

ESSAY

Patentability Policy Across the Executive Branch: What the DNA Patent Controversies Teach About Institutional Choice

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Arti K. Rai¹

Among patent law scholars, debate over questions of institutional choice is alive and well. Several law reviews have recently devoted entire issues to analysis of the Court of Appeals for the Federal Circuit (which hears all appeals in patent cases) as an institution.² The Supreme Court's recent flurry of activity on the patent front has prompted many articles debating its institutional role.³ Many of these contributions focus on policy questions and are comparative in their ambition: they compare courts to Congress and to the U.S. Patent and Trademark Office ("PTO") in terms of respective competence in making policy.⁴

¹ Elvin R. Latty Professor of Law, Duke Law School and Duke Institute for Genome Sciences and Policy. From 2009-2010, I served as the Administrator, USPTO 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 advisor to the Department of Commerce's Office of General Counsel. However, this article relies only on publicly available information and represents my views only. An earlier version of this Essay was delivered as the 9th Annual Meredith and Kip Frey Lecture in Intellectual Property at Duke Law School. I thank my intellectual property colleagues Jamie Boyle, David Lange, and Jerry Reichman for their insights.

² Loyola L. Rev 2010 (including articles by . . .) ; GW L.Rev. 2010 (including articles by . . .)

³ See, e.g., John Golden, *The Supreme Court as "Prime Percolator": A Prescription for Appellate Review of Questions in Patent Law*, 56 UCLA L. REV. 657 (2009) (arguing that Supreme Court review 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); Rochelle Cooper Dreyfuss, *What the Federal Circuit Can Learn from the Supreme Court – and Vice Versa*, 59 AM.U.L.REV. 787 (2010).

⁴ I use the term patent policy advisedly. I mean to distinguish it from the determinations of science-related adjudicative facts (e.g. what was the state of the scientific art at the time the patent applicant filed for her invention) that represent an important mechanism by which patent validity standards implement the policy goal of innovation. See Stuart Minor Benjamin and Arti K. Rai, *Who's Afraid of the APA: What the Patent System Can Learn From Administrative Law*, 95 GEORGETOWN LAW JOURNAL 269, 276 (2007); see also Arti K. Rai, *Engaging Facts and Policy: A Multi-Institutional Approach to Patent System Reform*, 103 COLUM. L. REV. 1035, 1044-1051 (2003) (discussing central role of adjudicative facts in

Patent law scholars have also begun to recognize the role of executive branch actors other than the PTO. For example, scholars have noted that the International Trade Commission (“ITC”), which issues injunctions barring the entry of goods that it finds infringe valid U.S. patents, ends up affecting patent policy, particularly with respect to remedies.⁵ The Department of Justice’s Antitrust Division is an important institutional policy actor at the patent and competition interface. The Federal Trade Commission (“FTC”) is also highly salient in this space⁶ – although the FTC is of course an independent agency, its work is closely integrated with that of the executive branch.⁷

That non-PTO executive branch actors would play a significant role in areas *other* than patent validity is unsurprising. The PTO’s authority under the patent statute is largely confined to adjudication of validity questions raised by patent applications. More notable, then, is the manner in which the Supreme Court’s renewed interest in patent law has made the Department of Justice’s Office of the Solicitor General a significant policy player on (*inter alia*) core issues

claim construction and validity determinations). Policy is also distinct from questions of patent law to which the patent statute provides clear answers.

⁵ See, e.g., Sapna Kumar, *Expert Court, Expert Agency*, __ U.C. DAVIS L. REV. __ (forthcoming 2011); Sapna Kumar, *The Other Patent Agency: Congressional Regulation of the ITC*, 61 FLA. L. REV. 529 (2009); David Schwartz, *Courting Specialization: An Empirical Study of Claims Construction Comparing Patent Litigation Before Federal District Courts and the International Trade Commission*, 59 WM. & MARY L. REV. 1699 (2009); Colleen V. Chien, *Patently Protectionist? An Empirical Analysis of Patent Cases at the International Trade Commission*, 50 WM. & MARY L. REV. 63 (2008); Kali Murray, *The Cooperation of Many Minds: Domestic Patent Reform in a Heterogeneous Regime*, 48 IDEA 289 (2008) (all discussing various aspects of the ITC’s role in the patent system)

⁶ C. Scott Hemphill, *An Aggregate View of Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, __ COLUM. L. REV. __ (2009) (discussing both adjudicatory actions by the FTC and the possibility of FTC engaging in rulemaking with respect to “reverse payments” in settlement of patent disputes between brand-name pharmaceutical firms and generic firms); Daniel Crane, *Technocracy and Antitrust*, 86 TEX. L. REV. 1159, 1200-01, 1206-1211 (detailing FTC’s extensive involvement in the issue of reverse payments and arguing that the FTC adjudicatory position with respect to these settlements essentially adopts a rule that should be given *Chevron* deference); cf. Murray, *supra note* __, at 304-316 (discussing FTC as an “expertise actor” and the ITC as a “replicative actor”)

⁷ See *infra* __.

of patent validity. Professor John Duffy’s recent contribution making this point is a novel, and important, addition to the institutional choice literature.⁸

Even less discussed in the literature is the reality that executive branch components other than the Solicitor General have influenced policy on patent validity. We recently saw a striking, and candid, acknowledgment of this influence in the context of *Association for Molecular Pathology v. Myriad*, a case challenging on patentable subject matter grounds the DNA-related product and process patents held by the diagnostic firm Myriad. The Federal Circuit amicus brief filed by the U.S. government in that case proclaims at the outset that

[t]he 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 federal agencies and components, including the Patent and Trademark Office, the National Institutes of Health, the Antitrust Division of the Department of Justice, the Centers for Disease Control, the Office of Science and Technology Policy, and the National Economic Council.

The need specifically to identify the interests of other agencies is unsurprising, as the amicus brief contravenes decades-old PTO policy regarding whether product claims to genomic DNA represent patentable subject matter.⁹

At least in the life sciences, moreover, this interest by other agencies in core questions of patent validity is not a one-off event. To the contrary, in the life sciences, agencies other than the PTO have, over the last 20 years, significantly influenced the evolution of the rules and

⁸ John Duffy, *The Federal Circuit in the Shadow of the Solicitor General*, 78 GEO.WASH.L.REV. 518 (2010).

⁹ The government’s brief doesn’t address Myriad’s DNA-related process/method claims. For this reason, I focus in this Essay on the product claims. *See infra* ____.

standards that govern patent validity.¹⁰ In the early 1990s, the National Institutes of Health (“NIH”) first raised the question of whether innovation goals would be served by patents on gene-related research that was several steps upstream from a full gene of known biological function. By the late 1990s, NIH had come to a conclusion. As large numbers of patent applications drawn to gene fragments of unknown biological function began to be filed, NIH sounded an alarm over the transaction cost problems broad patents on early-stage research would pose for subsequent research.

An apparent consequence of consistent NIH pressure was PTO guidelines that raised the bar posed by the patent law requirement of utility. These guidelines (subsequently upheld by the Federal Circuit) allowed the PTO summarily to reject all claims to gene fragments of unknown biological function. During the same period, NIH also influenced the evolution of guidelines interpreting the so-called written description requirement for patenting. These written description guidelines have had the effect of keeping patent scope for all DNA patents relatively narrow.

