28. *See Duffy, supra* note 13, at 523 (discussing the Court's return to patents beginning in the mid- to late 1990s).

29. Specifically, from 1996 through June 2011, the Court took nineteen cases. This figure is derived by taking the sixteen cases identified by Professor Duffy, *see id.* at 539, and adding to them the three patent cases (*Board of Trustees of the Leland Stanford Junior University v. Roche Molecular Systems, Inc.*, 131 S. Ct. 2188 (2011), *Microsoft Corp. v. i4i Ltd.*, 131 S. Ct. 2238 (2011), and *Global-Tech Appliances, Inc. v. SEB S.A.*, 131 S. Ct. 2060 (2011)) that the Court heard in its 2010 Term. According to Professor Jason Rantanen, from 1996 through March 2011, the Federal Circuit heard twenty-two cases en banc. Jason Rantanen, *Federal Circuit En Banc Patent Decisions*, PATENTLY-O (Mar. 8, 2011, 4:23 PM), <http://www.patentlyo.com/patent/2011/03/federal-circuit-en-banc-patent-decisions.html>. If one adds to that list *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276 (Fed. Cir. 2011) (en banc), decided by the Federal Circuit en banc in May 2011, one arrives at a total of twenty-three cases.

30. I reviewed the government's briefs in these seventeen cases to determine which agencies were listed on the briefs. The PTO was on the brief in all of the cases other than *Stanford*. That case involved patent issues raised by the Bayh-Dole Act, 35 U.S.C. §§ 200–212 (2006 & Supp. IV 2010), a statute governing the patentability of federally funded research that is not administered by the PTO, but by a sister agency within the Commerce Department: the National Institute of Standards and Technology. I address relevant questions raised by the inconsistent administration of the Bayh-Dole Act in Part II.C. *See infra* notes 143–44 and accompanying text. In addition to the PTO, the FTC was on the brief in *Illinois Tool Works v.*

disagreed with the Federal Circuit. And in all but one of those ten cases, the Court sided with the SG over the Federal Circuit.³¹

Two of the Court's most prominent decisions on core patentability questions—its 2010 decision in *Bilski v. Kappos*³² and its 2007 decision in *KSR International Co. v. Teleflex Inc.*³³—illustrate the strength of the executive branch's persuasive powers. *Bilski* addressed the threshold requirement of patentable subject matter—that is, the threshold requirement that an allegedly inventive product or process represent patent-eligible subject matter in the first instance. In *Bilski*, the PTO's position on behalf of the government regarding how best to identify processes that constitute patent-eligible subject matter was in tension with that taken by many three-judge panels of the Federal Circuit.³⁴ The government's proposed test—considering whether the process involved a machine or physical transformation—did not fully convince the Court. The Court did, however, state that the case provided a helpful “clue.”³⁵

Independent Ink, 547 U.S. 28 (2006), which addressed the question of whether a patent should be presumed to confer monopoly power. The Department of Health and Human Services was on the brief in *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193 (2005), which addressed the scope of the exemption from patent infringement provided in the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in scattered sections of 15, 21, 28, and 35 U.S.C.). As noted in the text, however, for cases litigated before the Supreme Court, the SG plays something of a convening role across the executive branch. Thus, interested agencies can and do provide input even when they are not explicitly listed on the brief.

31. The single case in which the Federal Circuit's position won out over the SG's position was *Stanford*. Thus the 9–0 winning streak cited by Professor Duffy in his article, see Duffy, *supra* note 13, at 540, had ended by the end of the 2010 Term.

32. *Bilski v. Kappos*, 130 S. Ct. 3218 (2010).

33. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007).

34. Sitting en banc in *Bilski*, the Federal Circuit largely adopted the position urged by the government. *In re Bilski*, 545 F.3d 943, 964 (Fed. Cir. 2008) (en banc) (“[W]e agree with the PTO that the machine-or-transformation test is the correct test to apply in determining whether a process claim is patent-eligible under [35 U.S.C. § 101].”), *aff'd sub nom. Bilski v. Kappos*, 130 S. Ct. 3218 (2010). In so doing, however, it also rejected the positions previously taken by many three-judge Federal Circuit panels.

35. *Bilski*, 130 S. Ct. at 3227. In any event, the Court's 5–4 decision to adopt a highly nebulous “abstraction” standard for whether an innovation constitutes patentable subject matter in the context of a process claim was, at best, only an initial step. Many commentators have complained about the lack of guidance provided by *Bilski*. See, e.g., Peter S. Menell, *Forty Years of Wondering in the Wilderness and No Closer to the Promised Land: Bilski's Superficial Textualism and the Missed Opportunity To Return Patent Law to Its Technology Mooring*, 63 STAN. L. REV. 1289, 1305–07 (2011) (discussing the costs of the Supreme Court's “ungrounded and incoherent” decisionmaking in the *Bilski* case). Shortly thereafter, the Court granted certiorari in another dispute about process as patentable subject matter, *Prometheus Laboratories, Inc. v. Mayo Collaborative Services*, 628 F.3d 1347 (Fed. Cir. 2010), *cert. granted*,

Although *Bilski* represented only a partial win for the government, *KSR* was an unequivocal win. *KSR* involved the patentability requirement of nonobviousness, generally considered to be the most important of the various patentability requirements.³⁶ To demonstrate nonobviousness, an applicant must show that her invention would not have been obvious to a scientist with “ordinary skill” in the relevant area of science.³⁷

Nonobviousness disputes often turn on whether relevant prior inventions and publications, known as “prior art,” can appropriately be combined to show obviousness. For years, the PTO’s position on combining prior art to show nonobviousness was rebuffed by the Federal Circuit. Specifically, to demonstrate the obviousness of an applicant’s invention, many three-judge panels required PTO examiners to identify in the prior art a specific document that provided a “teaching, suggestion, or motivation” (TSM) that had prompted the applicant to combine the prior art. Over a number of years, the PTO repeatedly argued that its examiners should not always have to point to documentary evidence indicating that particular prior art references should be combined. Rather, according to the PTO, in keeping with pre-Federal Circuit case law on official notice,³⁸ examiners should be able to invoke their own knowledge of what an ordinary scientist in the relevant area would be capable of doing.³⁹ But the Federal Circuit was not convinced. Although Federal

131 S. Ct. 3027 (2011), a case that raised the question of whether a process that involves administering a drug and then measuring metabolite levels to calibrate further dosages represented patentable subject matter. A petition for certiorari was also filed in the *Myriad II* case in late 2011. Petition for a Writ of Certiorari, Ass’n for Molecular Pathology v. Myriad Genetics, Inc. (U.S. Dec. 6, 2011), available at http://www.aclu.org/files/assets/association_of_molecular_v_myriad_petition_for_writ_of_certiorari.pdf.

36. See, e.g., Irving Kayton, *Nonobviousness of the Novel Invention—35 U.S.C. §103*, in NONOBVIOUSNESS—THE ULTIMATE CONDITION OF PATENTABILITY 2:101, 2:102 (John F. Witherspoon ed., 1980) (“[I]n virtually every patent infringement suit the defense of obviousness under [35 U.S.C. § 103] is asserted . . .”).

37. Patent Act of 1952, 35 U.S.C. § 103(a) (2006).

38. *In re* Application of Bozek, 416 F.2d 1385, 1390 (C.C.P.A. 1969) (noting that an examiner could, in reaching a conclusion of obviousness, rely on the “common knowledge and common sense of the person of ordinary skill in the art”).

39. See, e.g., *In re* Beasley, 117 F. App’x 739, 743–44 (Fed. Cir. 2004) (unpublished decision) (rejecting the PTO’s reliance on the “examiner’s and its own knowledge as skilled artisans” in determining nonobviousness); *In re* Lee, 277 F.3d 1338, 1343 (Fed. Cir. 2002) (rejecting the PTO’s reliance on an “examiner’s conclusory statements”); *In re* Zurko, 258 F.3d 1379, 1386 (Fed. Cir. 2001) (rejecting the Board’s efforts to base its decisions on “its own understanding or experience—or on its assessment of what would be basic knowledge or common sense”).

Circuit panels were not unanimous in rejecting the PTO's desire to rely on "common knowledge and common sense," a large number of panels penned excoriating opinions.⁴⁰

The PTO and SG declined to appeal any of these cases. But because the Federal Circuit often applied a rigid interpretation of the TSM test not only in direct reviews of PTO patent denials but also in collateral challenges to validity brought by defendants in infringement litigation, one such defendant, KSR, filed a petition for certiorari on the question. When the Supreme Court requested the SG's view as to whether it should grant certiorari,⁴¹ the executive branch responded with a strong statement in favor of the grant. In its brief recommending a grant of certiorari on the merits, the government emphasized the "unnecessary" pressure imposed on the PTO by the documentary TSM requirement. The government also noted that the requirement conflicted with settled administrative-law principles of official notice.⁴² In what was arguably the most important patent-law case in decades, the executive branch secured an unequivocal victory. The Court held that "[r]igid preventative rules that deny factfinders recourse to common sense . . . are neither necessary under [its] case law nor consistent with it."⁴³

40. See Benjamin & Rai, *supra* note 1, at 290–93 (discussing the language in certain panel opinions).

41. See Duffy, *supra* note 13, at 529–31 (discussing the Court's growing use of "Calls for Views of the Solicitor General" in patent cases and the importance of those calls in the Court's decisions to grant certiorari).

42. See Brief for United States as Amicus Curiae Supporting Petitioner at 17–19, *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007) (No. 04-1350), 2006 WL 2453601, at *26 ("The PTO should instead be allowed to bring to bear its full expertise—including its reckoning of the basic knowledge and common sense possessed by persons in particular fields of endeavor—when making the predictive judgment whether an invention would have been obvious to a person of ordinary skill in the art. The patent applicant should bear the burden of proving PTO's Board and examiners wrong.").

43. *KSR*, 550 U.S. at 421. Notably, although *KSR* did not itself involve the life sciences, the decision ended up having considerable influence on the life sciences. In the 1993 case *In re Bell*, 991 F.2d 781 (Fed. Cir. 1993), the PTO pressed the argument that for the average scientist working in the area, knowing a general method for selecting genes through the use of nucleotide probes, as well as the complete or partial amino acid of the protein for which a gene of interest coded, would render the DNA sequence for the gene obvious, *id.* at 783. The three-judge panel in that case dismissed as largely irrelevant the PTO's assessment of biotechnological science. See *id.* at 784 (discussing and rejecting the PTO's "proposition that, just as closely related homologs, analogs, and isomers in chemistry may create a *prima facie* case, the established relationship in the genetic code between a nucleic acid and the protein it encodes also makes a gene *prima facie* obvious over its correspondent protein" (citation omitted)). Two years later, in *In re Deuel*, 51 F.3d 1552 (Fed. Cir. 1995), the agency repeated the obviousness argument, only to be rejected again, with a pointed citation to *Bell*. See *id.* at 1559 ("The PTO's focus on known methods for

B. *The Role of NIH and Other Life-Science Agencies*

The Supreme Court does not, however, represent the only venue in which executive-branch agencies other than the PTO have influenced the debate on patent validity. In this Section, I discuss the role that NIH and other executive agencies interested in the life sciences have played. Notably, this role has emerged not only in litigation *ex post* but also in the process of guideline formulation *ex ante*.⁴⁴

The key example of guideline formulation *ex ante* was prompted by a debate over the patenting of fragments of genes known as “expressed sequence tags” (ESTs). My next discussion focuses on the evolution of this debate.

