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## Here Today, Gone Tomorrow? Post-Grant Review and PTAB Interpretation of § 101 Subject Matter after *Myriad*

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# NOTE

## HERE TODAY, GONE TOMORROW? POST-GRANT REVIEW AND PTAB INTERPRETATION OF § 101 SUBJECT MATTER AFTER *MYRIAD*

CONOR T. FLYNN<sup>1</sup>

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### ABSTRACT

Post-grant review is a new review procedure for granted patents

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in the United States. The procedure, instituted as a mechanism to get rid of “bad patents,” allows any outside party, within nine months of the patent grant date, to challenge the validity of a granted patent on any ground under the patent law, including patentable subject matter, provided that the petitioner can demonstrate that it is more likely than not that at least one of the claims challenged in the petition is unpatentable, or if there is a showing that “the petition raises a novel or unsettled legal question that is important to other patents.” This review and decision on novel or unsettled legal questions is done by a trial-like proceeding before the newly-created Patent Trial and Appeal Board, whose decisions are appealable to the Court of Appeals for the Federal Circuit. This note uses a model developed by positive political theory to argue that (1) the new post-grant review proceeding gives the PTO a considerable amount of power to determine what constitutes patentable subject matter; (2) the PTO’s power to determine what constitutes patentable subject matter may not create long-term security in what patentable subject matter is; and (3) that the best way to create security for long-term investment in patent protection may be for the Court of Appeals to take a more active, policymaking role in its review of PTAB decisions.

## INTRODUCTION

Post-grant review is a new review procedure for granted patents in the United States. The procedure, instituted as a mechanism to get rid of “bad patents,” allows any outside party to challenge the validity of a granted patent within nine months of the patent grant date, provided that the petitioner can demonstrate that “it is more likely than not that at least one of the claims challenged in the petition is unpatentable,” or if there is a showing that “the petition raises a novel or unsettled legal question that is important to other patents.” The review and decision on novel or unsettled legal questions is done by a trial-like proceeding before the newly-created Patent Trial and Appeal Board (PTAB), whose decisions are appealable to the Court of Appeals for the Federal Circuit.

Importantly, unlike the other post-grant procedures under the jurisdiction of PTAB, including *inter partes* review (IPR) and *ex parte* reexamination, post-grant review (PGR) permits the PTAB to review a granted patent for validity under any grounds for patentability under 35 U.S.C. § 282, including patentable subject matter, written description, and enablement. IPR and *ex parte* reexamination only review patent validity based on prior art and questions about claim scope raised during litigation.

Accordingly, the PTAB has been given the power to make determinations on “novel or unsettled legal questions” regarding what “patentable subject matter” is. This gives the PTO, and specifically the PTAB, significant power in determining the future of patent law. By law, patentable inventions must be new and useful, and either a process, machine, manufacture, or composition of matter, or any new and useful improvement thereof. Some authors have argued that this novel power to decide what is patentable is concerning, as it permits the PTO to significantly expand or shrink what can be patented.

This note is not concerned with the ethics or morality of what the PTAB might or might not consider patentable. This note does not consider whether the “outcomes” of various biotechnology inventions are desirable or undesirable. Rather, this note questions whether this new process can maintain the kind of institutional security that makes patents desirable. Indeed, the purpose of a patent under the Constitution is “to promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective . . . Discoveries.”<sup>2</sup> The investment in making scientific discoveries is secured by the exclusive right to profit from the discovery for a period of time, as protected by law. This security serves as a “carrot” by creating an incentive structure that entices innovation with a reasonably secure belief that one can enjoy the exclusive use of the idea for profit for a period of time. This protection creates other ancillary benefits as well, including investment in new businesses and job creation. This is especially pertinent in today’s knowledge-based, “idea economy.”

Anyone that has ever baked cookies understands that an unwieldy oven can dis-incentivize the desire to bake. It is well known in the art that wild temperature fluctuations during the baking process do not produce good cookies, let alone edible ones. One will only make cookies if one can be reasonably certain that at the end of the prescribed baking time the cookies will turn out reasonably edible. To be sure, if a baker knows that an oven can be unruly, the baker either won’t make the cookies, or will bake them in a different oven. This concept of security in long-term returns inducing investment is true throughout our daily lives: we invest in our retirement accounts and watch sporting events, for example. If we withdrew money from our retirement accounts every time there was a downturn in the market, the total potential return would be significantly diminished. If we weren’t reasonably sure that the rules of sporting events were to be enforced fairly we wouldn’t invest our time and money in watching

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<sup>2</sup> U.S. CONST. art. I, § 8, cl. 8.

them.<sup>3</sup> Like a reliable oven, patents and the legal system in which they operate create the type of institutional security that incentivizes investment in innovation.

The length of patent protection today is twenty years. Twenty years can span up to five presidential terms. As history has shown, views can change significantly during the course of these twenty years. When an inventor makes an investment in a patent, the inventor believes that the law governing that patent will remain the same for the duration of the patent, and makes business decisions and investments accordingly. For this reason, the new PGR mechanism whereby PTAB can make decisions on novel legal questions regarding patentable subject matter is concerning. The PTAB's decisions on legal questions regarding novelty, obviousness, written description, and enablement will be limited to the patent in question in the dispute, i.e., whether the prior art renders the granted patent unpatentable, or whether the invention is adequately enabled, or whether the invention is sufficiently described. Novel § 101 subject matter questions, however, can shrink or expand exactly *what* is patentable. The new PGR procedure, accordingly, may create considerable risk for those wishing to pursue patent protection, as what is patentable could change considerably over the course of twenty years, depending on the direction of the PTAB. This added volatility could have a chilling effect on both innovation and investment, as it adds risk to the calculation of whether to invest.