Particularly given contemporaneous Federal Circuit case law that effectively eliminated the non-obviousness requirement in genomics, the utility and written description guidelines performed a significant gatekeeping role. In fact, the available empirical evidence indicates that

¹⁰ Specific criteria of patent validity have variously been seen as more rule-like or more standard-like. The optimum mix of rules and standards is an active debate in patent law, as it is in other areas of law. In prior work, I have argued that policy goals, particularly with respect to technologies that follow different development paths, can often be achieved through facially neutral standards that have disparate impact. See Arti K. Rai, *Building a Better Innovation System: Combining Facially Neutral Patent Standards With Regulation of End Product Therapeutics*, 45 HOUSTON L.REV. 1037 (2008). An example of a facially neutral standard with disparate impact is the utility standard on which this Essay focuses.

these guidelines were a critical factor in forestalling the development of a genomic patent thicket.¹¹

As a normative matter, investigating the role of executive branch actors other than the PTO has payoffs for the debate over institutional choice in patent policy. Critics of a policymaking role for the PTO, even as limited to the context of validity, have been concerned about capture.¹² The capture issue is not only more complex than conventionally understood but it is mitigated by the reality that, at least in significant life science cases, PTO decision making on validity has been 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 likely to reach conclusions that are plausible. In many (though not all) circumstances the existence of debate should be a factor that counsels in favor of judicial deference.

Of course, for purposes of thinking more globally about a PTO role in policymaking over patent validity, the reality that substantial intervention by other executive branch actors has been limited to the life sciences (and a sometimes overlapping category of Supreme Court cases in which the Office of the Solicitor General is heavily involved) represents an obvious limitation. On the other hand, one might imagine creating institutional structures that would allow executive branch actors like the Antitrust Division of the Department of Justice to play a more systematic role.

¹¹ See *infra* ____.

¹² See, e.g., Craig Allen Nard, *Legal Forms and the Common Law of Patents*, 90 B.U. L.REV.51, 57 (2010) (discussing “capture-prone administrative rulemaking”); DAN BURK AND MARK LEMLEY, *THE PATENT CRISIS AND HOW COURTS CAN SOLVE IT* 106-07 (2009).

A more systematic role *ex ante* would be particularly useful. As the *AMP v. Myriad* litigation illustrates, when non-patent agencies get involved late in the game, the policy space is likely to be quite constrained. Appellate courts that adjudicate disputes *ex post* will legitimately be quite concerned about the retroactive effects of their decision making on large numbers of existing patents. Additionally, because concerns about retroactive effects are less likely to be operative when courts expand patent rights, *ex post* approaches may yield a one-way ratchet in favor of expansion.

Of course, *ex ante* decisionmaking is not appropriate for all cases. But given the PTO's general tendency to refrain from *ex ante* decisionmaking through guidelines (and its related lack of rulemaking authority over questions of patent validity), the current approach tilts excessively towards the *ex post*.

A larger role for *ex ante* decision making does not necessarily require the PTO, or the executive branch more generally, to have rulemaking authority over patent validity. Although such authority would obviously produce controlling law more quickly, reasonably expeditious and relatively deferential review of guidelines could achieve many of the benefits of such authority. As contrasted with rulemaking authority, a guideline-focused approach would also be politically feasible.

Part I of the Article discusses, and adds to, the literature discussing how patent policy is made across the executive branch. It focuses on the particularly pervasive role executive branch agencies other than the PTO have played in DNA patenting debates. Part II argues that acknowledging the role of other executive branch agencies diminishes the concern about capture, which represents the most important objection to a significant administrative policymaking

presence. Particularly when made *ex ante*, decisions on which knowledgeable agencies with different perspectives can agree should be worthy of respect by reviewing courts. Part III draws upon the example of DNA patenting to consider how the executive branch could be more involved in setting patentability policy *ex ante*.

I. *The Policy Role of Executive Branch Actors Outside the PTO*

A. *Existing Literature*

To some extent, the existing literature has noted the role of executive branch actors other than the PTO. One strand of scholarship has looked at the increasingly influential role of the ITC, particularly after the Supreme Court's 2006 decision in *eBay Inc. v. MercExchange, L.L.C.*¹³ *eBay* makes it clear that, under patent law's traditional equitable principles, it is inappropriate for district courts automatically to order injunctive relief upon a finding that a patent is valid and infringed. However, because the ITC's legislative authorization to issue an exclusion order upon a finding that a patent is valid and infringed is unaffected by *eBay*, the case makes the ITC an attractive forum for patentees and a potentially important policy actor in the area of remedies.¹⁴

Another strand of scholarship has focused on the FTC and the prominent role this independent agency has played in the extended debate about antitrust concerns raised by patent dispute settlements between brand-name pharmaceutical firms and generic firms. Several recent

¹³ See *supra* note __ and references cited therein.

¹⁴ Additionally, because the Federal Circuit has chosen to give the strong form of administrative deference enunciated by *Chevron v. Natural Resources Defense Council*, 467 U.S. 837 (1984), to certain ITC interpretations of what constitutes a valid defense against infringement, see *Kinik*, the ITC has played a policymaking role in this narrow arena.

contributors to this debate have argued that greater deference by courts to FTC positions would be appropriate.¹⁵

Most relevant for present purposes, Professor John Duffy has recently highlighted the role of the Office of the Solicitor General (“SG”) in working with the PTO and other interested agencies to shape patent policy across the board, including on core questions of patent validity. Adding to his analysis patent cases decided in the Court’s 2010 term, we can conclude that the executive branch participated either as a party or as an amicus in all but 2 of the 18 cases actually decided by the Court since 1996.¹⁶ In 10 of the sixteen cases, the executive branch disagreed squarely with the Federal Circuit. In all but one of these cases, the SG won out over the Federal Circuit.

Two of these cases, the Court’s 2010 decision in *Bilski v. Kappos* and its 2007 decision in *KSR Int’l Co. v. Teleflex, Inc.*, involved core questions of patentability – patentable subject matter and nonobviousness respectively. In both of these cases, the PTO’s position was in tension with that taken by the Federal Circuit (or at least many three-judge panels thereof).¹⁷ Surprisingly, the government’s argument in *Bilski* did not fully convince the Supreme Court.¹⁸ However, the Court’s 5-4 decision to adopt a highly nebulous “abstraction” standard for what

¹⁵ See *supra* ____.

¹⁶ The PTO was on the brief in all of these cases other than *Stanford v. Roche*. That case involved patent issues raised by Bayh-Dole, a statute governing the patentability of federally funded research that is currently administered not 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 Bayh-Dole *infra* _____. In addition to the PTO, the FTC was on the brief in *Illinois Tool Works*, 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 v. Integra*, which addressed the scope of the exemption from patent infringement provided in the Hatch-Waxman statute. Notably, for cases litigated at the Supreme Court, the SG plays something of a convening role across the executive branch. Interested agencies can provide input even when they are not explicitly listed on the brief.

¹⁷ The *en banc* *Bilski* court did adopt the position urged by the government. In so doing, however, it rejected positions various three-judge Federal Circuit panels had previously taken. By many accounts, the *en banc* court’s change in position was an (unsuccessful) attempt to avoid review by the Supreme Court.