1. *Ex Ante Influences on the Utility and Written-Description Requirements.* In 1991, well before any other institutional actor was paying attention to the issue, NIH director Bernadine Healy had to decide whether to file patent applications covering more than two thousand ESTs identified by NIH scientist J. Craig Venter. At that point, Venter knew only that the ESTs were somehow associated with neurological function and disease. In a “special report” published in the *New England Journal of Medicine*, Healy justified her decision to seek patents. She argued that simply putting the sequences into the public domain might undermine the possibility of patent protection for the full-length genes of which the ESTs were a part.⁴⁵ This result

potentially isolating the claimed DNA molecules is also misplaced because the claims at issue define compounds, not methods.” (citing *Bell*, 991 F.2d at 785)). The PTO and the SG chose not to appeal *Bell* or *Deuel*. More than a decade later, however, the PTO was able to use the Court’s decision in *KSR* to overturn these cases. The *KSR* Court discussed briefly the longstanding patent-law principle that although an invention that is “obvious to try” is not necessarily obvious, it might be obvious if the universe of possible solutions is finite and predictable. *KSR*, 550 U.S. at 421. The PTO seized upon this short discussion to set up a test case, *In re Kubin*, 561 F.3d 1351 (Fed. Cir. 2009). In the 2009 *Kubin* decision, a three-judge panel of the Federal Circuit unanimously agreed with the PTO and finally interred *Bell* and *Deuel*. *See id.* at 1358–61 (“Insofar as *Deuel* implies the obviousness inquiry cannot consider that the combination of the claim’s constituent elements was ‘obvious to try,’ the Supreme Court in *KSR* unambiguously discredited that holding.” (quoting *In re Deuel*, 51 F.3d at 1559)).

44. As discussed further in Part IV, the PTO does not have rulemaking authority over patent-validity standards. Thus, to the extent that it has discussed those standards *ex ante*, it has done so through guidelines.

45. *See* Bernadine Healy, *Special Report on Gene Patenting*, 327 *NEW ENG. J. MED.* 664, 667 (1992) (“Publishing the partial or full sequences of novel genes without filing for patents may thus foreclose future patenting by anyone who discovers the full gene by identifying its function and may make the newly discovered genes unattractive to private industry for use in product development.”).

was undesirable, according to Healy, because patent protection for full-length genes, particularly genes that produce therapeutic compounds, is essential to induce private-sector firms to pursue the expensive research and development (R&D) associated with clinical trials.⁴⁶

Healy's reasoning was flawed. As a matter of standard patent law, it is not clear why placing EST sequences in the public domain would undermine patents on full-length genes. Moreover, although Healy's analysis acknowledged the potential problem of "patent clutter" that would be created by the need for interested researchers to license multiple overlapping EST patents on the same gene, she dismissed this concern by suggesting that "socially responsible" licensing by NIH would mitigate the problem.⁴⁷

In this first round of the EST debate, the PTO provided a useful counterweight to Healy's position. It quickly rejected the initial patent claims on a number of different validity grounds.⁴⁸ This rejection proved something of a tipping point. NIH's decision to seek EST patents had been controversial from the outset. James Watson, the codiscoverer of DNA structure and head of NIH's project to map the entire human genome, had immediately denounced the decision and resigned his position with the project.⁴⁹ Perhaps not surprisingly, then, the arrival of a new NIH director under the newly elected Clinton administration caused NIH's approach to shift. The new NIH director, Harold Varmus, commissioned two prominent patent-law scholars, Professors Rebecca Eisenberg and Robert Merges, to analyze whether the applications met the patentability requirement of

46. *See id.* ("This concern is particularly serious in the case of a gene that codes for a novel compound that may be of great value in combating a rare disease."). As I discuss further in this Essay, patent applications for full-length genes began to be filed in the 1980s. *See infra* notes 79–80 and accompanying text.

47. *See Healy, supra* note 45, at 667–68 ("The effect of a patent is largely determined by how and whether it is licensed. . . . The NIH has a deservedly good reputation for licensing new forms of technology in a socially responsible manner.").

48. Among other issues, the PTO recognized that broad claims to small gene fragments could raise novelty concerns, as these fragments could overlap with much of the human genetic code. *See* Thomas B. Kepler, Colin Crossman & Robert Cook-Deegan, *Metastasizing Patent Claims on BRCA1*, 95 *GENOMICS* 312, 313 (2010) (discussing the application's rejection by PTO examiner James Martinell on several grounds, including novelty). Certain claims in the Myriad patents may raise similar concerns. *See Kepler et al., supra; see also infra* note 100 and accompanying text.

49. Watson had famously said that finding ESTs was a job that could be "run by monkeys." Tim Beardsley, *An Express Route to the Genome?*, *SCI. AM.*, Aug. 1998, at 30, 30 (internal quotation marks omitted).

practical usefulness or “utility.” Professors Eisenberg and Merges determined that the applications were vulnerable on utility grounds.⁵⁰

Varmus withdrew the applications. He justified his decision by noting the ESTs’ lack of proven biological utility, the “possible complications of having what is referred to as ‘patent clutter,’” and “the problem . . . of so-called ‘gotcha’ patents, in which someone would do a lot of work on a gene and find that a patent had already been established on the gene.”⁵¹ Varmus also observed, however, that although NIH had chosen to withdraw the patent applications, “the issue [was] not completely resolved.”⁵²

Varmus’s comment regarding the lack of resolution on the utility issue was a dramatic understatement. Indeed, in 1995, in response to complaints from the biotechnology patent bar that the agency had been applying the utility requirement too strictly, the PTO issued guidelines that were widely seen as lowering the utility threshold.⁵³ Although these liberalized guidelines addressed utility in the biotechnology context generally, they had an impact—perhaps unintended—on EST applications in particular. By the late 1990s, firms like Incyte and Human Genome Sciences were filing thousands of patent applications on ESTs of unknown biological function.

NIH was watching these developments very closely. Extensive public comments filed by NIH in subsequent PTO proceedings addressing the utility and written-description requirements illustrated the depth of NIH’s involvement. According to these comments, early in 1997, Varmus expressed to PTO Commissioner Bruce Lehman his concern that EST patents would chill genomics research.⁵⁴ At the

50. See Rebecca S. Eisenberg & Robert P. Merges, *Opinion Letter as to the Patentability of Certain Inventions Associated with the Identification of Partial cDNA Sequences*, 23 AIPLA Q.J. 1, 51 (1995) (“We believe that most of the claims set forth in the NIH patent applications probably are not patentable. Although the matter is not entirely free from doubt, we believe that it is more likely than not that the Federal Circuit would hold all of the claims invalid for lack of utility.”).

51. Harold Varmus, *Government, in INTELLECTUAL PROPERTY RIGHTS AND RESEARCH TOOLS IN MOLECULAR BIOLOGY: SUMMARY OF A WORKSHOP HELD AT THE NATIONAL ACADEMY OF SCIENCES, FEBRUARY 15–16, 1996*, at 66, 68 (Nat’l Research Council ed., 1997).

52. *Id.*

53. Utility Examination Guidelines, 60 Fed. Reg. 36,263 (July 14, 1995); see also ROBERT PATRICK MERGES & JOHN FITZGERALD DUFFY, *PATENT LAW AND POLICY: CASES AND MATERIALS* 238 (4th ed. 2007) (noting that “the biotechnology industry generally viewed the [1995] Guidelines as heralding liberalized treatment of biotechnology applications”).

54. Memorandum from Jack Spiegel, Dir., Div. of Tech. Transfer & Dev., Office of Tech. Transfer, Nat’l Insts. of Health, to Bruce Lehman, Comm’r of Patents & Trademarks 3 (Sept. 14, 1998) (on file with the *Duke Law Journal*) (“Soon after its February 14, 1997 public

same time, the NIH Office of Technology Transfer opined that ESTs should not be deemed to meet the utility standard simply because they could be used as probes to find the full genes of which they were a part.⁵⁵ When Commissioner Lehman responded that potential EST utilities distinct from probing might include forensic identification, tissue-type or origin identification, and chromosome identification and mapping, NIH persuaded the president of the National Academy of Sciences (NAS), Bruce Alberts, to weigh in with a letter rejecting Commissioner Lehman's position.⁵⁶ Notably, Alberts was not only president of the NAS—an organization chartered in 1863 to provide the government with independent scientific advice—but also an eminent molecular biologist.

The PTO continued to express resistance to these opinions. In the issue of *Science* dated May 1, 1998, PTO Biotechnology Examination Unit head John Doll stated that because ESTs could be used to perform research functions such as chromosome identification and gene mapping, the PTO would likely issue patents for them.⁵⁷ Doll's commentary was a response to an article coauthored by Professor Rebecca Eisenberg arguing that patents on ESTs would require follow-on inventors to go through a lengthy and costly licensing process that might chill their work.⁵⁸ Doll agreed that owners of patents on full-length genes would have to seek licenses from underlying EST patent owners, but he appeared sanguine about the possibility of cross-licensing.⁵⁹

announcement that the PTO considered ESTs patentable subject matter based upon their utility as probes, the Director of NIH (Dr. Harold Varmus) communicated his deep public health concern that such patents may have a chilling effect within the genomics industry.”)

55. Memorandum from Jack Spiegel, Dir., Div. of Tech. Transfer & Dev., Office of Tech. Transfer, Nat'l Insts. of Health, to Q. Todd Dickinson, Comm'r of Patents & Trademarks 82–83 (Mar. 22, 2000) (on file with the *Duke Law Journal*) (discussing an April 2, 1997, communication in which the PTO agreed with the NIH's assessment that “ESTs only disclosed as a probe for unknown genes [do] not [have] a sufficient patentable utility”).

56. See Memorandum from Jack Spiegel to Bruce Lehman, *supra* note 54, at 4–5 (quoting a letter from Alberts in which he stated, in reference to uses such as mapping and tissue typing, that “[d]isclosure of DNA sequence alone is plainly insufficient to enable scientists to use an EST for any of these purposes” (alteration in original)).

57. John J. Doll, *The Patenting of DNA*, 280 SCIENCE 689, 689–90 (1998).

58. See Michael Heller & Rebecca Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698, 700 (1998) (“High transaction costs may be an enduring impediment to efficient bundling of intellectual property rights in biomedical research.”).

59. Doll, *supra* note 57, at 689–90 (discussing examples of cross-licensing in other contexts involving broad initial patents).

Doll's position that owners of full-length gene patents would have to seek licenses from EST patent owners was an indication that EST patents would necessarily be broad. In June 1998, the PTO confirmed the patents' broad scope when it issued interim guidelines on another requirement of patentability, the so-called written-description requirement.⁶⁰ The written-description requirement, which requires that patentees show that they have "possession" of the invention that they are claiming, controls the scope of patent claims.⁶¹ Interestingly, though the guidelines were prompted by a 1997 Federal Circuit decision, *Regents of the University of California v. Eli Lilly & Co.*,⁶² which suggested that the written-description requirement would narrow the scope of DNA patents, the PTO guidelines suggested that claims to ESTs could be broad, encompassing groups of nucleic acids of which the ESTs were a part.⁶³

Ultimately, however, following—in the words of a subsequent NIH comment—"much formal and informal discourse on the subject,"⁶⁴ as well as the arrival of a new PTO commissioner, Q. Todd

60. Request for Comments on Interim Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112 ¶ 1 "Written Description" Requirement, 63 Fed. Reg. 32,639 (June 15, 1998).

61. For the Federal Circuit's 2010 en banc articulation of what this requirement means, see *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*, 598 F.3d 1336 (Fed. Cir. 2010) (en banc).

62. *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1566–67 (Fed. Cir. 1997).

