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THE UNINTENDED CONSEQUENCES OF POST-GRANT REVIEW OF PATENTS

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INTRODUCTION

The 2011 Leahy-Smith America Invents Act (AIA) was heralded as a landmark patent reform that would improve patent quality, create jobs, and boost the economy.[1] The law was broad in scope and made many important changes.[2] The AIA was also remarkable for one change it did not make. Many recent high-profile patent controversies have centered on what types of inventions should be eligible for patent protection. Critics have argued that software,[3] business methods,[4] and isolated human genes[5] should not receive any patent protection at all. Despite these and similar controversies, the AIA left the scope of patent coverage almost entirely untouched.[6] The language of section 101 of the Patent Act, which defines the types of inventions that are eligible for patent protection, was entirely unchanged.

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[1] Edward Wyatt, *Fighting Backlog in Patents, Senate Approves Overhaul*, N.Y. TIMES, Sept. 8, 2011, http://www.nytimes.com/2011/09/09/business/senate-approves-overhaul-of-patent-system.html (quoting the bill's sponsor, Senator Patrick Leahy, as saying "Higher-quality patents will infuse greater certainty into the patent system, which will better incentivize investment in American businesses, create jobs and grow our economy."). The AIA was signed into law on September 16, 2011. 157 CONG. REC. H6035 (daily ed. Sept. 9, 2011) Communication from the Clerk of the House, *reprinted in* 2011 WL 3990626 ("Senate passed without amendment H.R. 1249.").

[2] One of the AIA's most important provisions replaced the existing "first to invent" system with a "first to file" system. Wyatt, *supra* note 1 ("The bill changes the method for determining the priority of patent applications to a 'first to file' system from the long-standing 'first to invent' method."); *see also*157 CONG. REC. S1174 -75 (daily ed. Mar. 3, 2011) (describing the first to file system as the "primary, centerpiece reform" of the AIA). Changes were also made to the financing and operations of the Patent and Trademark Office (PTO). Wyatt, *supra* note 1.

[3] *See generally* Robert P. Merges, *Software and Patent Scope: A Report from the Middle Innings*, 85 TEX. L. REV. 1627, 1627 (2007) ("In the 1980s and early 1990s, it was commonly said that patents would severely damage the software industry.").

[4] *See generally* Bilski v. Kappos, 130 S. Ct. 3218 (2010).

[5] *See generally* Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 653 F.3d 1329 (Fed. Cir. 2011).

[6] Two provisions in the AIA address patent eligible subject matter in narrow areas, but not through Section 101. One provision limits the extent to which tax strategies can be patented by redefining prior art. The other states that "no patent may issue on a claim directed to or encompassing a human organism." Gene Quinn, *America Invents: A Simple Guide to Patent Reform, Part 2*, IPWATCHDOG (Oct. 13, 2011 5:32 PM), *available at* http://www.ipwatchdog.com/2011/10/13/america-invents-a-simple-guide-to-patent-reform-part-2/id=19823

While the AIA did not directly change the scope of section 101, it did introduce a new, long-anticipated procedure to challenge a patent that has already been issued. The new post-grant review procedure allows petitioners to challenge a patent's validity on many different grounds, including failure to satisfy existing section 101 requirements.[7] Moreover, section 324(b) allows the Director of the PTO (Director) to authorize post-grant review if a petition raises "a novel or unsettled legal question that is important to other patents or patent applications."[8] The legislative history does not clarify how Congress imagined the Director would use this power.[9]

Section 324(b) has not attracted mainstream media coverage, but patent specialists and attorneys have begun to speculate about its implications.[10] I argue that petitioners will bring controversial subject matter challenges under section 324(b) because the law surrounding Section 101 remains unsettled.[11] If these petitioners succeed, post-grant review may have the unintended consequence of indirectly redefining the scope of patent eligible subject matter.

Subject matter challenges are currently made in federal court. Post-grant review differs from litigation in two important ways. First, post-grant review allows third parties to challenge a patent without satisfying federal standing requirements. Second, post-grant review involves the PTO in challenges to patentable subject matter that have historically been left to federal judges.

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[7] *See infra* Part I.B.

[8] 35 U.S.C. § 324(b) (2011).

[9] *See infra* Part I.C.

[10] *See infra* Part I.D.

[11] *See infra* Part I; *see also* JOHN VILLASENOR, THE BROOKINGS INSTITUTION, THE COMPREHENSIVE PATENT REFORM OF 2011: NAVIGATING THE LEAHY-SMITH AMERICA INVENTS ACT, 7 (2011), *available at* http://www.brookings.edu/papers/2011/09_patents_villasenor.aspx ("This language amounts to an invitation to address 'novel or unsettled' legal questions through the PTO, raising a number of issues relating to respective roles the courts and the PTO will play in resolving them").

I argue that these differences may have two important impacts: (1) more subject matter challenges will be brought by interest groups for ideological, political, or policy reasons, and (2) the system will ultimately be more responsive to shifting popular preferences about what types of inventions should receive patent protection.

This Comment proceeds as follows. Part I explains that § 324(b) allows petitioners to raised novel and unsettled legal questions during post-grant review. Part II argues that the persistent uncertainties surrounding section 101 will allow petitioners to argue that patents do not cover patent eligible subject matter. Part III argues that the lack of traditional standing requirements for post-grant review will mean that more special interest groups will be able to bring subject matter challenges for ideological, political, or policy reasons. Part IV considers the relative institutional competencies of the federal courts and the PTO and argues that the post-grant review system may have the unintended consequence of making patent law more responsive to shifting popular preferences about what types of inventions merit patent protection. Part V proposes regulations and practices for the PTO and Federal Circuit intended to maximize the potential benefits of post-grant review and § 324(b).

I. POST-GRANT REVIEW

Post-grant review is a new, but long-anticipated, addition to the United States patent system. Part I explains how the post-grant review process, especially § 324(b), fits within the existing system for challenging patent validity. Subpart A briefly summarizes the history of post-grant review. Subpart B highlights relevant statutory provisions in the AIA, focusing specifically on § 324(b). Subpart C explains that early proposals for post-grant review did not explicitly contemplate review of novel or unsettled legal questions. Subpart D argues that

section 324(b) will likely be used to challenge patents under Section 101 because patent eligible subject matter is a perpetually unsettled area of law.

A. History of Post-Grant Review

The PTO has been widely criticized for granting patents to inventions that do not deserve patent protection.[12] It is uncontroversial that challengers should be able to invalidate these bad patents so that they do not improperly limit competition or innovation. Prior to enactment of the AIA, the PTO had a relatively limited role in reconsidering patent validity after a patent had been issued.[13] Challenges to patent validity were traditionally made in federal court. Over time, Congress slowly added procedures allowing third parties to ask the PTO to review issued patents.[14] These procedures included: (1) interference proceedings addressing issues of patentability; (2) protests in reissue proceedings; (3) *ex parte* reexamination, which allowed a third party to petition for reexamination of a patent; and (4) *inter partes* reexamination, whereby third parties could participate in the reexamination proceeding.[15] However, each of these proceedings suffered from serious limitations.

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[12] *See, e.g.*, Robert P. Merges, *As Many As Six Impossible Patents Before Breakfast: Property Rights for Business Concepts and Patent System Reform*, 14 BERKELEY TECH. L.J. 577, 591 (1999) ("The concerns about quality, especially in light of the data on overall volume, point to one conclusion: the patent system is in crisis.").

[13] Patent Quality Improvement: Post-Grant Opposition: Hearing Before the Subcomm. on Courts, the Internet, and Intellectual Prop., of the H. Comm. on the Judiciary, 108th Cong. 2 (2004) (statement of James A. Toupin, General Counsel of the United State Patent and Trademark Office), *available at* http://www.ogc.doc.gov/ogc/legreg/testimon/108s/toupin0624.htm. *See also* http://www.gpo.gov/fdsys/pkg/CHRG-108hhrg94459/html/CHRG-108hhrg94459.htm.