¹⁸ However, the *Bilski* Court did accept the government’s test as a “helpful clue.”

constitutes patentable subject matter in the context of a process claim represents less a loss on the part of the government than an abdication by the Court.¹⁹ Already the Court has granted certiorari in another “process as patentable subject matter” dispute, *Prometheus v. Mayo*.²⁰ Additionally, the *Myriad* case may well reach the Supreme Court as well.

By contrast, *KSR Int’l Co. v. Teleflex, Inc.*, was a huge win for the executive branch. The case involved a nonobviousness issue on which the PTO had repeatedly being rebuffed by the Federal Circuit. Specifically, many three-judge panels had required that PTO examiners identify a documentary “teaching, suggestion, or motivation” (“TSM”) to combine references to prior invention (so-called “prior art”) when using these references for purposes of demonstrating obviousness. In cases spread over a number of years, the PTO repeatedly argued that its examiners should not always have to point to documentary evidence indicating that particular references should be combined. Rather, in keeping with pre-Federal Circuit case law on official notice,²¹ examiners should be able to invoke their own knowledge of what an ordinary scientist in the area would be capable of doing.²² The Federal Circuit was not convinced. Although Federal 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.²³

¹⁹ Many commentators have complained about the lack of guidance provided by *Bilski*. See, e.g. Peter Menell, *Bilski’s Superficial Textualism*, 63 STAN.L.REV. 1289, 1305 (2011) (discuss the costs of the Supreme Court’s “ungrounded and incoherent” decisionmaking)

²⁰ That case raises the question of whether a process that involves administering a drug and then measuring metabolite levels to calibrate further dosage represent patentable subject matter.

²¹ *In re 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”)

²² See, e.g., *In re Beasley*, 117 F. App’x 739 (Fed. Cir. 2004); *In re Lee*, 277 F.3d 1338 (Fed. Cir. 2002); *In re Zurko*, 258 F.3d 1379, 1386 (Fed. Cir. 2001); *In re Dembiczak*, (also *Kotzab*?)

²³ See Benjamin and Rai, *supra* note __, at 290-93 (discussing language in certain panel opinions).

The PTO and SG did not choose to appeal any of these cases. However, because the Federal Circuit was often applying 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 called for the views of the Solicitor General as to whether it should grant certiorari, the executive branch weighed in with a very strong statement in favor. Both the brief recommending grant of certiorari and the amicus brief on the merits emphasized the significant workload pressures imposed on the PTO by a documentary TSM requirement as well as the requirement's conflict with settled administrative law principles of official notice. 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 our case law nor consistent with it.”²⁴

²⁴ Notably, although *KSR* did not 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 had 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. The three-judge panel in that case dismissed as largely irrelevant the PTO's assessment of biotechnological science. The court invoked instead analogies to chemical synthesis, analogies that had the effect of reducing non-obviousness in biotechnology to a novelty standard. Two years later, in *In re Deuel*, 51 F.3d 1552 (Fed. Cir. 1995), the agency made its case again, only to be rejected again (with a pointed citation to *Bell*). *Id.* at 1559 (“The PTO's focus on known methods for potentially isolating the claimed DNA molecules is also misplaced because the claims at issue define compounds, not methods.”) (citing *In re Bell*, 991 F.2d at 785). The PTO and SG did not choose to appeal *Bell* and *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 can be obvious if the universe of possible solutions is finite and predictable. The PTO seized upon this short discussion to set up a test case, *In re Kubin*. In its 2009 *Kubin* decision, a three-judge panel of the Federal Circuit unanimously agreed with the PTO and finally interred *Bell* and *Deuel*.

B. The Role of the Life Science Agencies

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

1. Ex Ante Influences on Utility and Written Description

In 1991, well before the issue was on the radar screen on any other institutional actor, NIH Director Bernadine Healy had to make a decision regarding whether to file patent applications on more than 2000 partial gene sequences, or expressed sequence tags (“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 sequence into the public domain might undermine the possibility of patent protection on the full-length genes of which the ESTs were a part.²⁵ This result was undesirable because patent protection for full-length genes, particularly genes that produced therapeutic compounds, was essential for development.²⁶

Healy’s reasoning has flaws. For example, as a matter of boilerplate patent law, it is not clear why placing EST sequences in the public domain would undermine patents on full-length

²⁵ Bernadine Healy, *Special Report on Gene Patenting*, 327 NEJM 664, 667 (1992).

²⁶ *Id.* As discussed further below, patent applications on full-length genes began to be filed in the 1980s. They were typically filed by research teams that had identified a protein with a particular useful therapeutic function (e.g. insulin, erythropoietin) and then worked “backwards” to clone the relevant gene.

genes. Moreover, although Healy’s analysis acknowledges the problem of “patent clutter” that might be created by multiple overlapping EST patents on the same gene, she dismisses it by suggesting that “socially responsible” licensing by NIH would mitigate this possibility.²⁷

In this first round of the EST debate, the PTO provided a useful counterweight. It quickly rejected the initial patent claims on a number of different validity grounds. This rejection proved something of a tipping point. NIH’s decision to seek EST patents had been controversial from the outset. The co-discoverer of DNA structure, and head of NIH’s project to map the entire human genome, James Watson had immediately denounced the decision and resigned his position.²⁸ Perhaps not surprisingly, then, the arrival of a new NIH Director under the newly-elected Clinton Administration caused NIH’s approach to shift.

In 1994, NIH Director Harold Varmus withdrew the EST applications. In 1996, at a National Academy of Sciences (“NAS”) workshop on patenting of early-stage biological research, he made a series of observations about why EST patenting generally was problematic, observations that would prove to be quite prescient. He noted lack of proven biological utility, “possible complications of having what is referred to ‘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.”²⁹ Varmus also observed, however, that although NIH had withdrawn its patent applications, “the issue [was] not completely resolved.”

²⁷ *Id.* at 668

²⁸ Watson had famously said that finding ESTs was a job that “could be done by monkeys” However, given the Federal Circuit’s virtual elimination of the non-obviousness requirement for genomics in the period from the early 1990s through 2009, *see supra* ____, the patenting of genomic inventions created by monkeys was not beyond the pale.

²⁹ Harold Varmus, Chapter 6 of NRC Summary of 1996 Workshop

Varmus’s comment was quite the understatement. In fact, the Federal Circuit’s 1995 decision in *In re Brana*³⁰ had castigated the PTO for using the requirement that a patentable invention have utility too aggressively in the biopharmaceutical context. In response to this decision, and more general dissatisfaction in the biopharmaceutical patent bar, the PTO had issued guidelines that were widely seen as lowering the utility bar.³¹

The factual focus of the *Brana* case had been what sort of experimental efficacy (e.g. efficacy *in vitro* vs. in animal models vs. in humans) an applicant must show when it seeks a patent on an allegedly therapeutic compound. Nonetheless, the case and the subsequent 1995 guidelines sent out a broader signal. 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 the subsequent PTO proceedings that addressed the utility and written description requirements for patenting illustrate the depth of NIH involvement. According to these comments, early in 1997 Varmus expressed to PTO Commissioner Bruce Lehman his policy concerns about EST patents chilling genomics research.³² At the 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.³³ When Commissioner Lehman responded with a statement that potential EST utilities distinct from probing might include forensic identification, tissue type or origin identification, and chromosome identification and mapping, NIH appears to have persuaded NAS President (and

³⁰ 51 F.3d 1560 (Fed Cir. 1995).