63. Request for Comments on Interim Guidelines, 63 Fed. Reg. at 32,640–41 (indicating that "generic" claims would "not typically present a written description problem"). In fairness to the PTO, applying the written-description requirement in the manner that the Federal Circuit did in *Regents of the University of California v. Eli Lilly & Co.* was problematic in terms of the scientific state of the art and as a departure from legal precedent. See Arti K. Rai, *Intellectual Property Rights in Biotechnology: Addressing New Technology*, 34 WAKE FOREST L. REV. 827, 833 (1999) ("[P]atent law doctrines of nonobviousness and written description have, in the context of biotechnology, been applied incorrectly by the Federal Circuit. I suggest that the CAFC's mistakes stem from its inability to deal adequately with new technology.").

64. Memorandum from Jack Spiegel to Q. Todd Dickinson, *supra* note 55, at 83. This formal and informal discourse included a number of meetings on the subject coordinated by the White House Office of Science and Technology Policy as well as other White House offices. Interview with an Anonymous Source (Jan. 4, 2012) (on file with the *Duke Law Journal*). The road to compromise was not altogether smooth. For example, on September 23, 1998, the PTO extended the comment period on the June 1998 written-description guidelines specifically to address the question of ESTs. Revised Interim Guidelines for Examination of Patent Applications Under the 35 U.S.C. § 112, ¶ 1 "Written Description" Requirement; Request for Comments, 64 Fed. Reg. 71,427, 71,428 (Dec. 21, 1999). At the same time, however, in October 1998, the PTO issued a patent claiming forty-four ESTs to Incyte Pharmaceuticals. U.S. Patent No. 5,817,479 (filed Aug. 7, 1996) (issued Oct. 6, 1998). Although this patent did state that the full genes from which the claimed ESTs had been drawn coded for kinases, the amount of actual information about biological function provided by that statement is small. The human genome contains about five hundred different protein kinases. G. Manning, D.B. Whyte, R. Martinez, T.

Dickinson, who had a deep background in patent law, the PTO changed its approach. Notably, although the biotechnology industry had urged an overall fortification of the utility standard in 1995, NIH's concerns about EST patents in particular were shared by firms in the biotechnology industry that would have to license such patents to perform their own work.⁶⁵ Thus, the PTO knew its shift in position would be supported by at least some influential members of the biotechnology-patent community.⁶⁶

In December 1999, the agency issued draft utility guidelines requiring all patent applications to demonstrate "specific, substantial, and credible" utility.⁶⁷ In addition to the guidelines, the PTO provided training materials for its patent examiners.⁶⁸ Those materials stated that assertions of generic utility would not suffice to show patentability, particularly with respect to EST patents.⁶⁹ Although NIH was not entirely happy with the details of the guidelines,⁷⁰ it

Hunter & S. Sudarsanam, *The Protein Kinase Complement of the Human Genome*, 298 SCIENCE 1912, 1912 (2002). Consistent with Doll's statement in *Science* about follow-on innovators' having to license EST patents and with the June 1998 guidelines, the claims granted to Incyte were broad, arguably encompassing not simply the ESTs but also the full genes of which the ESTs were a part. After the patent was issued, NIH sent in "supplemental comments" on the written-description guidelines expressing its surprise at the patent and emphasizing "the potential deleterious consequences to the development of genomics that may arise from large scale issuance of broad patents on research tool discoveries such as ESTs and SNPs." Supplemental Comments from Jack Spiegel, Dir., Div. of Tech. Transfer & Dev., Nat'l Insts. of Health, to Q. Todd Dickinson, Comm'r of Patents & Trademarks 5 (Nov. 12, 1998).

65. Thus, for example, in subsequent comments, Genentech heartily endorsed the PTO's shift in position with respect to both utility and written description. Letter from Sean A. Johnston, Vice President, Intellectual Prop., Genentech, Inc., to Q. Todd Dickinson, Comm'r of Patents and Trademarks 1 (Mar. 22, 2000) (on file with the *Duke Law Journal*) ("We were pleased to see that the initial version of the written description guidelines was modified significantly to reflect suggestions made by the public. Overall, we believe the latest version of the guidelines, as amplified by the training materials, accurately reflects the standards of utility and written description.").

66. As former Commissioner Q. Todd Dickinson has noted, the leadership provided by him and his chief patent-policy lieutenant, Stephen Kunin, "together with the influence of stakeholders inside and outside the government, facilitated the alteration in position." Interview with Q. Todd Dickinson (Jan. 3, 2012).

67. Revised Interim Guidelines, 64 Fed. Reg. at 71,440.

68. U.S. PATENT & TRADEMARK OFFICE, REVISED INTERIM UTILITY GUIDELINES TRAINING MATERIALS, available at <http://www.uspto.gov/web/menu/utility.pdf>.

69. See *id.* at 5-6, 50-52 (discussing the inadequacy of assertions of generic utility, particularly in the context of EST patents).

70. Most notably, contrary to NIH's wishes, the guidelines and accompanying training materials refused to adopt a per se rule against claims of utility based on structural similarity, or homology, to gene sequences of known function. See Memorandum from Jack Spiegel to Q.

praised the PTO's decision to move to a higher standard.⁷¹ The PTO utility guidelines were finalized in 2001.⁷² Under these guidelines, the PTO has approved few patent applications for ESTs of unknown biological function.

In December 1999, the PTO also issued revised interim guidelines on the written-description requirement.⁷³ Although some of the language in the guidelines was confusing,⁷⁴ the accompanying training examples stated that EST patent claims could not encompass the larger nucleic acid sequences of which they were a part.⁷⁵ Thus, even assuming that certain claims to ESTs happened to meet the utility threshold for patentability, follow-on researchers would probably be able to avoid, or "invent around," the claims.

As discussed further in Part IV, Congress has not granted the PTO rulemaking authority over questions of patent validity. Thus, neither the utility guidelines nor the written-description guidelines have the force of law. But the PTO's invocation of the utility guidelines to deny EST applications soon became the subject of a test case appealed to the Federal Circuit. The Federal Circuit's 2005 decision in that test case, *In re Fisher*,⁷⁶ noted that the PTO's utility guidelines comported with the court's own interpretation of the utility requirement.⁷⁷

Subsequent empirical work has demonstrated that industry players thought the utility and written-description guidelines were

Todd Dickinson, *supra* note 55, at 83–89 (sharply criticizing an example in the training guidelines that found utility based on sequence homology).

71. Francis Collins, head of the National Human Genome Research Institute, stated, "I think the Patent Office deserves credit for moving toward a stronger requirement for utility." *In the Crossfire: Collins on Genomes, Patents, and 'Rivalry,'* 287 SCIENCE 2396, 2397 (2000).

72. Utility Examination Guidelines, 66 Fed. Reg. 1092 (Jan. 5, 2001).

73. Revised Interim Guidelines for Examination of Patent Applications Under the 35 U.S.C. § 112, ¶ 1 "Written Description" Requirement; Request for Comments, 64 Fed. Reg. 71,427, 71,427 (Dec. 21, 1999).

74. NIH and other commentators expressed concern about the confusing language in the interim guidelines. See, e.g., Memorandum from Charles E. Ludlam, Vice President for Gov't Relations, Biotech. Indus. Org., to Q. Todd Dickinson, Comm'r of Patents & Trademarks 4–5 (Mar. 22, 2000). The final guidelines, issued in 2001, eliminated the confusion.

75. *Id.* at 4 (citing the seventh example in the training materials, which stated that a claim to an EST that attempted to encompass larger sequences of which the EST was a part would be invalid).

76. *In re Fisher*, 421 F.3d 1365 (Fed. Cir. 2005).

77. *Id.* at 1372.

quite important in forestalling patent thickets.⁷⁸ In other words, the ex ante intervention by NIH worked largely as the agency had hoped, yielding a reduction in the transaction-cost hurdles faced by follow-on researchers. Although NIH itself may have been most worried about the transaction costs faced by the researchers it sponsored, its intervention redounded to the benefit of the innovation ecosystem as a whole.

The relatively orderly sequence of events through which relevant institutional players addressed the EST controversy stands in contrast to the institutional debate over whether DNA sequences are patentable subject matter. In the latter debate, executive-branch players outside the PTO brought fresh and important perspectives to the table. These perspectives, however, came quite late in the debate.

2. Patentable Subject Matter. In the discussion of EST patenting described in the previous Section, NIH did not address whether and to what extent DNA sequences should constitute subject matter that is eligible for patenting in the first instance. Rather, NIH implicitly assumed that DNA sequences satisfied the threshold definition of subject matter eligible for patenting and focused instead on whether EST claims satisfied the utility and written-description requirements. As discussed below, NIH and other life-science agencies would not jump into the fray and voice an opinion with respect to whether DNA sequences should be patentable subject matter until decades later—almost a decade after the EST-patenting debate had concluded at the administrative level and several decades after the first DNA patents had been granted.

As the PTO began issuing DNA patents in the 1980s, the patent community converged relatively quickly on a certain conventional wisdom. In *Diamond v. Chakrabarty*,⁷⁹ a 1980 decision, the Supreme Court adopted a generally expansive view of patentable subject matter and deemed genetically altered bacteria eligible for patenting; this view, in turn, permitted patents on DNA excised from its natural cellular environment. Furthermore, patents on isolated DNA were a natural extension of lower court decisions handed down before the

78. John P. Walsh, Ashish Arora & Wesley M. Cohen, *Effects of Research Tool Patents and Licensing on Biomedical Innovation*, in PATENTS IN THE KNOWLEDGE-BASED ECONOMY 285, 286 (2003) (explaining that industry respondents credited “changes in the institutional environment, particularly new U.S. Patent and Trademark Office (USPTO) guidelines” with “reduc[ing] the threat of breakdown and access restrictions”).

79. *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

creation of the Federal Circuit, which allowed patents on purified versions of chemical and biochemical products, particularly if those products had a different utility when purified.⁸⁰ Thus, in the view of the patent community, although DNA in its cellular environment was a product of nature and hence not subject matter eligible for patenting, isolated DNA sequences were eligible for patenting. Indeed, the PTO invoked this line of reasoning in the late 1990s when some commentators raised the patentable-subject-matter issue in deliberations over the draft utility guidelines.⁸¹

Notably, the commentators challenging the PTO's patentable-subject-matter conclusions, unlike NIH, did not appear to have particular clout, so the PTO dismissed their arguments relatively quickly.⁸² Furthermore, perhaps because the conventional wisdom had become so firmly entrenched, the issue of patentable subject matter was, prior to *Myriad II*, never even raised in the Federal Circuit cases addressing gene patents.⁸³

80. *Parke-Davis & Co. v. H.K. Mulford Co.*, 189 F. 95, 103 (C.C.S.D.N.Y. 1911), *rev'd in part*, 196 F. 496 (2d Cir. 1912); *In re Application of Bergstrom*, 427 F.2d 1394, 1397 (C.C.P.A. 1970).

81. Utility Examination Guidelines, 66 Fed. Reg. 1092, 1093–94 (Jan. 5, 2001) (“Thus, an inventor’s discovery of a gene can be the basis for a patent on the genetic composition isolated from its natural state and processed through purifying steps that separate the gene from other molecules naturally associated with it.”). The PTO’s discussion also invokes *Chakrabarty* and the lower court cases involving purified chemicals.

82. *See Myriad II*, 653 F.3d 1329, 1380 (Fed. Cir. 2011) (Bryson, J., concurring in part and dissenting in part) (stating that the patentable-subject-matter comments “that the PTO issued at the time of its 2001 guidelines . . . [were], frankly, perfunctory”). Prior empirical work on comments provided by agencies also suggests that comments from sister agencies receive particular attention. *See* Stuart Minor Benjamin & Arti K. Rai, *Fixing Innovation Policy: A Structural Perspective*, 77 GEO. WASH. L. REV. 1, 87 (2008) (discussing various Federal Communications Commission (FCC) rulemakings and the particular attention the FCC has paid to comments from the National Telecommunications and Information Administration).