[14] *Id.*

[15] *Id.*

While interferences allowed challenges to a patent's validity on any ground, they occurred only when a priority issue arose between two similar patents.[16] Protests during reissue proceedings were rare, and involved limited third party participation.[17] *Ex parte* and *inter partes* reexamination were both limited to challenges "based on certain prior art references, namely patents or printed publications."[18] Moreover, third parties could not conduct discovery, develop evidence, or cross-examine a patent owner outside the interference context.[19] These limitations ultimately led many legal scholars to call for additional mechanisms for post-grant review.[20]

In June 2002, the PTO submitted a 21st Century Strategic Plan to Congress.[21] The report included "37 action initiatives comprising the five-year Strategic Plan."[22] One of the Action

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[16] *Id.* ("Although a patentability challenge can be raised on all grounds in interferences, interference proceedings only lead to challenges of patents when a pending application raises a priority issue as to a recently issued patent.").

[17] *Id.* ("Further, a third party may file a protest in a reissue proceeding; however, that is rare, and the third party has very limited participation.").

[18] *Id.*

[19] *Id.* ("[E]xcept in interferences, a third party cannot conduct discovery and develop evidence necessary to challenge patentability, nor can the third party challenge patent owner evidence by cross-examination.").

[20] *See, e.g.*, Mark D. Janis, *Rethinking Reexamination: Toward a Viable Administrative Revocation System for U.S. Patent Law*, 11 HARV. J.L. & TECH. 1, 117 (1997) ("Domestically, the ever-increasing pressures on the federal court system, coupled with the notoriously cumbersome nature of patent validity litigation, make plain the urgent need for a viable administrative alternative for patent validity adjudication."); Bronwyn H. Hall & Dietmar Harhoff, *Post-Grant Reviews in the U.S. Patent System-Design Choices and Expected Impact*, 19 BERKELEY TECH. L.J. 989, 1015 (2004) ("A properly designed post-grant review mechanism, similar to the one broadly described in Part VI, should generate considerable welfare gains for the intellectual property system."); Joseph Farrell & Robert P. Merges, *Incentives to Challenge and Defend Patents: Why Litigation Won't Reliably Fix Patent Office Errors and Why Administrative Patent Review Might Help*, 19 BERKELEY TECH. L.J. 943, 967 (2004) ("We have tried to show the crying need for an effective way to invalidate patents after they are issued without going to court."); Eric Williams, *Remembering the Public's Interest in the Patent System – A Post-Grant Opposition Designed to Benefit the Public*, 2006 B.C. INTELL. PROP. & TECH. F. 110702 (providing a public welfare rationale for adopting a new administrative post-grant opposition highlighting the adverse public effects of granting bad patents).

[21] UNITED STATES PATENT AND TRADEMARK OFFICE, THE 21ST CENTURY STRATEGIC PLAN (2003), *available at* http://www.uspto.gov/web/offices/com/strat21/index.htm (last visited October 22, 2012).

Papers arising from the Strategic Plan, "Post-Grant Review of Patent Claims," suggested that "[t]he patent laws should be amended to provide for a post-grant review of patentability of patent claims."[23] The PTO argued that post-grant review would "enhance the patent system as a whole by strengthening those patents that survive the review and eliminating those patents which contain unpatentable subject matter."[24] In 2003, the Federal Trade Commission (FTC) adopted the PTO's position and recommended "an administrative procedure for post-grant review and opposition that allows for meaningful challenges to patent validity short of federal court litigation."[25] In 2004, the National Research Council of the National Academies also advocated expanded opportunities for post-grant review.[26]

B. Statutory Language

Post-grant review was finally codified in the AIA. Any person "who is not the owner" of the patent may file a petition for post-grant review.[27] The petition must be filed within nine months of the date a patent is granted or reissued.[28] The AIA specifies that a petitioner "may request to cancel as unpatentable 1 or more claims of a patent on any ground that could be raised

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[22] *Id.*

[23] U.S. P.ATENT AND TRADEMARK OFFICE, ACTION PAPER, POST-GRANT REVIEW OF PATENT CLAIMS (2007), http://www.uspto.gov/web/offices/com/strat21/action/sr2.htm [hereinafter ACTION PAPER].

[24] *Id.*

[25] FED. TRADE COMM'N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY 8 (2003), 2003 WL 22507757 (F.T.C.).

[26] NAT'L RESEARCH COUNCIL OF THE NAT'L ACADS., A PATENT SYSTEM FOR THE 21ST CENTURY 96 (Stephen A. Merrill et al. eds., 2004), *available at* http://books.nap.edu/catalog.php?record_id=10976#toc ("The committee recommends that Congress seriously consider legislation creating an Open Review procedure, enabling third parties to challenge the validity of issued patents on any grounds in an administrative proceeding within the USPTO.").

[27] 35 U.S.C. § 321(a) (2011) ("[A] person who is not the owner of a patent may file with the Office a petition to institute a post-grant review of the patent.").

[28] 35 U.S.C. § 321(c) (2011).

under paragraph (2) or (3) of section 282(b) (relating to invalidity of the patent or any claim)."[29] Paragraph (2) of Section 282(b) provides that a patent can be challenged as invalid "on any ground specified in part II of this title as a condition for patentability."[30] The relevant conditions for patentability include patent eligible subject matter,[31] non-obviousness,[32] and novelty.[33] Thus, a petitioner may argue that the patent does not cover patent eligible subject matter under existing law. The petition must also identify "each claim challenged, the grounds on which the challenge to each claim is based, and the evidence that supports the grounds for the challenge to each claim."[34]

After a petition is filed, the patent owner has the "right file a preliminary response" arguing "why no post-grant review should be instituted based upon the failure of the petition to meet any requirement of this chapter."[35] The Director must then decide whether or not to authorize a post-grant review. The Director may only authorize review if at least one of two conditions is satisfied. First, the Director may authorize post-grant review under § 324(a) if he "determines that the information presented in the petition filed under section 321, if such information is not rebutted, would demonstrate that it is more likely than not that at least 1 of the claims challenged in the petition is unpatentable."[36]

Second, even if the claims appear to be patentable under existing law, section 324(b) provides "Additional Grounds" under which the Director may authorize a post-grant review.

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[29] 35 U.S.C. § 321(b) (2011).

[30] 35 U.S.C.A. § 282 (West 2012).

[31] 35 U.S.C. § 101 (2011).

[32] 35 U.S.C. § 102 (2011).

[33] 35 U.S.C. § 103 (2011).

[34] 35 U.S.C. § 322(a)(2) (2012).

[35] 35 U.S.C. § 323 (2012).

[36] 35 U.S.C. § 324(a) (2011).

The Additional Grounds provision allows the Director to authorize post-grant review if there is "a showing that the petition raises a novel or unsettled legal question that is important to other patents or patent applications."[37] The Director's decision institute or deny post-grant review is "final and non-appealable."[38]

Once the Director authorizes post-grant review, members of the newly created Patent Trial and Appeal Board (Board) will conduct the proceeding.[39] The Board is comprised of the Director, the Deputy Director, the Commissioner for Patents, the Commissioner for Trademarks, and administrative patent judges.[40] Administrative patent judges are appointed by the Secretary of Commerce and must be "persons of competent legal knowledge and scientific ability."[41] The Board's decision can be directly appealed to the specialized U.S. Court of Appeal for the Federal Circuit.[42]

C. Novel and Unsettled Legal Questions

Interestingly, none of proposals for post-grant review made by the PTO, FTC, and NRC made any mention of allowing post-grant review to resolve novel or unsettled legal questions. Congressional proposals for post-grant review in 2006 and 2007 similarly lacked the language

[37] 35 U.S.C. § 324(b) (2011).

[38] 35 U.S.C. § 324(e) (2011).