³¹ Utility Examination Guidelines, 60 Fed.Reg. 36263 (1995).

³² NIH Comments, September 14, 1998; March 22, 2000.

³³ *Id.*

eminent molecular biologist) Bruce Alberts to weigh in with a letter rejecting Lehman's position.³⁴

The PTO continued to express resistance. In a commentary published in the May 1, 1998 of *Science*, PTO Biotechnology Examination Unit head John Doll stated that because ESTs could be used to perform research functions like chromosome identification and gene mapping, PTO issuance of such patents was likely. Doll's commentary was a response to an article co-authored by law professor and NIH consultant Rebecca Eisenberg arguing that requirements to license patents on upstream inventions like ESTs could create significant transaction cost obstacles for follow-on inventors.³⁵ 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 such cross-licensing.

In June 1998, the PTO issued interim guidelines on the written description requirement of patentability further suggesting that the scope of EST patents would be broad. Ironically enough, though the guidelines were prompted by a 2007 Federal Circuit decision, *University of California v. Eli Lilly*,³⁶ that suggested written description would require a relatively *narrow* scope for DNA patents, the guidelines indicated that claims to ESTs could be *broad*, encompassing groups of nucleic acids of which the ESTs were a part.³⁷

³⁴ NIH Comments, September 14, 1998.

³⁵ See Michael Heller and Rebecca Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 *SCIENCE* 698 (1998).

³⁶ 119 F.3d 1559 (Fed. Cir. 1997).

³⁷ In fairness to the PTO, applying the written description guidelines in the manner that the Federal Circuit did in the *Eli Lilly* case was problematic in terms of the scientific state of the art and a departure from legal precedent. See Arti K. Rai, *Intellectual Property Rights in Biotechnology: Addressing New Technology*, 34 *WAKE FOREST L. REV.* 827 (1999).

By December 1999, however, following (in the words of a subsequent NIH comment) “much formal and informal discourse on the subject,”³⁸ the PTO changed its approach substantially. At that point, the agency issued draft utility guidelines requiring all patent applications to demonstrate “specific, substantial, and tangible” utility.³⁹ Although the guidelines were facially neutral with respect to technology, by its nature a rigorous utility standard has the biggest bite in areas of research like biotechnology where the process is multi-step and likely to produce intermediate products. Accompanying training materials for patent examiners stated that, with respect to EST patents in particular, assertions of generic utilities like ability to do gene mapping, would not suffice. Although NIH was not entirely happy with the details of the guidelines,⁴⁰ it praised the PTO’s move to a higher standard.⁴¹ The PTO utility guidelines were finalized in 2001. Under these guidelines, very few claims to EST of unknown function appear to have issued.

³⁸ March 22, 2000 NIH comment. For example, on September 23, 1998, the PTO had extended the comment period on the June 1998 written description guidelines specifically to address the question of ESTs. December 21, 1999 guidelines at 71428 (noting extension for this reason). At the same time, however, in October 1998, PTO actually issued a patent claiming 44 ESTs to Incyte Pharmaceuticals. Patent No. 5, 817, 479, human kinase homologs. Although this patent did state that the full-genes from which the claimed ESTs were drawn coded for kinases, the amount of actual information about biological function provided by that statement is minimal. The human genome contains about 500 different protein kinases. Manning G, Whyte DB. *et al.* (2002). "The protein kinase complement of the human genome". *Science* **298** (5600): 1912–1934. 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 EST but also the full genes of which the ESTs formed a part. After the patent issued, NIH sent in “supplemental comments” on the written description guidelines expressing its surprise at the patent 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.” NIH Supplemental Comments on Interim Guidelines on Written Description, October 1998.

³⁹ December 1999 guidelines

⁴⁰ Contrary to NIH’s wishes, the guidelines refuse to adopt a *per se* rule against claims of utility based on structural similarity to gene sequences of known function.

⁴¹ Francis Collins statement: “I think the Patent Office deserves credit for moving toward a stronger requirement for utility.” Eliot Marshall 287 *Science* 2396 (2000) Varmus testimony to House of Representatives Subcommittee on Courts and Intellectual Property, July 13, 2000

In December 1999, the PTO also issued revised interim guidelines on written description. Although some of the language in the guidelines was confusing,⁴² the accompanying training examples made it clear that EST claims could not encompass the larger nucleic acid sequences of which they were a part.

As discussed further below, Congress has not granted the PTO rulemaking authority over questions of patent validity. Thus neither the utility guidelines nor the written description guidelines had the force of law. However, the Federal Circuit’s 2005 decision in *In re Fisher*⁴³ affirmed the utility guidelines. The court’s decision declined to give the guidelines any deference.⁴⁴ The decision was also highly dismissive of policy arguments advanced by the PTO and its supporting amici to the effect that allowing patents on gene fragments would delay scientific progress by creating patent thickets.⁴⁵

Nonetheless, it stands to reason that the court paid some attention to the fact that had effectively been in place since 1999 and, judging by the eight amicus briefs filed in their favor (with no amicus briefs against), were reasonably well accepted.⁴⁶ The amicus briefs presumably also signaled to the Federal Circuit the extent to which this case was clearly being watched by the biopharmaceutical industry. As Colleen Chien has recently determined, the average number

⁴² The confusing language in the interim guidelines was stressed by NIH in its comments as well as several other commentators. The final guidelines, issued in 2001, eliminated the confusion.

⁴³ 421 F.3d 1365 (Fed. Cir. 2005).

⁴⁴ The court stated instead that the guidelines could “be given judicial notice to the extent they do not conflict with the statute.” *Id.* at 1372.

⁴⁵ *Id.* at 1378.

⁴⁶ Amicus briefs in favor of the guidelines were filed by the Association of American Medical Colleges (“AAMC”), the National Academy of Sciences (“NAS”), Dow AgroSciences, Eli Lilly, Baxter Healthcare, the American College of Medical Genetics (“ACMG”), and Genentech. Genentech, AAMC, NAS, and ACMG had also filed comments favoring the utility guidelines. Perhaps not surprisingly, BIO, which encompasses firms that patent upstream research and firms that face transaction cost impediments in licensing upstream research, expressed mixed views about the utility guidelines in this comments. BIO did not file an amicus brief in the Fisher case.

of amicus briefs received by the Federal Circuit in a case heard by a three-judge panel is less than 1.⁴⁷

The relatively orderly sequence of events through which relevant institutional player addressed the EST controversy stands in contrast to the institutional debate over patentable subject matter in the life sciences. Here, the role of executive branch players outside the PTO has brought fresh, and important, perspectives to the table. However, these perspectives might have been more usefully deployed earlier in the debate.