83. *Cf. Intervet Inc. v. Merial Ltd.*, 617 F.3d 1282, 1293 (Fed. Cir. 2010) (Dyk, J., concurring in part and dissenting in part) (noting that the question of whether isolated genomic DNA is patentable subject matter has evaded review). The conventional wisdom was reinforced by the fact that most DNA-patent litigation involved DNA that encoded protein drugs. The defendants in those cases were commercial competitors of the patent holders. The defendants often held their own DNA patents. The prominent biotechnology-patent litigator Jorge Goldstein, who was involved in many of these cases, observes that “[n]o defendant who wanted to obtain patent protection for the same or similar protein drug-encoding DNAs would ever consider raising as a defense that isolated human DNA sequences were not patent-eligible.” Jorge A. Goldstein, *Isolated Human Gene Patents: Taxonomies and Controversies 7* (Nov. 19, 2010) (unpublished manuscript), available at <http://www.law.illinois.edu/pdf/JorgeGoldstein2GenePatentChakrabartyPubNovember2010.pdf>. The history of DNA-patent litigation thus illustrates the manner in which parties’ views in litigation do not necessarily represent the full range of policy stances on a particular question.

The *Myriad* litigation brought a set of groups outside of the conventional patent community into the litigation process. The ACLU and the Public Patent Foundation filed a challenge on behalf of twenty largely academic plaintiffs engaged in breast-cancer diagnostic testing. In their complaint, the plaintiffs alleged that Myriad's broad product and process patents on the BRCA1 and BRCA2 genes were impeding both their clinical work and further research on additional mutations in the genes.⁸⁴

The district court's March 2010 decision in *Myriad I*⁸⁵ called into question decades of conventional wisdom. The court held invalid all fifteen contested claims related to seven patents held by Myriad, on the ground that the claims did not constitute patentable subject matter.⁸⁶ With respect to the product claims, the court held that because the basic informational character of DNA remains the same after it has been isolated, Myriad's claims impermissibly covered products of nature. According to the district court, *Chakrabarty* required that a patentable product be markedly different from any material found in nature.⁸⁷ Although the PTO was originally a defendant in the action and had filed a brief defending the patents, the district court dismissed the claims against the PTO; thus, the U.S. government did not have to participate in the inevitable Federal Circuit appeal.⁸⁸

Nevertheless, the U.S. government filed an amicus brief in the Federal Circuit, reversing the position taken by the PTO at the district court level. In its brief, the United States drew a distinction between claims to DNA sequences that are merely isolated—that is, excised from their original cellular environment and other genomic material—and claims to sequences that are laboratory-generated duplicates of exons—that is, the select portions of DNA sequences that actually code for a protein.⁸⁹ According to the government, the latter set of claims encompasses a manmade construct, not a product

84. Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office (*Myriad I*), 702 F. Supp. 2d 181, 206 (S.D.N.Y. 2010), *rev'd in part*, 653 F.3d 1329 (Fed. Cir. 2011).

85. Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office (*Myriad I*), 702 F. Supp. 2d 181 (S.D.N.Y. 2010), *rev'd in part*, 653 F.3d 1329 (Fed. Cir. 2011).

86. *Id.* at 220–37.

87. *Id.* at 223.

88. *Id.* at 238.

89. Brief for the United States as Amicus Curiae in Support of Neither Party, *supra* note 16, at 7–8.

of nature.⁹⁰ This laboratory-generated construct is known as cDNA. In the government's view, the district court was correct in striking down some of Myriad's claims—those involving genomic DNA (gDNA), but not those involving full-length cDNA.⁹¹

From a formal scientific or legal perspective, the distinction between gDNA and full-length cDNA is not entirely compelling. Although cDNA creation involves more human intervention than does gDNA creation, gDNA creation also generally involves some human intervention.⁹² Indeed, one reason patent-law practitioners and scholars have often been wary of relying too heavily on the patentable-subject-matter requirement is that line drawing in the area—whether through bright-line rules or more flexible standards—can be quite difficult.⁹³

From a policy standpoint, however, the U.S. government's distinction has some appeal. As the science agencies and offices named on the amicus brief⁹⁴ understand intimately, technology is moving beyond a focus on individual genes. Whole-genome sequencing of all 20,000 or so human genes is rapidly becoming the predominant focus of researchers. As a technical matter, whole-genome sequencing will not infringe full-length cDNA patents covering exons that have been spliced together. But it might infringe certain other DNA-patent claims, most notably claims to very short nucleotide sequences.⁹⁵ For firms engaged in whole-genome

90. See *id.* at 15 (“cDNAs . . . are synthetic molecules engineered by scientists to incorporate, in a single contiguous DNA segment, only the exons (*i.e.*], protein-coding sequences) of a naturally occurring gene, and to exclude the intervening introns and other regulatory regions that normally separate the exons in genomic DNA.”).

91. The government's brief did not address the method claims. Thus, I will not do so in this Essay. But these claims, as well as other method claims in various genetic diagnostic patents, are suspect on numerous grounds.

92. According to the plaintiffs in *Myriad*, however, gDNA fragments arise naturally in maternal plasma, in those suffering from cancer, and when DNA breaks. Plaintiffs-Appellees' Petition for Panel Rehearing at 4–5, *Myriad II*, 653 F.3d 1329 (Fed. Cir. 2011) (No. 2010-1406).

93. See, e.g., Tun-Jen Chiang, *The Rules and Standards of Patentable Subject Matter*, 2010 WIS. L. REV. 1353, 1407–10 (discussing the costs and benefits of “categorical” rules relative to “scope”-based standards).

94. These agencies and offices include not simply NIH, but also entities such as the White House Office of Science and Technology Policy, which was set up by Congress in the 1970s to coordinate science and technology policy across agencies.

95. In a recent paper, Professor Chris Holman analyzes 533 patents that explicitly mention a human DNA sequence in their claims. Christopher M. Holman, *Will Gene Patents Impede Whole Genome Sequencing?: Deconstructing the Myth that 20% of the Human Genome Is Patented*, 2 IP THEORY 1, 2–4 (2011). These 533 patents represented a subset of 4270 patents that then-doctoral candidate Kyle Jensen and Professor Fiona Murray had previously identified

sequencing, DNA-patent claims to very short sequences—found in the Myriad patents, as well as in other gene patents—represent a potential obstacle. Claims to very short sequences on which no splicing has been done would be invalid under the government’s test.

Conversely, the government’s position would leave undisturbed most of the patents that the biotechnology industry justifiably regards as being important for its business model. Specifically, the government’s position would leave intact a vast array of patents on therapeutic end-products—not simply full-length cDNA patents but also patents on other laboratory-generated constructs such as vectors and recombinant plasmids. Because therapeutic end-products require FDA approval and, hence, a large investment to bring them to market, patents on such products are quite important.⁹⁶ In contrast, because most gene-based diagnostics currently do not require FDA approval, the policy case for patent protection in those cases is weaker.⁹⁷

At the Federal Circuit level, Judges Alan Lourie and Kimberly Moore disagreed with the government’s position, finding both gDNA and cDNA to be subject matter eligible for patenting. But a version of the government’s position attracted support from one judge. In dissent, Judge William Bryson indicated that he would have drawn the line at full-length cDNA patents covering exons that had been spliced together. Judge Bryson specifically emphasized that Myriad’s product-patent claims to very short sequences of DNA might create

as “human gene patents” in a prominent paper. Kyle Jensen & Fiona Murray, *Intellectual Property Landscape of the Human Genome*, 310 *SCIENCE* 239, 239 (2005). Professor Holman concludes that of the 533 patents, the subset that is most likely to be infringed comprises claims to short fragments of DNA, such as a claim drawn to “any isolated DNA molecule comprising any sequence of 10 or more contiguous bases.” Holman, *supra*, at 9. Professor Holman also notes that this subset of claims is relatively small. But because the set of “human gene patents” identified by Jensen and Professor Murray is not only overinclusive, *id.* at 2–5, but also underinclusive, Jensen & Murray, *supra*, at 240, studies based on that set will not fully answer questions regarding possible thickets. Moreover, even a relatively small group in the subset examined by Holman might, if expanded to the entire human genome, yield several hundred claims to patents on short sequences.

96. The various data exclusivities provided to pioneer makers of biological therapies in the Biologics Price Competition and Innovation Act of 2009, Pub. L. No. 111-148, 124 Stat. 119 (2010), are fairly extensive but may not provide sufficient protection.

97. See, e.g., Robert Cook-Deegan, Subhashini Chandrasekharan & Misha Angrist, *The Dangers of Diagnostic Monopolies*, 458 *NATURE* 405, 405 (2009) (concluding, after assembling eight case studies addressing the effects of patents and licensing on access to genetic tests, that “patents have not caused irreparable harm in genetic diagnostics, but neither have they proven greatly advantageous”).

potential thickets for whole-genome sequencing.⁹⁸ He further noted that even if the short-DNA-sequence patents could be held invalid on the ground that they were excessive in scope,⁹⁹ “the costs involved in determining the scope of all those patents could be prohibitive.”¹⁰⁰ To support this point, Judge Bryson cited a prominent report written by the Advisory Committee to the secretary of Health and Human Services that discussed the potential for such thickets.¹⁰¹ Until it was disbanded, the committee was the flagship external source of advice for all components of the Department of Health and Human Services—including NIH—on policy questions raised by genetic testing.¹⁰²

The Federal Circuit’s July 2011 decision, however, is by no means the end of the road. Although the panel denied rehearing, the plaintiffs in the *Myriad* litigation have filed for certiorari. So the story continues to unfold.

In sum, the decades of debate over DNA-patent policy suggest that NIH has arguably been as important in shaping policy as the

98. See *Myriad II*, 653 F.3d 1329, 1379 (Fed. Cir. 2011) (Bryson, J., concurring in part and dissenting in part) (“Accordingly, efforts to sequence almost any gene could infringe claim 6 even though *Myriad*’s specification has contributed nothing to human understanding of other genes.”); *id.* at 1379–80 (citing SEC’Y’S ADVISORY COMM. ON GENETICS, HEALTH & SOC’Y, U.S. DEP’T OF HEALTH & HUMAN SERVS., GENE PATENTS AND LICENSING PRACTICES AND THEIR IMPACT ON PATIENT ACCESS TO GENETIC TESTS 49–62 (2010)) (“Broad claims to genetic material present a significant obstacle to the next generation of innovation in genetic medicine—multiplex tests and whole-genome sequencing. New technologies are being developed to sequence many genes or even an entire human genome rapidly, but firms developing those technologies are encountering a thicket of patents.”).

99. Judge Bryson emphasized excessive scope as creating patentability issues with respect to novelty and obviousness. See *id.* at 1380 (“In order to sequence an entire genome, a firm would have to license thousands of patents from many different licensors. Even if many of those patents include claims that are invalid for anticipation or obviousness, the costs involved in determining the scope of all of those patents could be prohibitive.” (citation omitted)). Professor Thomas Kepler, a computational biologist, and his colleagues at Duke University have calculated that over 80 percent of the cDNA sequences contributed to GenBank before the *Myriad* patent application contained at least one of the short DNA sequences claimed by *Myriad*. Kepler et al., *supra* note 48, at 312.

100. *Myriad II*, 653 F.3d at 1380.

101. See *id.* (citing SEC’Y’S ADVISORY COMM. ON GENETICS, HEALTH & SOC’Y, *supra* note 97, at 49–62).

102. Notably, the report was not cited in the government’s brief. In general, although the government’s distinction between gDNA and cDNA neatly tracks some relevant policy considerations of which at least NIH and the HHS are clearly aware, the brief itself does not discuss those policy considerations. See Brief for the United States as Amicus Curiae in Support of Neither Party, *supra* note 16, at 10–36 (discussing the distinctions between gDNA and cDNA in a purely formal manner).