[39] 35 U.S.C. § 326(c) (2011) ("The Patent Trial and Appeal Board shall, in accordance with section 6, conduct each post-grant review instituted under this chapter."). The Patent Trial and Appeal Board replaced the prior Board of Patent Appeals and Interferences. 35 U.S.C. § 6(a) (2011) ("Any reference in any Federal law, Executive order, rule, regulation, or delegation of authority, or any document of or pertaining to the Board of Patent Appeals and Interferences is deemed to refer to the Patent Trial and Appeal Board.").

[40] 35 U.S.C. § 6(a) (2011).

[41] *Id.* The Secretary of Commerce, in consultation with the Director, appoints administrative patent judges. *Id.*

[42] 35 U.S.C. § 329 (2011).

now found in § 324(b).[43] The reference to novel or unsettled legal questions seems to have first appeared in the Patent Reform Acts of 2008 and 2009, both of which were introduced by Senator Jon Kyl but never became law.[44]

The original version of the AIA also contained the § 324(b) "Additional Grounds" provision when Senator Leahy introduced it on January 25, 2011. However, there does not appear to be a single reference to § 324(b) in the Congressional record of either the House or Senate leading up to the bill's passage.[45] While there were several references to the benefits of post-grant review, these discussions invariably focused on more traditional challenges to patent validity, and failed to mention the possibility that novel or unsettled legal questions might be brought before the PTO.

D. Subject Matter Challenges Under § 324(b)

Given the lack of information about § 324(b), legal commentators and law firms have struggled to understand the significance of the provision. Several have concluded that petitioners will use the provision to argue that a patent does not cover patent eligible subject matter under Section 101.[46] By relying on § 324(b), petitioners are relieved of the burden of establishing "that

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[43] *See, e.g.* Patent Reform Act of 2006, S.3818.IS, 109th Congress (2005-2006); Patent Reform Act of 2007, S.1145.IS, 110th Congress (2007-2008).

[44] Patent Reform Act of 2008, S. 3600, 110th Cong. § 327 (2008); Patent Reform Act of 2009, S. 610, 111th Cong. § 327 (2009).

[45] I searched the entire Congressional record as aggregated by Westlaw, to no avail.

[46] Scott McKeown, a partner at the intellectual property firm Oblon, Spivak, McClelland, Maier & Neustadt, L.L.P., and editor of a patent law blog, has argued that "[i]t is hard to imagine too many novel or untested legal theories that are 'important to other patents or patent applications' that would not in some way involve application of 35 U.S.C. § 101." Scott A. McKeown, *Additional Grounds for Challenging Patents in Proposed Post Grant Review Legislation*, PATENTS POST-GRANT, (Apr. 1, 2011), http://www.patentspostgrant.com/lang/en/2011/04/additional-grounds-of-post-grant-review-expanded-in-house-bill. *See also* Kevin E. Noonan, *Post-Grant Review Provisions of S. 23*, PATENT DOCS, (Mar. 16, 2011), http://www.patentdocs.org/2011/03/post-grant-review-provisions-of-s-23.html ("Alternatively, a grantable petition may contain a showing that there is a 'novel or unsettled legal question['] that is

it is more likely than not that at least 1 of the claims challenged in the petition is unpatentable."[47] Subject matter challenges are particularly likely to involve "novel or unsettled" legal questions because Section 101 is a persistently unsettled area of law.[48] Moreover, unlike most validity challenges, subject matter challenges are often "important to other patents or patent applications"[49] because they challenge the patentability of certain types of inventions, rather than focusing on the details of particular patent at issue.[50] Part II explains the ways in which the law of patent eligible subject matter is a persistently unsettled, making it a likely basis for challenges under § 324(b).

II. UNSETTLED LAW: PATENT ELIGIBLE SUBJECT MATTER

As discussed above, unsettled areas of patent law are especially likely to generate petitions for post-grant review under § 324(b). One of the most unsettled questions in patent law is what types of inventions can be patented. The problem arises in part from the minimal statutory guidance provided by Congress in Section 101. The AIA did not make any changes to Section 101's language, despite numerous ongoing controversies about the scope of its definition of patentable subject matter.

Section 101 simply states: "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor."[51] The U.S. Supreme Court has explained that the statutory

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important to other patents or patent applications (*for example*, the ACLU's challenge to the patent-eligibility of gene patents; § 324(b)).")

[47] 35 U.S.C. § 324(a) (2011).

[48] *See infra* Part II.

[49] 35 U.S.C. § 324(b) (2011).

[50] *See, e.g.*, Petition for Writ of Certiorari at i, Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 653 F.3d 1329 (Fed. Cir. 2011) (No. 11-725) (asking "Are human genes patentable?").

[51] 35 U.S.C. § 101 (2011).

language "specifies four independent categories of inventions or discoveries that are eligible for protection: processes, machines, manufactures, and compositions of matter."[52] The Court has also consistently identified three exceptions to patentable subject matter: "laws of nature, physical phenomena, and abstract ideas."[53] This Part argues that the complexities inherent in the law of patent eligible subject matter make these claims especially likely under § 324(b).

A. Four Categories of Inventions

The U.S. Supreme Court has repeatedly emphasized that the statutory language of section 101 should be read broadly in order to give effect to Congressional intent to provide broad patent protection.[54] Nonetheless, new questions frequently arise about whether a particular invention falls within one of the four categories of patentable subject matter. Two recent cases demonstrate the complexity of the issues involved. *Bilski v. Kappos*[55] highlighted the controversy surrounding the patentability of business method patents.[56] *Mayo Collaborative Services v. Prometheus Laboratories, Inc*.[57] addressed the patentability of medical treatments and diagnostics.[58] Both cases demonstrate the difficulties inherent in determining what qualifies as a patent eligible process.

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[52] Bilski v. Kappos, 130 S. Ct. 3218, 3225 (2010).

[53] *Id.* (quoting Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980)).

[54] *Id.* ("In choosing such expansive terms . . . modified by the comprehensive 'any,' Congress plainly contemplated that the patent laws would be given wide scope.").

[55] 130 S. Ct. 3218 (2010).

[56] *Id.* at 3223.

[57] Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289 (2012).

[58] James J. Mullen, III & Kate McElhone, *The Threshold Patentability Question: The Supreme Court Entertains Oral Arguments in* Mayo v. Prometheus, MORRISON &FOERSTER (2011), http://www.mofo.com/files/Uploads/Images/111208-Mayo-v-Prometheus.pdf.

The applicant in *Bilski* sought a patent for a financial hedging strategy.[59] The patent was initially rejected, and the PTO's Board of Patent Appeals and Interferences affirmed, concluding the claims were "not directed to statutory subject matter under 35 U.S.C. § 101."[60] On appeal, the Federal Circuit ultimately affirmed the PTO's rejection of the patent, but issued five separate opinions revealing deep disagreements about the law of patentable subject matter.[61] The judges disagreed about the correct test for determining whether a process is patent eligible,[62] and whether business method patents should be categorically excluded from patent protection.[63]

In 2010, the U.S. Supreme Court issued a fractured opinion affirming the rejection of the patent, but rejecting the Federal Circuit majority's exclusive reliance on a machine-or-

[59] Bilski, 130 S. Ct. at 3223 (patent claimed "a procedure for instructing buyers and sellers how to protect against the risk of price fluctuations in a discrete section of the economy").

[60] Ex Parte Bernard L. Bilski & Rand A. Warsaw, No. 2002-2257, 2006 WL 5738364 (B.P.A.I. Sept. 26, 2006).

[61] *See Bilski*, 130 S. Ct. at 3218.