B. Patentable Subject Matter

In the debates over EST patenting, NIH did not engage the question of whether gene sequences should constitute patentable subject matter in the first instance. Although some commentators on the utility guidelines did engage the question, these commentators did not appear to have particular clout and the PTO dismissed their arguments quickly.⁴⁸ Meanwhile the conventional wisdom in the patent community held that while DNA in its cellular environment was a “product of nature” and thus not patentable subject matter, “isolated” DNA sequences – that is DNA sequences excised from the cellular environment – were patentable. Although no court cases (either at the Federal Circuit or at the Supreme Court) had specifically said this was the case, many patent lawyers assumed that the generally expansive view of patentable subject matter taken by the Supreme Court in the 1980 case *Diamond v. Chakrabarty* (involving a genetically altered bacterium) allowed patents on isolated DNA. Thus the issue of patentable

⁴⁷ Colleen Chien, Patent Amicus Briefs: What the Court’s Friends Can Teach Us About the Patent System (March 2011 draft)

⁴⁸ See *AMP v. Myriad*, Bryson dissent at 17 (stating that the patentable subject matter comments “that the PTO issued at the time of its 2001 guidelines were, frankly, perfunctory”).

subject matter was, prior to the *AMP v. Myriad* case, never even raised in the numerous cases in which the Federal Circuit addressed gene patents.⁴⁹

The district court decision in *Myriad* called into question decades of conventional wisdom. The court argued that because the basic “informational” character of DNA does not change even after it has been isolated, Myriad’s patent claims to genes implicated in breast cancer (primarily BRCA1 and BRCA2) impermissibly covered products of nature. According to the court, *Diamond v. Chakrabarty* requires a patentable product to be “markedly different” from that found in nature. The district court also held that Myriad’s claims to methods for detecting the genes in question impermissibly covered mental processes and thus were not patent-eligible.

At the district court, the PTO (which had obviously granted the patents) had been a defendant. Although the PTO filed a brief defending the patents, the district court dismissed the claims against the PTO and thus the U.S. government did not have to participate in the inevitable Federal Circuit appeal.

At the Federal Circuit level, the U.S. government not only chose to file an amicus brief, but it reversed its position. On appeal, the U.S. drew a distinction between claims to DNA sequences it viewed as merely “isolated” – that is excised from the cellular environment and from other genomic material – and claims to sequences that are a laboratory-generated duplicate of the select portions of DNA sequence (known as “exons”) that actually code for a protein. According to the government, the latter set of claims to exon sequences that have been spliced together with non-coding regions removed (“cDNA”) encompass a man-made construct, not a

⁴⁹ Cf. Judge Dyk’s dissent in *Intervet* (noting that question of whether isolated genomic DNA is patentable subject matter has evaded review)

product of nature. Thus, in the government’s view, the district court was correct in striking down some of Myriad’s claims (those drawn to genomic DNA, or gDNA) but not those drawn to full-length cDNA.⁵⁰

One can question whether drawing a line between gDNA and full-length cDNA is entirely compelling as a scientific or legal matter. While cDNA creation certainly involves more human intervention than does gDNA creation, gDNA creation generally also involves some human intervention.⁵¹ 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 can be quite difficult.⁵²

From a policy standpoint, however, the U.S. government’s reversal has some appeal. As the “science” agencies and offices whose interests are represented by the amicus brief (e.g. NIH, the Office of Science and Technology Policy, the Centers for Disease Control) well know, technology has moved well beyond a focus on individual genes. Whole genome sequencing of all 20,000 or so human genes is the state-of-the-art. As a technical matter, whole-genome sequencing will not infringe cDNA patents representing full genes. However, it might infringe certain gDNA patent claims, most notably claims to very short nucleotide sequences.⁵³ For those

⁵⁰ The government’s brief did not address the method claims. Thus, I will not do so in this Essay. However, these claims as well as other claims in various genetic diagnostic patents are suspect on numerous grounds. I discuss the full range of issues raised by the patentable subject matter requirement in Arti Rai, *The Conundrum of Patentable Subject Matter* (working paper, on file with author)

⁵¹ Appropriate caveats

⁵² Duffy, Eisenberg, many others on difficulties with rules and standards in PSM

⁵³ A recent working paper draft, see Chris Holman, *Will Gene Patents Impede Whole Genome Sequencing?: Deconstructing the Myth that 20% of the Human Genome is Patented* (working paper, on file with author) analyzes 533 patents that explicitly mention a human DNA sequence in their claims. These 533 patents represent a subset of 4270 patents that Kyle Jensen and Fione Murray had previously identified as “human gene patents” in a prominent paper. See Kyle Jesnen & Fiona Murray, *Intellectual Property Landscape of the Human Genome*, 310 *SCIENCE* 239 (2005). Holman concludes that, of the 533

firms that do whole-genome sequencing, therefore, these gDNA patent claims – found in the Myriad patents as well as other gene patents – represent a potential obstacle. So do certain other claims to very short nucleotide sequences that happen to occur only in a single exon. These claims would be invalid under the government’s test.⁵⁴

Conversely, cDNA patents encompassing full genes – which the government’s position would leave undisturbed – represent the patents that the biotechnology industry has some reason to regard as important for its business model. These patents protect therapeutic end-products, which require FDA approval and hence a large investment to bring to market. The various data exclusivities provided to biological therapies in the recent Biologics Price Competition and Innovation Act are fairly extensive but may not provide sufficient protection. In contrast, because most gene-based diagnostics currently do not require FDA approval, the policy case for patent protection in that case is somewhat weaker.⁵⁵

At the Federal Circuit level, a version of the government’s position has attracted support from one judge. While two of the three judges on the three-judge panel determined that all of Myriad’s product patent claims represented patentable subject matter, a dissent by Judge Bryson would have drawn the line at cDNA patents representing full genes. In fact, Judge Bryson

patents, the subset that is most likely to be infringed comprises claims to short fragments of DNA (e.g. a claim drawn to “any isolated DNA molecule comprising any sequence of 10 or more contiguous bases . . .”)

Holman also notes that this subset of claims is relatively small. However, because the set of “human gene patents” identified by Jensen and Murray is not only overinclusive (as Holman points out) but also underinclusive (as Jensen and Murray note in their article), studies based on that set will not answer questions regarding possible thickets.

⁵⁵ See, e.g., Robert Cook-Deegan et al., *The Dangers of Diagnostic Monopolies*, 458 NATURE 405 (2009).

specifically emphasized the potential thickets that the Myriad product patent claims to very short sequences of DNA might create for whole genome sequencing.⁵⁶ He further noted that even if the short DNA sequence patents could be held invalid on grounds of excessive scope,⁵⁷ “the costs involved in determining the scope of all those patents could be prohibitive.” In so doing Bryson cited a prominent report written by an Advisory Committee to the Secretary of Health and Human Services that discussed the potential for such thickets.⁵⁸ Until it was disbanded, the Committee was the flagship external source of advice to all components of the Department of Health and Human Services (including NIH) on policy questions raised by genetic testing.

The assertive role that executive branch agencies and offices other than the PTO have played in disputes over how patentability standards adds an important dimension to debates about institutional choice in patent policy. I turn next to these institutional questions.

II. *Patent Law and Policy: The Institutional Debate*

A. *General Considerations*

⁵⁶ See Bryson Dissent at 15 (“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.”) and 16 (“Broad claims to genetic material present a significant obstacle to the next generation of innovation in genetic medicine – multiplex test 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.”)

⁵⁷ Although Bryson emphasized excessive scope as creating issues of patentability issues with respect to novelty or obviousness, the written description requirement crafted with NIH’s influence in the period between 1999 and 2001, see *supra* ___, would potentially play a bigger role in patent invalidation.

⁵⁸ *Id.* at 16 (citing 2010 report by the HHS Secretary’s Advisory Committee on Genetics, Health, and Society).