PTO itself. The assertive role that non-PTO executive-branch actors have played in disputes over patentability standards adds an important dimension to debates over how institutions should be structured to produce sound patent policy. The next Part considers these institutional questions.

II. PATENT POLICY: THE INSTITUTIONAL DEBATE

Institutional-choice analysis—in this case, analysis of which government institutions should be responsible for crafting policy—requires an initial discussion of what sound patent policy entails. Without some articulation of normative goals and design principles, observers will have difficulty evaluating whether a particular institution is likely to promote appropriate goals and principles. Consequently, before turning to specific institutions, I begin with a brief normative discussion of goals and principles.

A. *Sound Patent Policy: General Considerations*

For purposes of this Essay, I assume that the appropriate goal of patent policy is a technocratic one: the efficient promotion of technological innovation.¹⁰³ If one assumes this goal, expertise in both economics and technology is a highly desirable attribute for any institution creating patent policy.

Although scholars agree that innovation is the goal, they disagree substantially over how patentability standards should be calibrated to promote innovation. Reasonable minds can and do differ as to whether certain types of subject matter should be eligible for patenting in the first instance, as to when in the R&D process patents should be allowed, as to what the appropriate standard for nonobviousness should be, and as to whether patents should be narrow or broad. More broadly, scholars differ on the extent to which patents—as opposed to, for example, competition law, public R&D

103. By “innovation,” scholars mean both the initial invention and the commercialization of the invention. A focus on the efficient promotion of innovation as a goal obviously excludes important distributional considerations as well as noninstrumental considerations such as democratic accountability. For purposes of this Essay, I adopt this admittedly narrow framework. I bracket distributional and noninstrumental considerations not because they are unimportant but because they are extremely challenging. Whether and how patent law should encompass concerns that are unrelated to innovation are questions I hope to address in future work.

funding, or spillovers into the public domain—are the central drivers of innovation.¹⁰⁴

Unassailable empirical evidence with respect to any of these questions does not exist. But a lack of confidence in the ultimate substantive answers only increases the importance of the processes through which competing views and evidence are put forward. To put the point another way, information-gathering and decisionmaking processes must be protected from capture by an unrepresentative set of arguments or interests.¹⁰⁵ Like expertise, avoidance of capture is a well-recognized design principle.

Less recognized, but equally important as a design principle, is some institutional capacity for prospective action. Actions taken long after an issue has arisen, and that have retroactive effect, raise concerns about disturbing settled expectations. Indeed, as discussed further in Section C, concerns about disturbing settled expectations pervaded Judge Kimberly Moore's opinion in *Myriad II*. Judge Moore's concern about settled expectations emerged in part from her view that patents represent property rights. But one does not have to view patents as property rights to be concerned about the retroactive effects of litigation. To the contrary, the Supreme Court has long struggled with the question of how to reconcile norms that strongly favor judicial retroactivity with the equity and efficiency concerns raised by retroactivity when a case yields a new legal principle.¹⁰⁶ As a practical matter, the Court's resolution of the issue for civil cases has

104. The theoretical and empirical literature on different strategies for promoting innovation is truly voluminous. See, e.g., Benjamin & Rai, *supra* note 82, at 2 n.3 (surveying the literature).

105. The possibility of capture emerges in significant part from the logic of collective action. See generally MANCUR OLSON, *THE LOGIC OF COLLECTIVE ACTION: PUBLIC GOODS AND THE THEORY OF GROUPS* (rev. ed. 1978) (arguing that groups with diffuse interests will have difficulty organizing to achieve collective action and optimal output). As a consequence of collective-action problems, small groups of players with concentrated interests will have an easier time organizing and influencing decisionmakers than will large, diffuse groups.

106. Many scholars have discussed the Court's tangled jurisprudence in this area. See, e.g., Jill Fisch, *Retroactivity and Legal Change: An Equilibrium Approach*, 110 HARV. L. REV. 1055, 1059–67 (1997) (assessing the Court's retroactivity doctrine); Alison L. LaCroix, *Temporal Imperialism*, 158 U. PA. L. REV. 1329, 1348–67 (2010) (examining “the Court's experiments in the twentieth century with limiting the retroactive effect of its own decisions”); Kermit Roosevelt III, *A Little Theory Is a Dangerous Thing: The Myth of Adjudicative Retroactivity*, 31 CONN. L. REV. 1075, 1081–1109 (1999) (analyzing the historical origins of retroactivity and modern retroactivity scholarship).

been a “firm rule of retroactivity.”¹⁰⁷ Until and unless that resolution is disturbed, judicial decisionmaking in the patent context will take place in the shadow of serious concerns about the negative effects of retroactivity.

Strong concerns about retroactivity can arise even in the absence of any concerns about stare decisis. Indeed, as *Myriad II* illustrates, concerns can arise even when the initial step down a path—in that case, the decision to deem virtually all DNA sequences to be subject matter eligible for patenting—was taken without any particular deliberation. Thus, to avoid the specter of policymaking by path dependence, some institutional capacity for prospectivity must be preserved.

Another negative effect of judicial decisionmaking in the shadow of retroactivity may be a tendency toward rights expansion. This effect could arise because, as a practical matter, judges are likely to be more wary of retroactivity when they contract patent rights, thereby affecting clearly identifiable entities upon whom the government has conferred specific authority, than when they expand rights, thereby affecting diffuse groups who may not be seen as having settled expectations about their ability to use information without any threat of infringement liability. The retroactive effect of the expansion of patent rights is also limited by the reality that a judicial decision that expands patent rights cannot, under standard patent-law doctrines such as the requirement of novelty, put back into the realm of patentability information that has already passed into the public domain because it had not been considered patentable under a prior, stricter standard.

To be sure, as Professor David Schwartz argues, the Federal Circuit has, on various occasions, contracted patent rights without paying attention to retroactivity.¹⁰⁸ As Professor Schwartz also notes, however, the Supreme Court—which generally receives the cases in which the potential for change is the largest—has repeatedly identified, and has generally heeded, concerns about retroactivity when it has been called upon to contract patent rights.¹⁰⁹

107. LaCroix, *supra* note 106, at 1365 & n.156 (quoting *Landgraf v. USI Film Prods.*, 511 U.S. 244, 279 n.32 (1994)) (internal quotation marks omitted).

108. David L. Schwartz, *Retroactivity in Patent Law 14–27* (Oct. 18, 2011) (unpublished manuscript), available at www.ssrn.com/abstract=1945554.

109. *Id.* at 29–32.

For the reasons discussed, institutional-choice analysis needs to take greater account of retroactivity. Nevertheless, concerns about retroactivity should not operate as a hair trigger. In certain cases, some amount of retroactivity and ex post action may be desirable or at least inevitable. For example, although ex ante bright-line rules provide clear answers and thus eliminate any concern about retroactivity in subsequent application, such rules have well-known shortcomings. Avoiding the errors and the potential for gaming produced by bright-line rules may be a good reason for using standards, even though such standards may in subsequent application have some retroactive effect.¹¹⁰ In addition, ex ante action should not preclude the possibility of subsequent adaptation and updating.

With these background principles of sound patent policy in mind, I now turn to the comparative competence of particular patent institutions.

B. Using Institutions To Promote Sound Patent Policy

Conventional institutional analysis—and the views of a large number of Federal Circuit judges¹¹¹—points to Congress as the obvious patent policymaker, at least in the first instance. Not only does Congress possess the ability to accumulate large amounts of policy-relevant information quickly, but it is also typically free to act prospectively, retroactively, or both, depending on the nature of a given problem.¹¹²

110. For a defense of standards over bright-line rules in the context of tax-law statutes and regulations, see generally David A. Weisbach, *Formalism in the Tax Law*, 66 U. CHI. L. REV. 860 (1999).

111. See, e.g., *Myriad II*, 653 F.3d 1329, 1355 (Fed. Cir. 2011) (“If the law is to be changed, and DNA inventions excluded from the broad scope of [35 U.S.C. § 101] contrary to the settled expectation of the inventing community, the decision must come not from the courts, but from Congress.”); *id.* at 1367 (Moore, J., concurring in part) (cautioning that courts should be “particularly wary of expanding the judicial exception to patentable subject matter when both settled expectations and extensive property rights are involved” and suggesting that courts should instead “defer to Congress”); *In re Fisher*, 42 F.3d 1365, 1378 (Fed. Cir. 2005) (stating that PTO arguments regarding scientific progress are “public policy considerations . . . more appropriately directed to Congress as the legislative branch of government”). See generally S. Jay Plager, *The Federal Circuit as an Institution: On Uncertainty and Policy Levers*, 43 LOY. L.A. L. REV. 749 (2010) (discussing the judicial tendency to see Congress as the relevant policymaker in patent law).

112. Standard legal doctrine holds that legislation operates prospectively. The Court has also given Congress considerable leeway in acting retroactively. See Fisch, *supra* note 106, at 1063–64 (“[T]he modern Court has been consistently deferential to legislative retroactivity.”).

Yet in spite of these promising attributes, patent-law scholars have often found the congressional option unsatisfactory.¹¹³ Congressional legislation faces many obstacles, or “vetogates,”¹¹⁴ prior to passage, and legislative priorities are often unduly skewed by political expediency. Thus, Congress is usually unable to act quickly in the face of rapid technological development, whether the needed action involves passing legislation in the first instance or revising legislation that no longer comports with technological reality.¹¹⁵

Moreover, the recent history of legislative patent-law reform demonstrates that members of Congress are susceptible to capture. This capture can take the “classic” form of a quid pro quo, in which a particular well-heeled interest group makes significant campaign contributions to a member of Congress in exchange for legislative promises. Alternatively, capture can take the form of informational capture, in which a well-heeled interest group inundates the congressional member with data purporting to show why the group’s preferred policy outcome advances the overall public welfare.

Informational capture is possible because, notwithstanding its staff of 32,000 individuals, Congress is significantly less capable of marshaling neutral expertise on technological and economic issues than one might expect. Most members of its staff work in constituent services. Congress can draw upon the resources of the Congressional Research Service, the Congressional Budget Office, and the Government Accountability Office (GAO), but each of these entities is constrained by its generalist focus. Meanwhile, Congress chose in 1994 to abolish its innovation-focused Office of Technology

113. In general, in keeping with their technocratic focus on efficiency as a normative goal, patent-law scholars use functional, not formal, institutional analysis. Here, I similarly focus on functional considerations.

114. See generally William N. Eskridge, Jr., *Vetogates*, *Chevron*, *Preemption*, 83 NOTRE DAME L. REV. 1441, 1444–48 (2008) (identifying nine different points at which “bills can die” before they become law).

115. See, e.g., Gary E. Marchant, *The Growing Gap Between Emerging Technologies and the Law*, in *THE GROWING GAP BETWEEN EMERGING TECHNOLOGIES AND LEGAL-ETHICAL OVERSIGHT: THE PACING PROBLEM* 19, 23 (Gary E. Marchant, Braden R. Allenby & Joseph R. Herkert eds., 2011) (reviewing literature that identifies procedural obstacles and skewed legislative prioritization as reasons why legislatures fail to keep up with emerging technologies). A much-discussed example of legislation that rapidly became outdated is the Semiconductor Chip Protection Act of 1984, Pub. L. No. 98-620, tit. III, 98 Stat. 3347 (codified as amended at 17 U.S.C. §§ 901–914 (2006)), which set up a sui generis regime of intellectual-property protection for chips.