[62] The majority reaffirmed that "the machine-or-transformation test is the applicable test for patent-eligible subject matter," rejecting several alternate tests for determining whether a process is patent eligible under § 101. *In re* Bilski, 545 F.3d 943, 959 (Fed. Cir. 2008) *aff'd but criticized sub nom.* Bilski v. Kappos, 130 S. Ct. 3218 (2010). Under the machine-or-transformation test, "an applicant [could] show that a process claim satisfie[d] § 101 either by showing that his claim [was] tied to a particular machine, or by showing that his claim transform[ed] an article." *Id.* at 961. In separate dissenting opinions, Judges Newman and Rader rejected the machine-or-transformation test. Judge Newman quarreled with the majority's redefinition of "the word 'process' in the patent statute, to exclude all processes that do not transform physical matter or that are not performed by machines." *Id.* at 976 (Newman, J., dissenting). Judge Rader criticized the majority for failing to "answer the most fundamental question of all: *why* would the expansive language of section 101 preclude protection of innovation simply because it is not transformational or properly linked to a machine (whatever that means)?" *Id.* at 1012 (Rader, J., dissenting).

[63] The majority rejected calls for a categorical exclusion of business method patents. *Id.* at 960 ("We further reject calls for categorical exclusions beyond those for fundamental principles already identified by the Supreme Court."). Judge Mayer argued that "[a]ffording patent protection to business methods lacks constitutional and statutory support, serves to hinder rather than promote innovation and usurps that which rightfully belongs in the public domain." *Id.* at 998.

transformation test for determining whether or not a process is patentable subject matter.[64] Four Justices also endorsed a categorical exclusion for business method patents, arguing that a "claim that merely describes a method of doing business does not qualify as a 'process' under § 101."[65] Acknowledging the complexity and unsettled nature of the legal issues involved, Justice Kennedy observed that "[s]tudents of patent law would be well advised to study" the five "scholarly opinions" produced below.[66]

Prometheus involved a medical patent "covering processes that help doctors who use thiopurine drugs to treat patients with autoimmune diseases determine whether a given dosage level is too low or too high."[67] In March 2012, a unanimous Supreme Court reversed the Federal Circuit and invalidated the patent. The Court concluded that the patent claims did not "add *enough* to their statements of the correlations [involved] to allow the processes they describe to qualify as patent-eligible processes that *apply* natural laws."[68] Of course, this conclusion raises the question: what is enough? The inherent difficulty involved in determining whether an invention qualifies as a patentable process guarantees that types of disagreements and complicated legal questions in *Bilksi* and *Prometheus* will resurface. The law is perpetually unsettled. Thus, going forward, questions about whether an invention falls within one of the four categories of patentable subject matter may arise during post-grant review.

B. Three Exceptions

[64] *Bilski*, 130 S. Ct. at 3226 ("The Court of Appeals incorrectly concluded that this Court has endorsed the machine-or-transformation test as the exclusive test.").

[65] *Id.* at 3232 (Stevens, J., concurring).

[66] *Id.* at 3224.

[67] Mayo Collaborative Services v. Prometheus Laboratories, Inc., 132 S. Ct. 1289, 1294 (2012).

[68] *Id.* at 1297.

There are three long-standing exceptions to patentable subject matter: "laws of nature, physical phenomena, and abstract ideas."[69] This area of patent law is also sufficiently unsettled to give rise to claims under § 324(b). The controversy surrounding patents on human genes provides a useful example. In May 2009 the American Civil Liberties Union (ACLU) and the Public Patent Foundation (PUBPAT) filed suit against the PTO and two patent holders arguing that isolated human genes are not patentable subject matter because they fall within the exceptions to patent eligible subject matter.[70]

One of the patent holders, Myriad Genetics, held the patent on two genes that could be used to conduct tests to determine breast cancer risk.[71] The plaintiffs argued that "Supreme Court precedent establishes that a product of nature is not patent eligible even if, as claimed, it has undergone some highly useful change from its natural form."[72] The government as amicus curiae agreed with the plaintiffs that "isolated and unmodified genomic DNAs are not patent eligible, but rather patent-ineligible products of nature, since their nucleotide sequences exist because of evolution, not man."[73]

The government's argument that isolated human genes are not patentable subject matter was a dramatic change from the "longstanding practice" of the PTO, the National Institutes of

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[69] *Bilski*, 130 S. Ct. at 3225 (quoting Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980)).

[70] *ACLU Challenges Patents on Breast Cancer Genes: BRCA*, ACLU (Sept. 25, 2012), http://www.aclu.org/free-speech-womens-rights/aclu-challenges-patents-breast-cancer-genes-0.

[71] Andrew Pollack, *Ruling Upholds Gene Patent in Canter Test*, N.Y. TIMES, July 29, 2011, http://www.nytimes.com/2011/07/30/business/gene-patent-in-cancer-test-upheld-by-appeals-panel.html ("Myriad, which holds the patents on the genes called BRCA1 and BRCA2 with the University of Utah Research Foundation, charges more than $3,000 for its breast cancer risk test.").

[72] Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 653 F.3d 1329, 1349 (Fed. Cir. 2011), *vacated sub nom*. Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 132 S. Ct. 1794 (2012), *vacated, appeal reinstated*, 467 F. App'x 890 (Fed. Cir. 2012).

[73] *Id.* at 1350.

Health, and other government agencies that had previously obtained patents for isolated human genes.[74] Unmoved by the government's dramatic change of position, the Federal Circuit held that isolated human genes are patent eligible.[75] On March 26, 2012 the Supreme Court ordered the Federal Circuit to reconsider the case in light of their holding in *Prometheus*.[76] The ongoing controversy highlights the complexity of the legal and policy issues[77] involved in determining whether an invention falls within the exceptions for laws of nature, physical phenomena, or abstract ideas.[78]

Unsettled legal questions about the three exceptions to patentable subject matter are strong candidates for post-grant review under § 324(b). If subject matter challenges are heard through the post-grant review process, rather than in federal court, those challenges may be impacted by two important differences between post-grant review and litigation: new challengers and a new forum. Parts III and IV argue that these differences may ultimately impact what types of invention receive patent protection.

III: NEW CHALLENGERS

Outside of the limited PTO procedures discussed in Part I.A above, a patent's validity could historically only be challenged in a declaratory judgment action in federal court, or as a

[74] Brief for the United States as Amicus Curiae in Support of Neither Party, Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 653 F.3d 1329 (Fed. Cir. 2011) (No. 2010-1406), 2010 WL 4853320, at *18 (Oct. 29, 2010).

[75] Ass'n for Molecular Pathology, 653 F.3d at 1350 ("[W]e conclude that the challenged claims to isolated DNAs . . . are directed to patent-eligible subject matter under § 101.").

[76] Andrew Pollack, *Justices Send Back Gene Case*, N.Y. TIMES, March 27, 2012, http://www.nytimes.com/2012/03/27/business/high-court-orders-new-look-at-gene-patents.html.

[77] In addition to the legal question of patentability, the Myriad case raised important policy questions about the prudence of allowing patents on isolated human genes. Unfortunately, those issues are beyond the scope of this paper.

[78] *See* Bilski v. Kappos, 130 S. Ct. 3218, 3225 (2010) (quoting Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980)).

defense to a claim of patent infringement in litigation.[79] Federal standing requirements severely limit who can challenge a patent's validity in a declaratory judgment action.[80] In *Myriad*, for example, the Federal Circuit concluded that only one of the many original plaintiffs had standing to sue.[81] In contrast, anyone who is "not the owner of the patent" can file a petition for post-grant review.[82] This Part explores the potential unintended consequences of allowing parties who would not satisfy federal standing requirements to challenge a patent's validity and raise novel and unsettled legal questions through the post-grant review process.

A. Federal Standing Requirements

Federal standing doctrine imposes three limitations on prospective plaintiffs. First, "the plaintiff must have suffered an injury in fact—an invasion of a legally protected interest which is (a) concrete and particularized, and (b) actual or imminent, not conjectural or hypothetical."[83] Second, "there must be a causal connection between the injury and the conduct complained of-the injury has to be 'fairly ... trace[able] to the challenged action of the defendant.'"[84] Third, "it must be 'likely,' as opposed to merely 'speculative,' that the injury will be 'redressed by a favorable decision.'"[85] If a plaintiff fails to satisfy any of these requirements, they cannot sue in federal court. In the patent context, that means they cannot challenge the validity of a patent.