Conventional institutional considerations – and a large number of Federal Circuit judges⁵⁹ – point to Congress as an obvious policymaker. Patent law scholars have often found this option unsatisfactory.⁶⁰ One much rehearsed reason is that Congressional action must overcome many “vetogates.”⁶¹ Thus Congress is unable to act quickly in the face of rapid technological development, whether that action involves passing legislation in the first instance or revising legislation that no longer comports with technological reality.⁶²

Moreover, like the political science literature generally, 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*, where a particular well-heeled interest group makes significant campaign contributions to the member in question. Alternatively, we can see “informational capture,” where the well-heeled interest group inundates the member with data purporting to show why its preferred policy outcome advances overall public welfare.⁶³

⁵⁹ See, e.g., opinions by Judges Moore and Lourie in *AMP v. Myriad*; *In re Fisher*, 42 F.3d 1365, 1378 (2005) (stating that PTO arguments regarding scientific progress were “public policy considerations . . . more appropriately directed to Congress as the legislative branch of government”); see generally Jay Plager, Loyola L.A. L. Rev. (discussing judicial tendency to see Congress as the relevant policymaker).

⁶⁰ In general, the institutional analysis that patent law scholars use tends to be functional, not formal. Here I focus on functional considerations as well.

⁶¹ See generally William Eskridge, *Vetogates, Chevron, and Preemption*, 83 NOTRE DAME L. REV. 1441 (2008).

⁶² Cites. A much-discussed example of legislation that rapidly became outdated is the Semiconductor Chip Protection Act, which set up a sui generis regime of intellectual property protection for chips.

⁶³ Informational capture is quite possible because, notwithstanding its staff of 32,000, Congress is significantly less capable of marshaling neutral expertise on technological issues than one might suppose. Most members of its staff work in constituent services. Congress can draw upon the resources of the Congressional Research Service (“CRS”), the Congressional Budget Office (“CBO”), and the Government Accountability Office (“GAO”), but each of these entities is quite constrained by its generalist focus. Meanwhile, Congress chose in 1994 to abolish its innovation-focused Office of Technology Assessment (“OTA”), even though OTA reports were generally very highly regarded. See Second Report of the Renewing Congress Project.

To be sure, the dynamics of capture have played out differently in the six-year process leading to the recently-passed America Invents Act than in debates over (for example) regulation of the financial system. In contrast with financial system reform, where the well-heeled groups uniformly tend to be on the side of less regulation, in patent reform we have had well-heeled interest groups representing at least some competing views. These groups – including the biopharmaceutical industry, the ICT industries, non-practicing entities and other “upstream” patent holders, independent inventors, and universities – do not necessarily represent all relevant interests. Certain consumers of patented products, whether ordinary consumers or research scientists employed by universities (who may have views different from those of university administrators), are hardly represented, if at all. But the divergent groups that are represented have at least produced conflicting arguments and data.

In theory, the result of an interest group melee could be a roughly acceptable compromise. But the many vetogates discussed above tend to preclude passage of legislation that one or more well-heeled groups opposes (even if for no particularly good reason).⁶⁴ As a consequence, the America Invents Act is more modest in its ambitions. Although the significant procedural improvements it puts in place are very important, particularly to the extent that they will allow

⁶⁴ For example, before the Supreme Court rendered the question moot by deciding *EBay v. MercExchange* in 2006, a significant obstacle to the passage of patent reform legislation was opposition by the biopharmaceutical industry 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” before the Subcomm. On Courts, the Internet, and Intellectual Property of the House Committee on the Judiciary, 109th Cong. 28-29 (2005) (statement of Robert B. Chess, 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 is currently facing many challenges, post *EBay* case law on remedies is not one of them.

the PTO to function more efficiently,⁶⁵ the reform's improvements represent those that command wide consensus among important interest groups.

The limited sphere in which Congress can act has caused the institutional discussion to focus on courts and the executive branch. Within the executive branch, scholars have typically compared courts to the PTO. This comparison is understandable, as Congress has conferred upon the PTO sole authority to adjudicate the validity of patent applications. Numerous scholars have argued that, as between these entities, courts represent the appropriate policymaker. They have noted that the patent statute has a structure like the Sherman Act and thereby delegates authority to the courts to make federal common law.⁶⁶ Moreover, the history of court (and common law) primacy arguably dates back to the first patent statute of 1790.⁶⁷

Scholars who argue for the primacy of courts recognize the familiar limitations courts face with respect to large-scale policy formulation. Courts can only act *ex post*, in the context of specific disputes presented to them. Thus important issues can be left undecided for long periods of time. Adjudicating a concrete dispute can be in tension with formulating policy with prospective impact.⁶⁸ Additionally, despite the input sometimes provided by amicus briefs, courts do not have the ability systematically to collect and analyze empirical data. Nonetheless, these scholars believe that courts are superior not only to Congress but also to the administrative process.

⁶⁵ See Arti K. Rai, *Growing Pains in the Administrative State: The PTO's Troubled Quest for Managerial Control*, 157 U.PENN.L.REV. 2051, __ (2009) (discussing PTO fee-setting authority as a key feature of any patent reform).

⁶⁶ Burk & Lemley (2009); Nard (2010). In earlier work, I also made this argument. Rai (2003).

⁶⁷ Nard (2010).

⁶⁸ Polk Wagner, contribution to Loyola L.A. symposium

The normative case against giving the PTO policymaking authority has several elements. One is that patents are “property rights” and therefore should not be subject to administrative regulation.⁶⁹ This argument has little merit. Even assuming that patents are property rights,⁷⁰ and even further assuming they are constitutionally protected property rights for purposes of the Takings Clause, agencies like the EPA clearly regulate tangible property rights. When we have longstanding models for administrative regulation of tangible property rights, the case for carving intangible property rights seems dubious.

Indeed, for those who are concerned with settled expectations associated with property rights, judicial development of patent law is arguably *more* likely to disrupt these expectations than administrative development. Not only can administrative rule changes explicitly be made prospective but boilerplate administrative law doctrine counsels against retroactive rulemaking absent specific Congressional authorization.⁷¹ In contrast, court decisions on patentability questions are almost always retroactive in their effects.

This retroactivity feature may also cause *ex post* decisionmaking by courts to tilt towards expansion. When a court expands the universe of material that can be the subject of a patent, it is unlikely to be extremely concerned about retroactivity. Patents previously denied or invalidated cannot be resurrected.⁷²

⁶⁹ Orin Kerr

⁷⁰ To put it mildly, this question is contested. *See, e.g.*, Mark Lemley, *Property, Intellectual Property, and Free Riding*, 83 TEX.L.REV. 1031, 1035 & n.8 (listing numerous articles by scholars who regard patents as different from ordinary property). The argument for equating *existing* patents to property rights is particularly weak in the information technology industries, where portfolios comprising large numbers of patents with unclear boundaries are the norm. *See infra* ____.

⁷¹ *See, e.g., Bowen v. Georgetown University Hospital*, 488 U.S. 204 (1988).

⁷² To be sure, firms that had previously practiced the now-patentable technology as a trade secret may plead retroactive effect. Under boilerplate patent law, although they may not be able to patent the trade

For purposes of moving to an administrative model, the real challenge arises from concerns about capture. Precisely what capture means for administrative approaches to patent law is, however, not as straightforward as some scholars have assumed. In contrast with *quid pro quo* capture for members of Congress, such capture for agency heads obviously cannot take the form of direct monetary contributions. For this reason, theorists of agency capture have typically been concerned with such issues as a revolving door between the agency and the industry it regulates; informational capture; and agency officials currying favor with industry in order to secure larger budgets from Congressional appropriators who are more directly captured.