Assessment (OTA), even though OTA reports were generally very highly regarded.¹¹⁶

In the patent context, this capture dynamic does not necessarily lead to legislation that is entirely one-sided. For example, in the six-year process leading up to the AIA, different congressional actors embraced well-heeled interest groups with competing views. Both the backers of biopharmaceutical firms and universities opposed to substantial reform and the backers of large high-technology firms supportive of substantial reform enjoyed congressional support.¹¹⁷

In theory, the result of this interest-group melee could be a roughly acceptable compromise. In practice, however, the many vetogates Congress faces tend to preclude passage of legislation that one or more well-heeled groups oppose, even if those groups oppose the legislation for no particularly strong reason.¹¹⁸ As a consequence, the AIA is modest in its ambitions. The reforms include only those improvements that commanded wide consensus among important interest groups.¹¹⁹

Congress's limited ability to act has caused the institutional discussion to focus on courts and agencies. Typically, scholars have viewed the PTO as the main agency engaged in policymaking involving patent validity. This attention is understandable, given that

116. The discussion in this paragraph and the preceding one is largely taken from Benjamin & Rai, *supra* note 82, at 42–46.

117. See, e.g., Gregory N. Mandel, *Will America Reinvent Itself? Patent Reform in 2011*, BUS. L. TODAY, 1–2 (Aug. 2011), <http://apps.americanbar.org/buslaw/blt/content/2011/08/keeping-current-patents.pdf> (discussing the divergent R&D models employed by various firms and noting that the “crosscurrents of [these] opposed powerful industry groups led to a stalemate on patent reform efforts in 2005”).

118. For example, before the Supreme Court rendered the question moot by deciding *eBay*, a significant obstacle to the passage of patent-reform legislation was the biopharmaceutical industry's opposition to a provision that would have overturned the Federal Circuit's rule in favor of automatic permanent injunctive relief. See, e.g., *Amendment in the Nature of a Substitute to H.R. 2795, the “Patent Act of 2005”*: Hearing on H.R. 2795 Before the Subcomm. on Courts, the Internet & Intellectual Prop. of the H. Comm. on the Judiciary, 109th Cong. 28–29 (2005) (statement of Robert B. Chess, Chairman, Nektar Therapeutics) (“If you allowed courts to weigh equities and balance hardships, our patents would be weakened, and research and development would suffer.”). These predictions of doom proved unfounded. Although the biopharmaceutical industry faces many challenges, post-*eBay* case law on remedies is not one of them.

119. But the significant procedural improvements the AIA put in place are very important, particularly to the extent that they allow the PTO to function more efficiently. Many of these improvements are discussed in Arti K. Rai, *Allocating Power over Fact-Finding in the Patent System*, 19 BERKELEY TECH. L.J. 907 (2004); and Arti K. Rai, *Growing Pains in the Administrative State: The Patent Office's Troubled Quest for Managerial Control*, 157 U. PA. L. REV. 1051 (2009) [hereinafter Rai, *Growing Pains*].

Congress has conferred upon the PTO the sole authority to adjudicate the validity of patent applications.¹²⁰ Moreover, now that the PTO has the power to conduct postgrant review proceedings that resemble formal adjudications, the focus on the PTO is likely to intensify.

Numerous scholars argue that, as between courts and the PTO, courts represent the more appropriate policymaker. These scholars assert that because the Patent Act has a structure similar to the Sherman Act's, Congress has thereby delegated authority to the courts to make federal common law.¹²¹ Moreover, the history of court and common-law primacy arguably dates back to the first patent statute of 1790.¹²²

Scholars who favor courts recognize the limitations the judicial branch faces with respect to large-scale policy formulation. Courts can act only in the context of specific cases and controversies presented to them. Thus, as the *Myriad* litigation illustrates, important issues may be left undecided for long periods of time. Moreover, the goal of resolving a particular controversy may sometimes be in tension with the goal of broad-based policy formulation.¹²³ Scholars who favor courts also acknowledge limitations with respect to the two patent-specific considerations discussed in the previous Section: expertise and avoidance of capture. Even a specialized court like the Federal Circuit does not have the expertise systematically to understand every area of science or to

120. Patent Act of 1952, 35 U.S.C. § 2(a)(1) (2006).

121. See, e.g., BURK & LEMLEY, *supra* note 20, at 103 (suggesting that the Patent Act is more akin to the Sherman Act, 15 U.S.C. §§ 1–7 (2006), than the tax code because judicially created doctrines play a large role in the application of both the Patent Act and the Sherman Act); Nard, *supra* note 20, at 53 (2010) (“[T]he patent code, much like the Sherman Act, is a common law enabling statute, leaving ample room for the courts to fill in the interstices . . .” (footnotes omitted)). In prior work, I have also made this argument. See Arti K. Rai, *Engaging Facts and Policy: A Multi-Institutional Approach to Patent System Reform*, 103 COLUM. L. REV. 1035, 1116–20 (2003) (discussing analogies between the patent and antitrust statutes and stating that “the patent statute, as currently structured, contemplates . . . judicial development of patent common law”).

122. Nard, *supra* note 20, at 53 n.9 (“[T]he structure of the patent code and corresponding delegation of judicial lawmaking power has remained a fixture since 1790.”).

123. R. Polk Wagner, *The Two Federal Circuits*, 43 LOY. L.A. L. REV. 785, 789–90 (2010) (exploring the Federal Circuit’s dual role as a “decider” of cases and a “manager” of the jurisprudence and explaining that those two roles may “diverge”).

collect and analyze economic data.¹²⁴ Furthermore, like other specialized courts, the Federal Circuit is susceptible to capture.¹²⁵

Scholars do not appear to have recognized, however, the extent to which judicial modes of policymaking operate in the shadow of retroactivity. As noted in Section A, retroactivity makes significant contraction of patentability difficult, even if a particular patent-issuance practice emerged without deliberation and thus resembles, in the words of Judge Bryson in *Myriad II*, a “collective right of adverse possession.”¹²⁶

Scholars also overestimate the normative case against administratively driven, prospective policymaking. One common argument against a large administrative presence in patent law is that patents are property rights and therefore should not be subject to administrative regulation. This argument has little merit. Even assuming that patents are property rights,¹²⁷ and even further assuming that patents are constitutionally protected property rights for purposes of the Takings Clause,¹²⁸ patents could still be subject to regulation. Agencies such as the Environmental Protection Agency (EPA) routinely regulate tangible property rights. Given that the American legal system has longstanding models for the administrative regulation of tangible property rights, the case for carving out an exception for intangible property rights seems dubious.

Indeed, for those who are concerned about protecting settled expectations associated with property rights, judicial development of

124. Although Federal Circuit clerks generally have a technical background and the Federal Circuit has a small technical staff, this level of staffing does not approach that of the PTO. At the conclusion of FY2011, the PTO had 6785 examiners. U.S. PATENT & TRADEMARK OFFICE, PERFORMANCE AND ACCOUNTABILITY REPORT: FISCAL YEAR 2011, at 187 tbl.29 (2011), available at <http://www.uspto.gov/about/stratplan/ar/2011/USPTOFY2011PAR.pdf>. Moreover, as discussed further in Part IV, it has set up an Office of the Chief Economist.

125. See Benjamin & Rai, *supra* note 1, at 314–16 (suggesting that capture can be seen in “various empirical studies indicat[ing] that the Federal Circuit is substantially less likely . . . to find patents invalid than its predecessor regional courts of appeals”).

126. *Myriad II*, 653 F.3d 1329, 1381 (Fed. Cir. 2011) (Bryson, J., concurring in part and dissenting in part).

127. To put it mildly, this issue is contested. See, e.g., Mark A. Lemley, *Property, Intellectual Property, and Free Riding*, 83 TEX. L. REV. 1031, 1035 n.8 (2005) (listing numerous articles by scholars who regard patents as being different from ordinary property). The argument for equating patents with property rights is particularly weak in the information-technology industries, in which portfolios comprising large numbers of patents with unclear boundaries are the norm. See *infra* Part III.

128. U.S. CONST. amend. V (“[N]or shall private property be taken for public use, without just compensation.”).

patent law should be more troubling than administrative development, as it is more likely to disrupt these expectations. Not only can administrative rule changes explicitly be made prospective, but standard administrative-law doctrine also counsels against retroactive rulemaking absent specific congressional authorization.¹²⁹ Even for agencies like the PTO, which does not have rulemaking authority over questions of patent validity, ex ante decisionmaking through guidelines that can be quickly assessed by the courts in the context of particular test cases is less likely to have retroactive effects than traditional judicial decisionmaking.

Notably, with the AIA's establishment of robust procedures for postgrant administrative review, PTO guidelines can be challenged quickly, not only in decisions to deny patents but also in decisions to grant patents that will later be susceptible to challenge postgrant. In fact, the AIA specifically authorizes the PTO director to institute postgrant review proceedings to address "novel or unsettled legal question[s] that [are] important to other patents or patent applications."¹³⁰ Such novel or unsettled questions could obviously include questions first identified in PTO guidelines.

The most compelling objection to an administrative approach to patent policymaking arises from concerns about capture. The administrative-capture argument deserves serious attention even though, as noted, the Federal Circuit is itself not immune from capture. Precisely what capture means for administrative approaches to patent law is not as straightforward as some scholars assume. In contrast with the quid pro quo style of capture associated with members of Congress, agency heads cannot be captured through direct monetary contributions. For this reason, theorists of agency capture have typically been concerned about such issues as a revolving door between the agency and the industry groups it regulates, informational capture, and efforts by agency officials to curry favor with industry groups that will then act on the agency's behalf in securing budget increases and other benefits for the agency from captured members of Congress.¹³¹

129. See, e.g., *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988) ("[C]ongressional enactments and administrative rules will not be construed to have retroactive effect unless their language requires this result.").

130. Leahy-Smith America Invents Act, Pub. L. No. 112-29, sec. 6, § 324(b), 125 Stat. 284, 307 (2011) (to be codified at 35 U.S.C. § 324(b)).

131. See, e.g., Rachel E. Barkow, *Insulating Agencies: Avoiding Capture Through Institutional Design*, 89 TEX. L. REV. 15, 22–23 (2010) (providing an overview of the key issues

As noted earlier, however, the regulated industries in the patent system are numerous and possess diverse views of patents. A PTO decision putting forward a strict interpretation of the patent-validity requirements might therefore be just as useful for generating support from relevant interest groups as a lax view of such requirements. Thus, for example, 2011 PTO examination guidelines focused on software-application claims significantly restrict the potential scope of such claims.¹³²

Ultimately, insofar as the PTO is biased, it is biased for many of the same reasons that the Federal Circuit has sometimes been seen as biased. Both institutions tend to perceive patents—as opposed to, for example, competition law, public R&D funding, or spillovers into the public domain—as the central drivers of innovation. Relatedly, both institutions hear disproportionately from patent lawyers. Although patent lawyers may represent both plaintiffs and defendants in cases, associations of patent lawyers are often perceived as being quite pro-patentee.¹³³ The available empirical data on amicus briefing backs up that perception—in Federal Circuit and Supreme Court cases, 55 percent of amicus briefs filed by bar associations favor the patentee, a percentage that is considerably higher than the 5 percent filed by high-tech companies in favor of the patentee or the 28 percent filed by the government.¹³⁴

contributing to agency capture such as the “revolving-door phenomenon” and “information advantage”).

132. See Supplementary Examination Guidelines for Determining Compliance with 35 U.S.C. 112 and for Treatment of Related Issues in Patent Applications, 76 Fed. Reg. 7162, 7171 (Feb. 9, 2011) (“Specifically, the scope of the claims must be less than or equal to the scope of the enablement provided by the specification.”). Holding the line of validity can also discourage frivolous applications and reduce workload. Concerns about PTO workload loomed large in the government’s decision to take a strong stance against a rigid TSM test. See *supra* text accompanying notes 37–42.