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[79] *See, e.g.* Ass'n for Molecular Pathology, 653 F.3d 1329 (declaratory judgment action).

[80] *Id.* at 1343 ("Whether an actual case or controversy exists so that a district court may entertain an action for a declaratory judgment of non-infringement and/or invalidity is governed by Federal Circuit law.").

[81] *Id.* at 1344 ("Under the facts alleged in this case, we conclude that one Plaintiff, Dr. Ostrer, has established standing to maintain this declaratory judgment suit.").

[82] 35 U.S.C. § 321(a) (2011).

[83] Ass'n for Molecular Pathology, 653 F.3d at 1343.

[84] *Id.*

[85] *Id.*

Disagreements have arisen about how to apply these general standing principles to declaratory judgment actions challenging patent validity. The Federal Circuit has repeatedly attempted to develop multi-part standing tests specifically for the patent context. In 2007, the Federal Circuit stated "that a [patent] licensee must, at a minimum, stop paying royalties (and thereby materially breach the agreement) before bringing suit to challenge the validity or scope of the licensed patent."[86] The U.S. Supreme Court rejected this rigid standing requirement for declaratory judgment actions in *MedImmune, Inc. v. Genentech, Inc*.[87] The Supreme Court reemphasized that "[b]asically, the question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment."[88]

Despite the Supreme Court's guidance in *MedImmune*, the Federal Circuit again advocated a patent-specific standing analysis in *Myriad*. According to the Federal Circuit, "to establish an injury in fact traceable to the patentee, a declaratory judgment plaintiff must allege both (1) an affirmative act by the patentee related to the enforcement of his patent rights, and (2) meaningful preparation to conduct potentially infringing activity."[89] Scholars have criticized this rigid analysis as an inappropriate departure from the principles laid out in *MedImmune*,[90] and the ACLU challenged this statement of the law in the *Myriad* petition for certiorari.[91]

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[86] Gen-Probe Inc. v. Vysis, Inc., 359 F.3d 1376, 1381 (Fed. Cir. 2004), *abrogated by* MedImmune, Inc. v. Genentech, Inc., 549 U.S. 118 (2007).

[87] 549 U.S. 118, 128-29 (2007).

[88] *Id.* at 127.

[89] Ass'n for Molecular Pathology, 653 F.3d at 1343.

[90] Megan M. La Belle, *Standing to Sue in the* Myriad Genetics *Case*, 2 CAL. L. REV. CIRCUIT 68, 70 (2011) ("This Essay argues that the *Myriad* court misinterpreted and misapplied Supreme Court standing precedent, fashioned a test that is far too narrow, and wrongly concluded that Dr. Ostrer was the only plaintiff with standing to sue.").

Whether or not the test set forth by the Federal Circuit in *Myriad* survives, general standing requirements will continue to limit who can challenge a patent's validity in federal court. In contrast, the post-grant review process will allow anyone to bring a challenge. The PTO's early proposals for post-grant review considered three different standing options, but the ultimate recommendation was to have no standing requirement at all.[92] Congress followed that advice in the AIA. The remainder of this Part considers the costs and benefits of removing standing requirements for post-grant review proceedings. I argue that the implications may be greatest in cases raising subject matter challenges under § 324(b), where interest groups are most likely to challenge patents for ideological, political, or policy reasons.

B. Costs of Eliminating Standing Requirements

The costs of allowing any person or organization to petition for post-grant review include potential procedural complications and a greater threat of harassment for patent owners.

Procedural Complications. While the PTO ultimately recommended that there should be no standing requirements for post-grant review, their analysis of the issue acknowledged the potential procedural complications that may arise as a result. Specifically, the "[l]ack of a standing requirement may create Article III and prudential standing issues on judicial review as to review petitioners, possibly (1) precluding judicial review of holding that claim is patentable or (2) necessitating USPTO participation, including a greater burden on the USPTO Solicitor's

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[91] Petition for Writ of Certiorari, Ass'n for Molecular Pathology v. Myriad Genetics, 132 S. Ct. 1794 (2011) (No. 11-725).

[92] The first option considered was to have no standing requirement for post-grant review. ACTION PAPER, *supra* note 23. The second would have allowed "[a]ny petitioner who believes that it is or will be economically damaged by the patent [to] file a petition for review at any time." *Id.* The third option would have limited standing to "[a]ny petitioner who believes that it is or will be 'damaged' by the patent may file a petition for review (1) within 12 months of the issuance of any claim challenged, or (2) within 4 months of being placed in 'substantial apprehension' of being sued for infringement of any claim challenged." *Id.*

Office."[93] Essentially, some parties who challenge patents in post-grant review may not have standing in federal court to appeal the decision. Congress sought to avoid this outcome by including a provision in the AIA that states: "Any party to the post-grant review shall have the right to be a party to the appeal."[94] However, it is unclear whether this provision will actually guarantee standing because the Constitution limits Congressional power to confer standing in federal court.[95]

Threat of Harassment. In addition to procedural complications, the lack of standing requirements for post-grant review increases the risk that patent owners will suffer harassment from frivolous petitions.[96] Without any standing requirements, any person or organization can file a petition for post-grant review. The PTO has recognized that the lack of a standing requirement "may lead to proceedings that are politically or personally motivated involving subject matter of commercial significance."[97] Interest groups making patentable subject matter challenges for ideological, political, or policy reasons may specifically target owners of controversial patents. These challenges would often be addressed to broad legal and policy questions, rather than weaknesses specific to a given invention. Thus, the costs of eliminating standing may be unevenly distributed among patent owners. Depending on the regulations ultimately adopted by the PTO, even meritless petitions may require an initial response from the patent owner. Patent owners would then be forced to incur substantial costs preparing and submitting their responses.

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[93] *Id.*

[94] 35 U.S.C. § 329 (2011).

[95] *See generally* Lujan v. Defenders of Wildlife, 504 U.S. 555 (1992).

[96] ACTION PAPER, *supra* note 23 ("Lack of a standing requirement makes use of a review proceeding more viable as a harassment tool.").

[97] *Id.*

C. Benefits of Eliminating Standing Requirements

The lack of a standing requirement for post-grant review has benefits that offset some of the costs. Eliminating standing requirements increases the number of people and organizations that can challenge a patent's validity. The benefits of allowing anyone to petition for post-grant review include: simplicity, improved patent quality, and increased involvement by expert advocates.

Simplicity. Eliminating standing requirements will simplify post-grant review proceedings because the PTO will not need to determine whether a petitioner satisfies any type of standing requirement.[98] In federal court, standing analysis often becomes a distracting and time-consuming part of litigation. Parties must spend time and resources arguing over whether or not the plaintiff may even bring the case in federal court. Post-grant review avoids these complications by eliminating standing requirements altogether.

Improved Patent Quality. One of the primary goals of introducing post-grant review was improving patent quality. High quality patents are those that genuinely deserve patent protection. The costs of low quality patents "include entry deterrence of would-be innovators, a slower pace of innovation, and increases in patent application activity that are costly both to the firms and to society."[99] When the PTO recommended no standing requirement for post-grant review, they

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[98] *Id.* (explaining that the lack of standing requirement "[s]implifies proceeding and conserves resources because the Board will not need to adjudicate standing").

[99] Hall & Harhoff, *supra* note 20, at 992; *see also* Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 NW. U. L. REV. 1495, 1515 (2001) ("First, bad patents that are litigated impose litigation costs on society; those costs have already been considered. Second, bad patents that are licensed impose legal fees on licensees; those costs too have already been considered. Third, some licensees may pay a royalty rather than fight even a bad patent in court. Those royalty payments are a social cost to bad patents that I have not yet considered. Finally, it is possible that the mere existence of bad patents that aren't litigated or licensed may nonetheless deter some lawful competitive conduct.").

argued that greater access to the process would create "the strongest quality check on patents."[100] Eliminating standing requirements may improve patent quality by allowing any person or organization to challenge low-quality, invalid patents.