As noted earlier, however, the “regulated industries” in the patent system are numerous and are diverse in their views of patents. Holding the line on patent validity requirements might be just as useful for purposes of getting relevant interest group support as taking a lax view of such requirements. Holding the line of validity can also discourage frivolous applications and reduce workload. As discussed earlier, concerns about PTO workload loomed large in the government’s decision to take a strong stance against a rigid TSM test.⁷³

Ultimately, to the extent that the PTO is biased, it is biased for some of the same reasons that the Federal Circuit has sometimes been seen as biased. Both institutions tend to perceive

secret themselves, others could do so and assert the patent against these prior users. As they did when business methods were declared patentable by the Federal Circuit in 1998, these prior users may push for an exemption from patent infringement. But the concerns of these prior users are not necessarily going to be at the forefront of judicial concern.

⁷³ Patent scholars sometimes suggest that because the PTO’s operations depend on applicant fees, it will be biased in favor of patentability. This argument is too facile, however. Boilerplate constitutional law requires that, absent explicit Congressional authorization, agencies can only charge fees sufficient to recover costs. So long as denying applications is as likely to result in cost-recovery as granting applications, dependence on fees should not, in and of itself, be a source of bias. A bias problem arises primarily because Congress has historically set fee schedules in a manner that requires patent grants substantially to subsidize denials. Rai, *Growing Pains*, *supra* __, at __. The fee-setting authority conferred on the PTO through the America Invents Act allows the PTO to fix this bias.

patents (as contrasted with, for example, competition law, public R&D funding, or spillovers into the public domain) as the central driver of innovation.

Reasonable minds can differ over whether the PTO’s view, and that of the Federal Circuit, is correct. We don’t have unassailable empirical evidence regarding the relative importance of patents, even for particular players in particular industries. But our lack of confidence in the ultimate substantive answer makes a process in which competing views (and, ideally, evidence) are put forward even more important. To the extent possible, those views should be aired in a process that allows for decisions to be reached before substantial R&D investments based on these decisions have been made.

B. The DNA Patenting Controversies as Institutional Choice Case Studies

If the institutional desiderata include, first, deliberation and subsequent agreement amongst diverse actors and, second, *ex ante* decisionmaking, the DNA patenting controversies provide useful contrasts. In the case of the utility and written description guidelines, we had both elements. Thus the Federal Circuit majority in *Fisher* had good reason for upholding the executive action.

Indeed, on both legal and policy grounds, the court should have gone significantly further. In general, boilerplate administrative law prescribes that PTO actions should be given at least the weak form of deference prescribed the Supreme Court in *Skidmore v. Swift & Co.*⁷⁴ *Skidmore* holds that an administrative judgment is given deference “depend[ing] upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with

⁷⁴ 323 U.S. 134 (1944)

earlier and later pronouncements, and all those factors which give it power to persuade . . .”⁷⁵

Under *Skidmore*, the fact that agencies with different points of view have reached agreement after extensive debate surely suggests, at a minimum, thoroughness of consideration.

Additionally, although *Skidmore* doesn’t explicitly favor *ex ante* judgments, such judgments are by their nature likely to address issues of first impression and thus less likely to violate *Skidmore*’s preference for consistency with “earlier and later pronouncements.”

Conversely, as the majority opinion by Judge Lourie in *AMP v. Myriad* emphasizes,⁷⁶ Supreme Court case law on the importance of “longstanding practice” and “settled expectations” in the patent arena counsel against the government’s position. Judge Moore’s concurrence put the point even more sharply – if she were deciding the case “on a blank canvas” she might well have concluded that certain type of claims drawn to gDNA sequences were not patentable subject matter. However, “settled expectations tip[ped] the scale in favor of patentability.”⁷⁷

These judges’ discomfort with the prospect of enacting significant retroactive change is legitimate.⁷⁸ But this legitimate discomfort makes for a significant policymaking gap. Indeed, a process where *ex ante* guidelines are almost never used and courts are reluctant to disturb the accidental status quo that arises, tilts the balance not only towards the *ex post* but towards the merely random. Even for those who warn (quite rightly) about the dangers of proactive

⁷⁵ *Id.* at 140.

⁷⁶ Lourie opinion at 48

⁷⁷ Moore opinion at 19. The case is also peculiar because, as noted by Judge Bryson, the PTO did not sign the government’s amicus brief. However, as Bryson rightly noted, judicial speculation on this question was not appropriate because the “Department of Justice speaks for the Executive Branch, and the PTO is part of the Executive Branch . . .”

⁷⁸ They may overestimate, however, the extent of *investment-backed* settled expectations involved. As discussed earlier, the government’s position would leave untouched core cDNA claims covering therapeutic products.

policymaking in areas of rapidly changing technology, this situation should be seen as undesirable.

Of course, for purposes of thinking more broadly about an *ex ante* policymaking role across the executive branch, the fact that the cases that have emerged thus far are limited to NIH and the life sciences presents a limitation. Even within the life sciences, moreover, NIH is not necessarily the ideal sister agency to engage with the PTO. Although NIH’s mission encompasses not only seeking “fundamental knowledge” but also the “application of that knowledge to enhance health,”⁷⁹ NIH is not an expert in the law and economics of how life science research moves into application. In fact, as discussed earlier, it employed flawed legal and economic reasoning in its initial decision to seek EST patents. Moreover, although NIH subsequently raised utility and written description questions with respect to DNA patenting, it did not raise patentable subject matter questions.

Nor is legal and social science work necessarily NIH’s highest priority. GAO reports from the 1990s cite significant deficiencies in the agency’s implementation of the basic accountability and reporting provisions of Bayh-Dole (the statute that governs commercialization of federally funded research). More recent work that Bhaven Sampat and I have done indicate some improvement over time but a mixed record overall.⁸⁰

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

⁷⁹ www.nih.gov/about/mission.htm

⁸⁰ [Cite data]

requires enlisting other agencies and executive branch components. The next section discusses possible agency and executive branch players.

III. *Beyond the Utility and Written Description Guidelines: Other Ex Ante Approaches to Patent Validity*

A. *A Thought Experiment on Ex Ante Approaches to Software*

Perhaps even more than gene patents, software patents are highly controversial. Some commentators have argued that software *per se* should not constitute patentable subject matter. Many others have complained about the poor quality of software patents, particularly with respect to undue breadth and unclear boundaries. Consequences of this poor quality (and related large quantity) include patent thickets. At a minimum, these thickets require firms to expend resources on maintaining large defensive patent portfolios.⁸¹

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

After this decision, the PTO began to receive significant numbers of applications encompassing software. The PTO tried, however, to use patentable subject matter doctrine to hold the line on software patent scope. Perhaps most notably, in the 1994 case of *In re*

⁸¹ Cite to literature on overall negative welfare effects

Alappat,⁸² the PTO determined 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. According to the PTO, applications that could encompass (as these applications did) any general purpose computer represented unpatentable mathematical algorithms.