Patent scholars sometimes suggest that because the PTO’s operations depend on applicant fees, the agency will be biased in favor of patentability. But this argument is too facile. Standard constitutional law requires that, absent explicit congressional authorization, agencies can only charge fees sufficient to recover costs. As long as denying applications produces cost recovery in the same manner as granting applications, dependence on fees should not, in and of itself, be a source of bias. A bias problem instead arises primarily because Congress has historically set fee schedules in a manner that requires patent grants substantially to subsidize denials. Rai, *Growing Pains*, *supra* 119, at 2067–68. The fee-setting authority conferred on the PTO through the AIA allows the PTO to fix this bias.

133. Colleen V. Chien, *Patent Amicus Briefs: What the Courts’ Friends Can Teach Us About the Patent System*, 1 U.C. IRVINE L. REV. 395, 421–22 (2011).

134. *Id.* at 421 nn.155–56.

Reasonable minds can differ over whether the views of the PTO and the Federal Circuit are correct. Scholars do not, after all, have unassailable empirical evidence regarding the relative importance of patents, even for particular players in particular industries. As noted, however, lack of confidence in any ultimate substantive answer only makes the process by which competing views are put forward even more important. More frequently than is done in the existing system, those views should be aired in a decisionmaking process that occurs before substantial R&D investments have been made. Although ex ante decisionmaking is not always possible or desirable, the existing system, in which most important policy questions are left open until the Federal Circuit or the Supreme Court happens to take a case implicating them, tilts unduly towards the ex post alternative.

C. *The DNA-Patenting Controversies as Institutional-Choice Case Studies*

If the institutional desiderata include expertise, avoidance of capture, and prospective action, the DNA-patenting controversies provide a useful dichotomy: In the debate over the utility and written-description guidelines, expertise was deployed in a prospective manner that avoided capture. By contrast, in the patentable-subject-matter debate, non-PTO expertise questioning the conventional wisdom was deployed late in the game and was therefore significantly less useful.

When faced with the PTO's utility guidelines in *In re Fisher*, the Federal Circuit had good reason to uphold them. Indeed, the court's opinion should have gone significantly further than its lukewarm statement that the guidelines could be given "judicial notice to the extent they do not conflict with the statute."¹³⁵ In general, PTO actions should be given at least the default level of deference prescribed by the Court in *Skidmore v. Swift & Co.*¹³⁶ The *Skidmore* default, which applies when higher levels of deference do not, holds that agency action is given deference "depend[ing] upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade."¹³⁷ Under *Skidmore*, an

135. *In re Fisher*, 421 F.3d 1365, 1372 (Fed. Cir. 2005) (quoting *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 964 (Fed. Cir. 2002)) (internal quotation mark omitted).

136. *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944).

137. *Id.* at 140.

agreement reached by expert agencies after extensive debate surely exhibits, at a minimum, thoroughness of consideration.

By contrast, in *Myriad II*, the *Skidmore* preference for “consistency with earlier . . . pronouncements” was violated. More generally, concerns about retroactive impact counseled against judicial adoption of the government’s position. Judge Moore’s concurrence put the point particularly sharply: according to Judge Moore, if she were deciding the case “on a blank canvas,” she might well have concluded that certain types of claims involving gDNA sequences were not patentable subject matter.¹³⁸ In response, Judge Bryson’s dissent noted that the courts could look to precedent that had reversed long-held PTO determinations; for example, the Supreme Court’s landmark decision in *Chakrabarty* had reversed the settled PTO practice of denying patents to microorganisms.¹³⁹ Judge Moore’s rebuttal highlighted the manner in which judicial retroactivity can create a one-way ratchet in patent law; she observed that “there is a clear difference between allowing additional patent protection where none previously existed, and denying patent protection decades (or centuries) after the fact, thereby eliminating a large number of property rights.”¹⁴⁰

For purposes of thinking more broadly about the executive branch’s prospective policymaking role, however, the relevance of the DNA-patenting case studies is limited. Most of the prospective agency action outside of the PTO has come from NIH in the context of the life sciences. Even within the life sciences, NIH is not necessarily the ideal sister agency to engage with the PTO. Although NIH’s mission encompasses both seeking “fundamental knowledge” and the “application of that knowledge to enhance health,”¹⁴¹ NIH is not necessarily an expert in the law and economics of transforming life-science research into commercial invention. Indeed, NIH employed flawed legal and economic reasoning in its initial decision to seek EST patents. Moreover, although NIH subsequently raised utility and written-description objections to DNA patenting, it did not raise patentable-subject-matter questions.¹⁴²

138. *Myriad II*, 653 F.3d 1329, 1366 (Fed. Cir. 2011) (Moore, J., concurring in part).

139. *Id.* at 1381 (Bryson, J., concurring in part and dissenting in part).

140. *Id.* at 1370 (Moore, J., concurring in part).

141. *Mission*, NAT’L INSTS. OF HEALTH (Mar. 3, 2011), www.nih.gov/about/mission.htm.

142. *See supra* Part I.B.2.

Nor is legal and social-science work necessarily NIH's highest priority. GAO reports from the 1990s cited significant deficiencies in the agency's implementation of the basic accountability and reporting provisions of the Bayh-Dole Act,¹⁴³ the statute that governs the commercialization of federally funded research.¹⁴⁴

In sum, although NIH has played a very valuable role in pushing the patent community to consider certain issues of DNA patenting *ex ante*, a more comprehensive *ex ante* approach will require enlisting other agencies and executive-branch components. The next Part discusses agencies and components that could fulfill this role. For purposes of investigating the question concretely, Part III uses software patents as an example.

III. BEYOND THE UTILITY AND WRITTEN-DESCRIPTION GUIDELINES: OTHER EX ANTE APPROACHES TO PATENT VALIDITY

As noted, non-PTO executive-branch actors such as NIH have played useful roles in the evolution of patentability policy in the field of biotechnology. But biotechnology is only one area of innovation and, even within this area, the record of involvement by executive-branch actors other than the PTO is less than perfect. Resolving the institutional need for greater *ex ante* policymaking requires broadening the perspective with which scholars have generally approached the institutional-choice question. In this Part, I attempt to do so by invoking an entirely different, but equally important, area of technology: software.

Software patents are highly controversial, perhaps even more so than gene patents. Some commentators argue that software should *per se* not constitute patentable subject matter. Many others complain that software patents have undue breadth and suffer from unclear boundaries.¹⁴⁵ These commentators also contend that the consequences of the poor quality and large quantity of software patents include patent thickets. At a minimum, these thickets require

143. Bayh-Dole Act, 35 U.S.C. §§ 200–212 (2006 & Supp. IV 2010).

144. U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-99-242, TECHNOLOGY TRANSFER: REPORTING REQUIREMENTS FOR FEDERALLY SPONSORED INVENTIONS NEED REVISION 5–6 (1999).

145. *See, e.g.*, JAMES BESSEN & MICHAEL J. MEURER, PATENT FAILURE: HOW JUDGES, BUREAUCRATS, AND LAWYERS PUT INNOVATION AT RISK 187–214 (2008) (discussing the vagueness and undue breadth of software patents).

firms to expend significant resources maintaining large defensive patent portfolios.¹⁴⁶

The problems of excessive breadth and unclear boundaries can be traced in part to the evolution of patentable-subject-matter jurisprudence in the 1980s and 1990s. In the 1981 case *Diamond v. Diehr*,¹⁴⁷ a 5–4 majority of the Supreme Court shifted from skepticism toward software claims to measured acceptance. The Court concluded that a patent claim to a process for curing rubber that relied heavily on software implementing the Arrhenius equation was patentable because the process as a whole “transformed” the rubber into a “different state or thing.”¹⁴⁸

After this decision, the PTO began to receive significant numbers of applications for patents encompassing software. The PTO tried, however, to use the patentable-subject-matter doctrine to limit the scope of software patents. Perhaps most notably, in the 1994 case of *In re Alappat*,¹⁴⁹ the PTO asserted that the “means plus function” claims in question—essentially, claims to any computer “means” that could perform particular mathematical functions—did not represent patentable subject matter.¹⁵⁰ According to the PTO, applications that could encompass any general-purpose computer represented unpatentable mathematical algorithms.

Sitting en banc, the Federal Circuit rejected the PTO’s conclusion. The majority determined that the claims in question covered a “specific machine” that produces a “useful, concrete, and tangible result.”¹⁵¹ Judges Glenn Archer and Helen Nies did, however, author a powerful dissent pointing out that the patent applicant was simply claiming “old circuitry elements in an arrangement *defined by a mathematical operation, which only performs the very mathematical operation that defines it.*”¹⁵² Their dissent largely adopted the position

146. See, e.g., Rai, *Growing Pains*, *supra* note 119, at 2068–70 (discussing the literature on patent thickets, defensive patent portfolios, and the possibility of using certain types of filing fees to control thickets).

147. *Diamond v. Diehr*, 450 U.S. 175 (1981).

148. *Id.* at 183.

149. *In re Alappat*, 33 F.3d 1526 (Fed. Cir. 1994) (en banc).

150. *Id.* at 1565.

151. *Id.* at 1544.

152. *Id.* at 1563.

taken by the PTO, as well as by Seagate, the single technology company that chose to file an amicus brief in the case.¹⁵³

Now imagine that the PTO's resistance to the broad scope of software patents had been supported by another executive-branch agency. Specifically, the PTO might have found support in the DOJ Antitrust Division, an agency with deep economic expertise and a vision of innovation that relies heavily on competition. Further, suppose that the bond between the PTO and the Antitrust Division had been forged because they had worked together to issue, through the notice-and-comment process, guidelines that identified the appropriateness, under *Diehr* and other Supreme Court case law, of rejecting claims that purported to cover a mathematical operation performed via a generic computer. The PTO and Antitrust Division might then have worked together to convince the SG to file a petition for certiorari.

If the SG's track record of success in convincing the Supreme Court to take patent cases had been applicable,¹⁵⁴ the Court might well have taken the case. At the Supreme Court level, additional technology companies would presumably have supported limitations on the patents' scope.¹⁵⁵ Were the Supreme Court then to have held in favor of the government, it might have provided some early resolution of software patent-scope questions.

In reality, the Federal Circuit did not squarely address the issue of software-patent scope until over a decade later. Starting in 2008, in cases such as *Aristocrat Technologies Australia PTY Ltd. v. International Game Technology*,¹⁵⁶ three-judge panels on the court began holding that "means plus function" patent claims that encompassed any computer "means" were invalid under the disclosure section of the Patent Act unless the application in question included specific information about the algorithm involved.¹⁵⁷

153. See Richard H. Stern & Edward P. Heller, III, In re Alappat: *The Gordian Knot Retwisted*, 2 U. BALT. INTELL. PROP. L.J. 187, 187 (1994) (discussing the problems with allowing patents on algorithms when "the claims are 'limited' to use of the algorithm in programmed computer equipment"). Professor Stern was the author of Seagate's amicus brief, and Heller was patent counsel for Seagate Technology.

154. Duffy, *supra* note 13, at 519.

155. Not surprisingly, patent cases before the Court draw far more amicus briefs than do cases before the Federal Circuit. Chien, *supra* note 133, at 417–18.

156. *Aristocrat Techs. Austl. PTY Ltd. v. Int'l Game Tech.*, 521 F.3d 1328 (Fed. Cir. 2008).

157. *Id.* at 1333; see also *Finisar Corp. v. DirecTV Grp., Inc.*, 523 F.3d 1323, 1340 (Fed. Cir. 2008) ("[T]he patent must disclose, at least to the satisfaction of one of ordinary skill in the art, enough of an algorithm to provide the necessary structure . . .").