Megan La Belle explains that "[i]f patents are successfully challenged, previously patented innovations may then be used and exploited by the public. The result is enhanced consumer choice, increased competition, and lower costs, all of which bring significant economic benefits to society."[101] La Belle argues that in order to maximize these benefits, "courts should be moving toward legal standards that encourage, rather than dissuade, the filing of suits like *Myriad*."[102] Eliminating standing requirements for post-grant review is a significant step in this direction. Parties who would not have satisfied federal standing requirements will now be able to challenge patents through post-grant review.

Expert Advocates. Eliminating standing requirements may also increase involvement by relevant experts. First, "potential infringers and their customers . . . may have rich information on patent validity."[103] These parties may not satisfy federal standing requirements. In post-grant review, interested third parties with technical knowledge will now be able to bring their expertise to bear. Second, specialized advocacy organizations may challenge more patents for ideological or policy reasons. The involvement of the ACLU and PUBPAT in the *Myriad* case is one example of this type of policy-oriented litigation.[104] *Myriad*, however, barely survived when the Federal Circuit determined that only one plaintiff had standing. Removing standing

[100] ACTION PAPER, *supra* note 23.

[101] La Belle, *supra* note 90, at 71.

[102] *Id.*

[103] Farrell & Merges, *supra* note 20, at 964.

[104] *See supra* Part II.B.

requirements completely will make it easier for organizations to challenge patents without searching for co-plaintiffs to satisfy the standing requirements.

IV: A NEW FORUM

As discussed above, § 324(b) invites petitioners to raise novel and unsettled legal questions through post-grant review in the PTO, rather than the federal courts. Many of these challenges may focus on the types of patents that should receive patent protection because this area of law is perpetually unsettled.[105] Moving these questions to a new forum raises important questions about the appropriate roles of the PTO and the federal courts.[106] This Part compares the newly created Patent Trial and Appeal Board (Board) to the federal courts on five metrics: (1) efficiency, (2) expertise, (3) bias, (4) independence, and (5) responsiveness. I argue that one of the most important potential changes arising from post-grant review could be that the Board will be more responsive to shifting popular preferences about what constitutes patent eligible subject matter.

A. Efficiency

The post-grant review process is intended to be a quicker, cheaper process than litigation in federal district court.[107] Lowering costs for challengers was a primary goal for advocates of post-grant review. Scholars worried that the incentives built into patent litigation discourage

[105] *See supra* Part II.

[106] Patent law reform in the United States, Hjerrild & Levin, September 16, 2011, *available at* http://hlipr.com/index.php/patent-news/105-patent-law-reform-in-the-united-states (last visited Oct. 24, 2011) ("Some commentators have noted that use of this kind of language may amount to an invitation for third parties to address 'novel or unsettled' legal questions through the USPTO, an issue which raises a number of issues relating to the role which the Courts of Law and the PTO, respectively, will play in resolving such "novel or unsettled" legal questions.").

[107] 157 CONG. REC. S5319-21 (statement of Sen. Jon Kyl), 2011 WL 3902927, at*1 ("By allowing post-grant review of patents . . . the bill creates an inexpensive substitute for district court litigation and allows key issues to be addressed by experts in the field.").

challenges to patent validity because challengers who successfully invalidate patents must share the benefits of their success with everyone, while bearing all of the costs.[108] Joseph Farrell and Robert Merges argue that misaligned incentives make litigation "an unreliable tool for assessing patent validity."[109] In their view, litigation suffers from "skewed incentives" that result in skewed outcomes.[110] The problems with patent litigation led Ferrell and Merges to advocate for additional, low-cost review of patents within the PTO.[111] Lowering the costs of post-grant review will encourage petitioners to challenge bad patents. Patent owners will also benefit from a cheaper alternative to litigation.

Several features of the post-grant review process were designed to save petitioners and patent owners time and money. The Director must determine whether to institute a post-grant review within three months of receiving a preliminary response from a patent owner, or, if no such response is filed, within three months from "the last date on which such response may be filed."[112] The Director must also prescribe regulations "requiring that the final determination in any post-grant review be issued not later than 1 year after the date on which the Director notices the institution of a proceeding under this chapter, except that the Director may, for good cause shown, extend the 1-year period by not more than 6 months, and may adjust the time periods in

[108] 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, 323 (2007) ("[I]n litigation, collective action problems exist because the rules on non-mutual defensive issue preclusion enunciated by the Supreme Court effectively cause the challenger who successfully invalidates a patent to provide a public good.").

[109] Farrell & Merges, *supra* note 20, at 948.

[110] *Id.*

[111] *Id.* at 964 (advocating "a lower-cost, post-issuance proceeding in which customers, competitors, and others could adduce evidence of invalidity").

[112] 35 U.S.C. § 324(c) (2011).

this paragraph in the case of joinder."[113] While it remains to be seen how quick post-grant review actually is, the 18-month deadline should make it consistently speedier than litigation in district court.

B. Expertise

Our legal system is designed to take advantage of expertise. Appellate review is premised in part on the belief that trial courts are more competent at resolving issues of fact, while appellate courts specialize in resolving issues of law.[114] Specialized administrative agencies like the PTO are often believed to have "superior expertise and institutional advantages over courts."[115] Indeed, "[o]ne of the central rationales for creating administrative agencies was that they would have greater expertise and focus than generalist legislatures or courts."[116] The specialized Federal Circuit was created in part because expertise is considered especially important in patent cases, where the legal issues are complex and technical knowledge may be helpful.

While the entire post-grant review system is premised on the belief that the PTO currently "issues many patents that should not be enforced, either on economic or on legal grounds,"[117] proponents of post-grant review have consistently celebrated the fact that post-grant

[113] 35 U.S.C. § 326(a)(11) (2011).

[114] Thomas W. Merrill, *Article III, Agency Adjudication, and the Origins of the Appellate Review Model of Administrative Law*, 111 COLUM. L. REV. 939, 940 (2011) ("The trial court, which hears the witnesses and makes the record, is assumed to have superior competence to resolve questions of fact; the reviewing court is presumed to have superior competence to resolve questions of law.").

[115] Sapna Kumar, *Expert Court, Expert Agency*, 44 U.C. DAVIS L. REV. 1547, 1549 (2011).

[116] Benjamin & Rai, *supra* note 108, at 309.

[117] Farrell & Merges, *supra* note 20, at 944.

review will allow experts at the PTO to address the most important issues in the field.[118] Members of the Board, who have expertise in the patent area, will conduct post-grant reviews and evaluate the challenged patents. The Board is comprised of the Director, the Deputy Director, the Commissioner for Patents, the Commissioner for Trademarks, and administrative patent judges.[119] Administrative patent judges are appointed by the Secretary of Commerce and must be "persons of competent legal knowledge and scientific ability."[120]

However, the Board's relative advantages with respect to the more technical areas of patent validity do not necessarily come with a capacity to address novel or unsettled legal questions.[121] Scott McKeown has argued that the PTO is "best equipped to review issues of technology and prior art, not novel *legal* questions."[122] He suggests "untested legal theories that have far reaching public policy implications are best left to the courts and legislators."[123]

Concerns about the PTO's competence to address questions about patent eligible subject matter may be compounded by limits on discovery during post-grant review. The AIA requires the Director to establish regulations for discovery during post-grant review.[124] Interestingly, the Director is instructed to limit discovery "to evidence directly related to factual assertions advanced by either party in the proceeding."[125] These limitations might threaten the PTO's

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[118] 157 CONG. REC. S5319-21 (statement of Sen. Jon Kyl), 2011 WL 3902927, at *1("By allowing post-grant review of patents . . . the bill creates an inexpensive substitute for district court litigation and allows key issues to be addressed by experts in the field.").