Sitting *en banc*, the Federal Circuit reversed. Judges Archer and 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.*”⁸³ This dissent largely adopted the position taken by the PTO as well as by the single technology company, Seagate, that chose to file an *amicus* brief in that case.⁸⁴

Now let’s imagine that the PTO had been backed in its resistance to broad scope by an executive branch agency with deep economic expertise and a vision of innovation that relies heavily on competition – say the Antitrust Division of the Department of Justice. Let us further suppose that the bond between the PTO and the Antitrust Division had been forged because they had worked together to issue, via notice and comment, guidelines that identified the appropriateness, under *Diehr* and other Supreme Court case law, of disallowing claims that purported to cover a mathematical operation performed via a generic computer. The PTO and

⁸² 33 F.3d 1526 (Fed. Cir. 1994).

⁸³ *Id.* at 1563 (emphasis in original).

⁸⁴ See Richard H. Stern and Edward P. Heller, III, *In re Alappat: The Gordian Knot Retwisted*, 2 U. BALT. INTELL. PROP. L.J. 187, 187 (1994) (discussing problems with allowing patents on algorithms, “so long as the claims are ‘limited’ to use of the algorithm in programmed computer equipment). Stern was the author of Seagate’s *amicus* brief and Heller was patent counsel for Seagate Technology.

Antitrust Division might then have worked together to convince the Solicitor General to file a petition for certiorari.

If the Solicitor General’s current track record of success in convincing the Supreme Court to take patent cases were applicable,⁸⁵ the Court might well have taken the case. At the Supreme Court level, technology companies other than Seagate would presumably have supported limitations in patent scope.⁸⁶ A decision favorable to the government might have provided some early resolution of software patent scope questions.

In the real world, the Federal Circuit did not squarely address issues of software patent scope until over a decade later. Starting in 2008, however, in cases like *Aristocrat Tech v. International Game Tech*,⁸⁷ three-judge panels on the court have held that “means plus function” patent claims that encompassed any computer “means” were invalid under the disclosure section of the patent statute unless the application includes some specific information about the algorithm involved. Although these cases are valuable (especially as interpreted in recent PTO examination guidelines)⁸⁸ they stake out a position that is more modest than the position advanced by the PTO in *Alappat*. Again, this should come as no surprise – court decisions that attempt to scale back rights will often be modest in their ambition.

As a real world matter, how might we engineer more frequent consultation *ex ante* between the PTO and “competition-oriented” executive branch agencies like the Antitrust

⁸⁵ Duffy

⁸⁶ Not surprisingly, patent cases at the Supreme Court draw many more amicus briefs than do cases at the Federal Circuit. Chien

⁸⁷ 521 F.3d 1328 (Fed. Cir. 2008); *see also* Finisar Corp. v. DirecTV Group, Inc., 523 F.3d 1323 (Fed. Cir. 2008).

⁸⁸ Supplementary Examination Guidelines for Determining Compliance with 32 U.S.C. 112 and for Treatment of Related Issues in Patent Applications, 76 Fed.Reg. 7162-7175 (2011).

Division of the Justice Department. In general, such inter-agency coordination is provided by White House offices and components like the Office of Management and Budget or the National Economic Council. Prominent thinktanks have recently emphasized the pressing need to have individuals within these offices focused on inter-agency innovation and competitiveness strategy.⁸⁹ One component of these officials' job description should include facilitating consultation between agencies with diverse perspectives on innovation.

B. *Rulemaking Authority Over Questions of Patentability?*

For those with an administrative law bent, the preceding discussion of guidelines and *ex ante* decisionmaking might seem a half-measure. Why not simply have rulemaking authority to which courts would have to give the strong form of deference enunciated in *Chevron v. Natural Resources Defense Council* and its progeny? Such rules 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.

Most scholarly discussions of an administrative model for the PTO (including my own) have generally stopped short of advocating rulemaking authority on core questions of patentability – that is, 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.⁹⁰ In prior work, I have argued that conferring such authority might be premature

⁸⁹ John Podesta et al., Center for American Progress report; various ITIF reports

⁹⁰ The existing scope of the PTO's rulemaking authority is not entirely clear. The Federal Circuit, and many commentators, have framed the question in terms of substance versus procedure. *See, e.g., Tafas v. Doll*. For an engaging argument that the substance versus procedure distinction is not grounded in the language of the Patent Act and that the PTO may have rulemaking authority that extends beyond the strict confines of procedure, *see* Sarah Tran (working paper); *see also* Bryson opinion in *Tafas*. Neither Tran

because the PTO lacks the large cadre of economists and policy-oriented thinkers possessed by other agencies (e.g. the Federal Communications Commission, the Federal Trade Commission) that do work on questions of technological innovation and have at least some rulemaking authority.

Since that time, however, the PTO has created, and staffed, an Office of the Chief Economist. Early versions of the 2007 patent reform bill included language conferring on the PTO rulemaking authority not only over questions of patentability but also over all aspects of the Patent Act. Perhaps in reaction to this brief Congressional interest, several scholarly articles have advanced the powerful suite of administrative law arguments that favor conferring such authority on agencies that tackle technologically and economically complex questions. These commentators have argued that Congress should confer on the PTO rulemaking authority either over all issues of patent validity or as limited to specific questions such as patentable subject matter.⁹¹

Notably, in the context of a grant of rulemaking authority to the PTO, Congress could explicitly require the PTO to consult with specific agencies. Congress has already embedded such consultation requirements within a variety of statutes.⁹² At least one empirical study, involving the Federal Energy Regulatory Commission (“FERC”), has found that appropriately designed consultation requirements can force an agency to pay attention to concerns that it would otherwise ignore. Specifically, in that case, Congressional passage of strict consultation

nor Bryson argues, however, that the PTO has rulemaking authority over questions such as patentable subject matter, obviousness, and the like.

⁹¹ See, e.g., Jonathan S. Masur, *Regulating Patents*; Michael Burstein, *Rules for Patents*; John M. Golden, *Patentable Subject Matter and Institutional Choice*

⁹² See Lisa Schultz Bressman, *Procedure as Politics in Administrative Law*, 107 COLUM. L.REV. 1749, 1799 & n.275 (2007) (listing statutes containing consultation requirements).

requirements in the Electric Consumer Protection Act (ECPA) of 1986, “force[ed] FERC to pay attention to the environmental concerns it had long ignored.”⁹³

The very quick elimination of any expanded rulemaking authority from the 2007 predecessor to the America Invents Act suggests that a move in this direction may be not politically feasible, at least for the near future. In the meantime, an approach based on *ex ante* PTO guidelines backed by the full weight of the executive branch has already shown some promise and could be made a much more integral part of patent policymaking.

Conclusion

Among patent scholars who address institutional questions, a significant percentage tends to favor courts 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, this capture story is less obviously true than it might seem. Further, at least in DNA patenting cases, where PTO decisionmaking has been heavily influenced by other executive branch decisionmakers, the conclusion has been eminently defensible against charges of capture.

To a greater extent than is currently the case, however, executive branch firepower should be deployed *ex ante*. *Ex post* development of law by the courts not only has familiar limitations but, in the context of patent law, it may yield a one-way ratchet towards expansion. When courts expand patent rights, they generally don’t have to worry too much about retroactive effects. Patents previously denied or invalidated cannot be resurrected. By contrast, as the

⁹³ J.R. DeShazo and Jody Freeman, *Public Agencies as Lobbyists*, 105 COLUM. L. REV. 2217, 2222 (2005).

Myriad case illustrates, courts have legitimate concerns about retroactive effect when they are called upon to curtail such rights.