Although these cases are quite valuable—especially as they have been interpreted in recent PTO-examination guidelines¹⁵⁸—they stake out a position that is somewhat more modest than the position advanced by the PTO in *Alappat*. In addition, the cases came more than a decade after widespread complaints regarding the vagueness and overbreadth of software patents had begun to emerge.

As a real-world matter, how might policymakers engineer more frequent consultation *ex ante* between the PTO and “competition-oriented” executive-branch agencies such as the DOJ Antitrust Division? In general, pressure to engage in interagency consultation is often provided by powerful White House offices and components such as the Office of Management and Budget or the National Economic Council. Prominent think tanks have recently emphasized the pressing need for individuals within these offices to focus on interagency innovation and long-term competition strategy.¹⁵⁹ The official job descriptions for members of these offices should include facilitating, or even mandating, consultation between agencies with diverse perspectives on innovation.

IV. RULEMAKING AUTHORITY OVER QUESTIONS OF PATENTABILITY?

To those with an administrative-law bent, the preceding discussion of guidelines and *ex ante* decisionmaking might seem a half-measure. Why not simply confer upon the PTO rulemaking authority over questions of patent validity? Under standard administrative-law doctrine, courts would then have to give such rules the strong form of deference enunciated in *Chevron* and its progeny.

158. See Supplementary Examination Guidelines for Determining Compliance with 32 U.S.C. 112 and for Treatment of Related Issues in Patent Applications, 76 Fed. Reg. 7162, 7168 (Feb. 9, 2011) (“The structure corresponding to a . . . claim limitation for a computer-implemented function must include the algorithm needed to transform the general purpose computer or microprocessor disclosed in the specification.”).

159. See, e.g., JOHN PODESTA, SARAH ROSEN WARTELL & JITINDER KOHLI, CTR. FOR AM. PROGRESS, A FOCUS ON COMPETITIVENESS: RESTRUCTURING POLICYMAKING FOR RESULTS 19 (2010), available at <http://www.americanprogress.org/issues/2010/12/pdf/competitiveness.pdf> (recommending the development of an Interagency Competitiveness Task Force, led by a new deputy at the National Economic Council, that would “oversee[] White House coordination of competitiveness initiatives, and monitor[] their implementation by agencies”). In prior work endorsed by the Information Technology and Innovation Foundation, Professor Stuart Benjamin and I propose the creation of a White House Office of Innovation Policy that would coordinate innovation policy across agencies. STUART MINOR BENJAMIN & ARTI K. RAI, STRUCTURING U.S. INNOVATION POLICY: CREATING A WHITE HOUSE OFFICE OF INNOVATION POLICY (2009), available at http://www.itif.org/files/WhiteHouse_Innovation.pdf.

Additionally, as contrasted with guidelines, which are likely to be prospective in nature only because they are likely to address issues presented in more recent applications, administrative-law doctrine affirmatively requires that, absent specific congressional authorization, rules address issues prospectively.¹⁶⁰ Rules enacted pursuant to congressionally delegated authority also would not have to wait for court approval to have the imprimatur of law. Indeed, unless challenged, they would be law. Rulemaking could therefore produce controlling authority even more quickly than guidelines.

Yet most scholarly discussions of an administrative model for the patent system, including my own, have generally stopped short of advocating a congressional grant of rulemaking authority on core questions of patentability—that is, authority over such questions as what constitutes patentable subject matter, what represents nonobviousness, and what type of disclosure is necessary to satisfy Section 112 of the Patent Act.¹⁶¹ In prior work, I argue that conferring such authority would be premature because the PTO lacks the large cadre of economists and policy-oriented thinkers possessed by other agencies—such as the Federal Communications Commission and the FTC—that work on questions of technological innovation and that have at least some rulemaking authority.¹⁶²

Since that work was published, however, the PTO has created and staffed an Office of the Chief Economist. Early versions of the 2007 patent-reform bill¹⁶³ included language conferring on the PTO rulemaking authority not only over questions of patentability but also

160. See *supra* note 129.

161. The existing scope of the PTO's rulemaking authority is not entirely clear. The Federal Circuit, as well as many commentators, have framed the question in terms of substance versus procedure. See, e.g., *Tafas v. Doll*, 559 F.3d 1345, 1354 (Fed. Cir. 2009) (analyzing “whether the Final Rules are substantive or procedural”). For an engaging argument that the substance-versus-procedure distinction is not grounded in the language of the Patent Act and that the PTO might have rulemaking authority that extends beyond the strict confines of procedure, see Sarah Tran, *Administrative Law, Patents, and Distorted Rules*, 80 GEO. WASH. L. REV. (forthcoming 2012) (manuscript at 8), available at <http://ssrn.com/abstract=1920417>. See also *Tafas*, 559 F.3d at 1366 (Bryson, J., concurring) (“While I think it is generally fair to characterize that statute as authorizing the promulgation of ‘procedural’ regulations, however, I do not think it necessary, or particularly helpful, to consider whether those regulations would be deemed ‘substantive’ . . .”). Neither Professor Tran nor Judge Bryson argues, however, that the PTO has rulemaking authority over issues such as patentable subject matter, obviousness, or the like.

162. Rai, *supra* note 121, at 1132–33.

163. Patent Reform Act of 2007, S. 1145, 110th Cong. (2007).

over all aspects of the Patent Act.¹⁶⁴ Perhaps in reaction to this expression of congressional interest, several scholarly articles advance the conventional suite of administrative-law arguments that favor conferring significant rulemaking authority on agencies that tackle technologically and economically complex questions.¹⁶⁵ These commentators argue that Congress should grant the PTO rulemaking authority over all issues of patent validity or, at the very least, over specific questions such as what constitutes patentable subject matter.¹⁶⁶ As these scholars emphasize, concerns about certain pathologies of the administrative state—including concerns about capture or about decisionmaking that is unduly responsive to changes in presidential administration—are hardly limited to the patent context. To the contrary, as discussed in Part II, the issue of PTO capture is more complex than most scholars acknowledge. Given the existence of competing well-heeled interest groups with diverse views, one-sided capture is unlikely.

Notably, in the context of a grant of rulemaking authority to the PTO, Congress could explicitly require the PTO to consult with specific agencies before making a rule. Congress has already embedded such consultation requirements within a variety of statutes.¹⁶⁷ At least one empirical study involving the Federal Energy Regulatory Commission (FERC) found that appropriately designed consultation requirements can force an agency to consider concerns

164. *Id.* § 11.

165. *See, e.g.*, Michael J. Burstein, *Rules for Patents*, 52 WM. & MARY L. REV. 1747, 1785 (2011) (“[S]ound patent policymaking depends on the ability of the decision maker to marshal relevant information On balance, agency rulemaking is more likely to reflect those characteristics than judicial adjudication.”); John M. Golden, *Patentable Subject Matter and Institutional Choice*, 89 TEX. L. REV. 1041, 1096 (“The categorical, policy-laden nature of the resulting interpretive questions suggests that these questions are better left to primary resolution by a policy organ specially concerned with such questions—namely, an administrative agency.”); Jonathan S. Masur, *Regulating Patents*, 2010 SUP. CT. REV. 275, 279 (“The time has come to consider reorienting patent law’s institutional arrangements to bring them more into line with the rest of the administrative state.”).

166. *See, e.g.*, Burstein, *supra* note 165, at 1806 (“Given the importance of innovation to economic growth and cultural well-being, it is critical that the institutions responsible for making innovation policy decisions be rationalized. Granting the PTO substantive rule-making authority is a good first step.”); Golden, *supra* note 165, at 1111 (“[T]he best agency to carry out . . . rulemaking [related to patentable subject matter] is the USPTO.”); Masur, *supra* note 165, at 279 (“[T]he most straightforward means of achieving this would be for Congress to endow the PTO with substantive rule-making authority.”).

167. *See* Lisa Schultz Bressman, *Procedure as Politics in Administrative Law*, 107 COLUM. L. REV. 1749, 1799 n.275 (2007) (listing the statutes containing consultation requirements).

that it would otherwise ignore.¹⁶⁸ Specifically, congressional passage of strict consultation requirements in the Electric Consumers Protection Act of 1986¹⁶⁹ “forc[ed] FERC to pay attention to the environmental concerns it had long ignored.”¹⁷⁰

The swift elimination of the expanded rulemaking-authority provision from the 2007 predecessor to the AIA suggests that a move in this direction might not be politically feasible, at least not in the political climate and setting in which the AIA was passed. No prominent interest group is advocating for such authority, and many interest groups view the regulation of patents as being inconsistent with the principle that patents are property rights. As the example of the EPA, among many others, illustrates, the view that agencies never regulate property rights is incorrect. Nonetheless, that view continues to hold sway among many powerful groups. Until that view is abandoned, an intermediate approach is needed. An approach based on ex ante PTO guidelines backed by the full weight of the executive branch has already shown some promise. Especially to the extent that courts properly give significant deference under *Skidmore* to considered executive-branch decisions, a guidelines-based approach should be made a much more integral part of patent policymaking.

In fact, the executive branch could also use the postgrant-review authority conferred upon the PTO by the AIA to go one step further. As a doctrinal matter, under current Supreme Court precedent interpreting the contexts in which *Chevron* applies, the government could ask for *Chevron* deference toward decisions made in postgrant review proceedings.¹⁷¹ As a normative matter, in cases in which the PTO is applying guidelines formulated after widespread consultation with relevant stakeholders, courts should be inclined to give those guidelines strong deference. To be sure, administrative-law scholars generally disfavor large-scale policymaking through agency adjudication. As they rightly note, for purposes of policymaking, agency adjudication suffers from some of the same defects as

168. J.R. DeShazo & Jody Freeman, *Public Agencies as Lobbyists*, 105 COLUM. L. REV. 2217, 2221–22 (2005).

169. Electric Consumers Protection Act of 1986, Pub. L. No. 99-495, 100 Stat. 1243 (codified as amended in scattered sections of 16 U.S.C.).

170. *Id.*

171. *United States v. Mead Corp.*, 533 U.S. 218, 226–27 (2001) (holding that *Chevron* deference generally applies in proceedings that resemble formal adjudications).

adjudication in the courts.¹⁷² Rulemaking, not adjudication, is the innovation of the administrative state. But in this case, adjudication would have been preceded by an activity much like rulemaking: guideline formation through widespread consultation with relevant stakeholders.

CONCLUSION

Among patent scholars who address institutional questions, a significant number tend to favor the judiciary over the PTO as the policymaker of choice. Even though courts have familiar limitations with respect to policymaking, scholars often argue that the PTO is more likely to be captured. On closer examination, however, this capture story is less obviously true than it might seem. Further, at least in DNA-patenting cases, in which PTO decisionmaking has been heavily influenced by other executive-branch decisionmakers, the conclusions reached by the executive branch have been defensible vis-à-vis charges of capture.

Executive-branch firepower should be deployed to a greater extent ex ante. The ex post development of patent law by the courts poses many familiar problems. Less recognized, but important, it often yields a one-way ratchet toward the expansion of patent protection. When courts expand patent rights, they generally do not have to worry much about retroactive effects. By contrast, as the *Myriad* case illustrates, courts face legitimate concerns about retroactive effect when they are called upon to curtail such rights.

More frequent ex ante intervention would avoid these problems without precluding ex post development and adaptation. Moreover, whereas the existing system forces courts to act with only limited guidance from technologically and economically sophisticated executive-branch agencies, this Essay's call for ex ante intervention would help lay a sound foundation for further ex post development. Ultimately, as the DNA-patenting cases demonstrate, early and robust executive-branch discussion of patent policy should be welcomed by all those interested in improving the patent system.

172. Cf. M. Elizabeth Magill, *Agency Choice of Policymaking Forum*, 71 U. CHI. L. REV. 1383, 1384–85 (2004) (noting the widespread view that rulemaking is the preferred policymaking vehicle).