[119] 35 U.S.C. § 6(a) (2011).

[120] *Id.* The Secretary of Commerce, in consultation with the Director, appoints administrative patent judges. *Id.*

[121] Benjamin & Rai, *supra* note 108, at 312 ("As contrasted with agency factfinding, an agency's legal interpretations and its policy decisions are not as dependent on the understanding of technical data.").

[122] McKeown, *supra* note 46.

[123] *Id.*

[124] 35 U.S.C. § 326(a)(5) (2011).

[125] *Id.*

ability to effectively resolve novel and unsettled legal questions, especially those related to the scope of patentable subject matter. Competently answering these types of questions often requires information and evidence that goes beyond "factual assertions" directly related a single patent.

C. Bias

The downside of the PTO's narrow focus is the threat of bias "as a result of capture by narrow interests."[126] The threat of bias stems "from the logic of collective action: small groups of players with concentrated interests will have an easier time organizing, and influencing, decisionmakers than will large, diffuse groups."[127] While interest groups may also influence the courts, there is general agreement that federal judges are less likely to be captured than agencies, in part because of the constitutional protections for judicial independence.[128] On the other hand, bias may be less of a concern in post-grant review than in other agency contexts because "the trial-type context of formal adjudications . . . alleviates the fear of powerful interests presenting arguments privately to the decisionmaker and more generally reduces concerns about bias affecting the agency's decision."[129]

D. Independence

[126] Benjamin & Rai, *supra* note 108, at 310.

[127] *Id.*

[128] *Id.* at 311-12 ("This conclusion flows in significant part from the facts that agencies usually have a somewhat narrow focus; that agency officials often come from, and plan to return to, the industry that they regulate; and that powerful interest groups can help to provide agency members with benefits that they prize (budgetary clout on Capitol Hill and future employment are the two most often cited). By contrast, judges have life tenure and thus less concern about their future employment, have salaries and budgets that are largely free from congressional meddling, and may have a greater desire for prestige (which powerful interest groups cannot easily provide.")).

[129] *Id.* at 313.

The framers of the Constitution probably did not anticipate the modern scope of the administrative state, but they did appreciate that not all adjudicative bodies are created equal. The constitutional guarantees of lifetime tenure and undiminished compensation for federal judges reflect the framers' understanding that judicial independence is important and vulnerable.[130] Members of the Board do not have the same constitutional protections afforded federal judges. As a result, they may be less independent from the executive branch or Congress.

Consider, for example, what might have happened if post-grant review had been available when the ACLU and PUBPAT filed their complaint in *Myriad*. Rather than filing suit in district court, they might have filed a petition for post-grant review with the PTO.[131] Their petition likely would have asked the same question they raised in their petition for certiorari: "Are human genes patentable?" Given the arguments made by vocal advocates on both sides of the issue, the Director may have decided that the patent eligibility of human genes was an unsettled legal question affecting other patents. Having made this determination, the Director could have authorized review under §324(b).

If made aware of the petition, the government might have begun publicly expressing its agreement with the petitioners that isolated human genes are not patentable. The members of the Board conducting the post-grant review might have been uncomfortable disagreeing with the government's public position and popular opinion. After all, Board members are appointed to their positions and do not enjoy Article III protections. Thus, Board members may be somewhat more likely than federal judges to side with the government. Of course, concerns about independence are somewhat mitigated by the opportunity for appeal to the Federal Circuit.

E. Responsiveness

[130] *See* U.S. Const. art. III, § 1.

[131] For explanatory purposes, I ignore here the time limits on filing petitions.

Some may argue that the Board's alleged lack of independence would be better characterized as a healthy responsiveness to government or public preferences for the types of inventions that should receive patent protection. There is wide agreement that "the major normative goal of patent law is fostering innovation--both initial invention and the commercialization of such invention."[132] Ideally, whether or not certain types of inventions receive patent protection would depend on whether or not patent protection is necessary to foster innovation. If innovation in certain fields would take place even without patent protection, then patents in those fields are not worth the social costs arising from patent monopolies in that area. Unfortunately, the slow pace of statutory patent reform makes it impractical for Congress to redefine patent eligible subject matter as quickly as technology advances.

Thus, if the government has fully analyzed an issue and takes the position that certain subject matter should not be patent eligible, some may argue the PTO ought to follow that guidance. However, even if the PTO is more responsive than the federal courts to changing attitudes about patent eligible subject matter, the ultimate impact of that responsiveness depends on the level of deference the Federal Circuit applies to the PTO's post-grant review decisions. Part V.B below discusses the levels of deference the Federal Circuit will give to patent validity and other legal questions resolved in post-grant review.

V. PROPOSED REGULATIONS & PRACTICES

The PTO and the courts must make many important decisions as they develop regulations and practices for implementing post-grant review. One important task will be clarifying the role that § 324(b) is meant to play in the post-grant review process. Another will be determining the level of deference that will be given to the PTO's rulings on novel or unsettled legal questions.

[132] Benjamin & Rai, *supra* note 108, at 274-75.

This Part suggests regulations and best practices for the PTO and the Federal Circuit when novel and unsettled legal questions are considered during post-grant review.

A. PTO

In public comments to the PTO, the drug company Novartis raised five questions about how the parties and the PTO should address novel or unsettled legal questions in petitions for post-grant review:

> (1) whether the petitioner must assert that the questions raised should be considered a novel or unsettled legal question; (2) the evidence required to establish what is a novel or unsettled legal question; (3) whether the Director has leeway to determine, without an assertion on the part of the petitioner, that a petition raises a novel or unsettled legal question; (4) what, if any, arguments or evidence may the patentee present to avoid a finding that the petition raises a novel or unsettled legal question; and (5) whether a finding that a petition raises a novel or unsettled legal question is appealable.[133]

The PTO's response to these questions will impact the efficacy and efficiency of post-grant review. I make two recommendations. First, the PTO should require petitioners to explicitly state the novel or unsettled legal questions they believe they are raising, and should make a preliminary determination about those questions before requiring the patentee to respond. Second, sanctions should be imposed when petitioners raise legal questions that the PTO has already publicly determined are settled.

1. Preliminary Determinations

In order to prevent harassment of patent owners, while allowing legitimate challenges to proceed, the Director should implement regulations that require petitioners to state whether or not they believe their petition raises any novel or unsettled legal questions. If a petitioner asserts that they have raised a novel or unsettled legal question, the petitioner should be required to clearly state what the question is. The petitioner should also be required to explain how the

[133] Letter From Betty Ryberg, Vice President, Novartis Corp., to U.S. Patent and Trademark Office (Nov. 4, 2011) (on file with author).

question affects other patents or patent applications. The patent owner should not be expected to respond until the PTO has made a preliminary determination that the petition does in fact raise a novel or unsettled legal question affecting other patents or patent applications under § 324(b). If the PTO makes a preliminary determination that a petition satisfies § 324(b), the patent owner should then be able to present evidence and arguments to rebut that conclusion.

This system would protect patent owners from frivolous petitions because they would not need to file any response unless the PTO determines that a novel or unsettled legal question exists. This protection would be especially important to owners of controversial types of patents. For example, Scott McKeown speculates that subject matter challenges will be forthcoming under § 324(b) on the "patentability of gene sequencing, aspects of human cloning, genome mapping, and the like." It is possible that organizations will file petitions for review of every newly issued patent in these controversial areas, arguing that the patentability of such inventions remains an unsettled question. Patent owners should only be required to respond to those petitions that the PTO agrees raise a novel or unsettled legal question.

The system described above would also help the PTO efficiently evaluate petitions. It would be too difficult and time consuming for the PTO to attempt to determine whether a petition raises a novel or unsettled question without any guidance from the petitioner. Forcing the petitioner to clearly state their legal questions will allow the PTO to determine more quickly whether there is relevant precedent that addresses the questions presented.

2. Sanctions

The AIA gives the Director explicit authority to impose "sanctions for abuse of discovery, abuse of process, or any other improper use of the [post-grant review] proceeding, such as to

harass or to cause unnecessary delay or an unnecessary increase in the cost of the proceeding."[134] The Director should implement regulations that clearly state that sanctions may be imposed if a petition is filed that claims to state a novel or unsettled legal question that the PTO has already publicly determined does not satisfy the requirements of § 324(b). The threat of sanctions would encourage petitioners to review the PTO's prior decisions before filing duplicative petitions. Of course, petitioners should be free to argue in good faith that a previously rejected question has subsequently become unsettled in light of intervening judicial opinions or actions by Congress or the PTO.

B. Federal Circuit

After a post-grant review is complete, the parties may appeal directly to the Federal Circuit. On appeal, the Federal Circuit will apply a strong presumption of validity to patents that survive post-grant review. I predict that the Federal Circuit will also be required to give *Chevron* deference to the Board's other legal conclusions made during post-grant review, including statutory interpretations of section 101 regarding patent eligible subject matter.

1. Presumption of Patent Validity

Prior to the enactment of the AIA, Doug Lichtman and Mark Lemley argued that if Congress were to implement post-grant review, "decisions made as part of that more intense review should be accorded deference by later decision-makers."[135] Stuart Benjamin and Arti Rai have argued that strong deference to findings of patent validity in post-grant review "could reduce the intensity of the collective action problem" typically associated with challenging patent

[134] 35 U.S.C. § 316(a)(6)(2012).

[135] Doug Lichtman & Mark A. Lemley, *Rethinking Patent Law's Presumption of Validity*, 60 STAN. L. REV. 45, 50 (2007).

validity.[136] Lichtman and Lemley argue that the results of review proceedings deserve more deference when the proceedings are adversarial and when more time passes between issuance and later review.[137] Adversarial processes are more likely to effectively weed out weak patents. Additionally, when more time passes between issuance and later review, more and better information becomes available for evaluating the legitimacy and value of the invention. Post-grant review as enacted will be an adversarial process, suggesting a high level of deference is appropriate. However, the short nine-month window for filing a petition argues against a high level of deference because there will be less "opportunity for reliable outsider evaluations to come to light."[138]

Regardless of the optimal level of deference, in practice the presumption of validity for patents surviving post-grant review will be at least as strong as the presumption for regularly issued patents. Section 282 of the Patent Act of 1952 states: "A patent shall be presumed valid."[139] Shortly before the AIA was enacted, the Supreme Court held in *Microsoft Corp. v. i4i Ltd. P'ship* that "§ 282 requires an invalidity defense to be proved by clear and convincing evidence."[140] Despite extensive criticism,[141] the AIA retained this presumption of validity. In light of the Court's decision in *i4i*, the Federal Circuit will likely apply a strong presumption of

[136] Benjamin & Rai, *supra* note 108, at 326.

[137] Lichtman & Lemley, *supra* note 135, at 51 ("[T]he more adversarial the process, the greater the appropriate deference, because adversarial interactions are particularly good at bringing forward evidence and arguments. Similarly, the more time that passes between issuance and evaluation, the greater the deference, this time because delay means that there was more opportunity for reliable outsider evaluations to come to light.").

[138] *Id.*

[139] 35 U.S.C.A. § 282 (West 2012).

[140] Microsoft Corp. v. i4i Ltd. P'ship, 131 S. Ct. 2238, 2242 (2011).

[141] *See, e.g.*, Lichtman & Lemley, *supra* note 135, at 48. *But see*, Janis, *supra* note 20, at 105 ("An effective U.S. inter parties patent proceeding would follow suit, applying the presumption of validity in the proceeding and giving it the same evidentiary effect that it would have in litigation.").

validity to any patent that is upheld in the post-grant review process. A strong presumption of validity in this context should be less controversial than in typical district court litigation, where "the presumption precludes what would often be a worthwhile second look."[142] Patents that survive post-grant review have already received a second look.

2. Deference to Other Questions of Law

Consider again what might have happened if post-grant review had been available when the ACLU and PUBPAT filed the *Myriad* suit. The Director may have authorized their petition pursuant to § 324(b) in order to address the question of whether human genes are patent eligible subject matter under Section 101. In order to answer this question, the Board would need to interpret the language of Section 101 in conjunction with the traditional exceptions to patent eligible subject matter discussed in Part II.B above. If the Board had concluded that Section 101 excludes human genes, then the question would be whether or not the Federal Circuit would give deference to the Board's statutory interpretation. Because the patent would have been rejected, the *i4i* presumption of patent validity would be irrelevant.

Principles of administrative law should be relevant to determining the appropriate level of deference in this context. Historically, however, the Federal Circuit has paid little attention to general administrative law principles.[143] This patent law exceptionalism made some sense prior to the AIA because the PTO did "not typically render legal interpretations of the patent statute to which courts must give *Chevron* deference."[144] However, as explained above, post-grant review

[142] Lichtman & Lemley, *supra* note 135, at 48.

[143] Benjamin & Rai, *supra* note 108, at 270 ("[T]he inattention to administrative law principles has long been a striking feature of the patent system."). Until 1999, the Federal Circuit denied that the Administrative Procedure Act applied to its review of PTO decisions. *Id.*

[144] *Id.* at 271.

will require the PTO to interpret section 101 more frequently. Thus, administrative law principles are more relevant to patent law than ever before.

Prior to the enactment of the AIA, Benjamin and Rai sought to identify "administrative-law-based mechanisms of judicial review that would allow the U.S. system to take full advantage of the cost savings and increased accuracy potentially offered by post-grant review."[145] They observed that most post-grant review proposals included "sufficient formality to satisfy *Mead's* test for application of *Chevron* deference."[146] *Chevron* requires courts to defer to an agency's statutory interpretation if (i) the statute is silent or ambiguous on the specific issue, and (ii) the agency interpretation is reasonable.[147] The post-grant review procedure implemented by the AIA is similar to the proposals that Benjamin and Rai were evaluating, and should also give rise to *Chevron* deference.

Benjamin and Rai argue that applying *Chevron* deference to post-grant review is desirable because "a decisionmaking process like post-grant review would entail sufficient rigor that we should have more confidence in it than we would other PTO actions."[148] While Benjamin and Rai's analysis seems sound for general questions of patent validity, they did not specifically address is issues raised by § 324(b) because that provision had not yet been proposed. Some observers might argue that the novel and unsettled legal questions about patent eligible subject matter raised under § 324(b) are too far outside the PTO's area of expertise to warrant *Chevron* deference. However, Congress' explicit decision to grant the PTO the authority to

[145] *Id.* at 279.

[146] *Id.* at 328.

[147] Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837, 842-44 (1984).

[148] Benjamin & Rai, *supra* note 108, at 328.

answer these questions, without specifying any alternate level of review, suggests that *Chevron* deference is appropriate.

CONCLUSION

Section 324(b) of the AIA authorizes post-grant review petitioners to raise novel and unsettled legal questions that affect other patents. The law of patent eligible subject matter under Section 101 is perpetually unsettled. Therefore, petitioners are likely to argue that challenged patents do not cover patent eligible subject matter. Moving subject matter challenges from litigation to post-grant review could mean that more subject matter challenges will be brought by interest groups for ideological, political, or policy reasons. Additionally, the system may be more responsive to shifting popular preferences about what constitutes patent eligible subject matter. These changes may have the unintended consequence of impacting the substantive law of patent eligible subject matter. The PTO must exercise careful discretion in setting regulations related to § 324(b), including appropriate sanctions for frivolous petitions and a system to conduct preliminary evaluations of legal questions before patent owner involvement in required. Perfecting the post-grant review system for addressing novel and unsettled legal questions is critical because the Federal Circuit will likely be required to give significant deference to the Board's legal conclusions.