This note further argues that the federal judiciary may be the best tool to create security in investing in patent protection in this brave new world of post-grant review. As PTAB's decisions are appealable to the Court of Appeals for the Federal Circuit, the Federal Circuit is tasked with ensuring that the PTO does not stray far in its policymaking function. The Federal Circuit should be the "yin" to the PTO's "yang." As a byproduct, patent law, specifically what constitutes patentable subject matter, should not stray far from its intended statutory purpose. A reasonable expectation that the law will not stray from its statutorily intended purpose creates the type of security that incentivizes investment in the first place. An inventor under this scheme is, presumably, more secure in his belief that what is patentable today will be patentable in twenty years, and is thus incentivized to invent and obtain protection for the invention in order to profit off of her investment. However, after several 9-0 Supreme

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<sup>3</sup> This author, a Buffalo Bills season ticket holder, continues to invest even though a negative return is expected. A reasonably fairly refereed game is at least expected.

Court decisions overturning Federal Circuit decisions, there is an underlying concern that the Federal Circuit has become too “pro-patent,” and has stopped being a check on the PTO. Even though this concern may not be accurate, the perception may have a chilling effect on a party’s decision to pursue patent protection.

This note uses a model developed by positive political theory, which looks at government and institutional actors as “players” in a game theory analysis to predict policy outcomes, to argue that (1) the new post-grant review proceeding gives the PTO a considerable amount of power to determine what constitutes patentable subject matter; (2) the PTO’s expanded power to determine what constitutes patentable subject matter may not create long-term security in what patentable subject matter is; and (3) the best way to create security for long-term investment in patent protection is for the Court of Appeals for the Federal Circuit to take a more active, policymaking role in their review of PTAB decisions, perhaps by expanding PTAB appeal jurisdiction beyond the Federal Circuit.

### I. POST-GRANT REVIEW UNDER AIA GIVES THE PTO CONSIDERABLE POWER TO DETERMINE WHAT CONSTITUTES PATENTABLE SUBJECT MATTER.

The new post-grant review procedure under the new AIA gives the PTO a considerable amount of power to determine what constitutes patentable subject matter. First, this section discusses how and why post-grant review was included in the AIA. Second, this section discusses the post-grant review process in depth. Third, this section discusses the new power of the patent and trademark office to decide novel questions of law with respect to patentability.

#### A. *The humble beginnings of post-grant review*

Large numbers of low-quality patents hurt innovation.<sup>4</sup> Validity challenges are thus important and useful for achieving the patent system’s goal of promoting innovation by maintaining a “balance of fostering favorable conditions for inventors . . . while preserving the public’s interest in a competitive market for further progress.”<sup>5</sup>

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<sup>4</sup> Mark Consilvio & Jonathan R.K. Stroud, *Unraveling the U.S.P.T.O.’s Tangled Web: An Empirical Analysis of the Complex World of Post-Issuance Patent Proceedings*, 21 J. INTELL. PROP. L. 33, 39 (2013); see also *Lecture: Innovation, Incentives, Competition, and Patent Law Reform: Should Congress Fix the Patent Office and Leave Litigation Management to the Courts?*, 20 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 1135, 1140-41 (2010).

<sup>5</sup> Eric B. Cheng, *Alternatives to District Court Patent Litigation: Reform by*

Congress, in creating a public mechanism to challenge bad patents and rid the patent office of bad patents, sought to “create certainty for patentees, their competitors, and society in general.”<sup>6</sup>

Europe has long challenged the validity of issued patents with opposition proceedings.<sup>7</sup> In general, an opposition proceeding lets a third party bring an action before the European Patent Office (“EPO”) within the first nine months of a patent grant.<sup>8</sup> The opposition proceedings, importantly, give the *public* an opportunity to “assert knowledge, acts, and other disclosures” missing from the PTO’s original examination process.<sup>9</sup>

Challenges to patent validity in the United States have traditionally been handled in federal court, however, over time, Congress added procedures allowing third parties to petition the PTO to review issued patents.<sup>10</sup> These procedures included interference proceedings addressing issues of patentability; protests in reissue proceedings; and *ex parte* and *inter partes* reexaminations, which allowed third parties to petition for the reexamination of patents.<sup>11</sup>

Unfortunately, these proceedings were limited in their scope.<sup>12</sup> Interferences occurred only when a priority issue arose between two similar patents, protests during reissue proceedings were rare and had limited third party involvement, *ex parte* and *inter partes* reexamination were both limited to challenges based on prior art, and third parties in these challenges could not “conduct discovery, develop evidence, or cross-examine a patent owner outside the interference context.”<sup>13</sup>

Enter post-grant review (PGR), which was borne largely out of criticism the PTO received for granting patents to inventions that might be underserving of protection.<sup>14</sup> According to Congress, the

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*Enhancing the Existing Administrative Options*, 83 S. CAL. L. REV. 1135, 1138 (2010).

<sup>6</sup> *Id.* at 1139.

<sup>7</sup> *Id.* at 1143-46.

<sup>8</sup> *Id.*

<sup>9</sup> *Id.* (Some countries in the EPC, such as Germany, have their own opposition proceedings that precede the existence of the EPC opposition proceedings to challenge the validity of nation-specific patents); see, e.g., N. Thane Bauz, *Reanimating U.S. Patent Reexamination: Recommendations for Change Based Upon A Comparative Study of German Law*, 27 CREIGHTON L. REV. 945 (1994) (For a more in-depth look at the history of patent law).

<sup>10</sup> Karen A. Lorang, *The Unintended Consequences of Post-Grant Review of Patents*, UCLA J.L. & TECH., Spring 2013, 1, 3-8.

<sup>11</sup> *Id.*

<sup>12</sup> *Id.*

<sup>13</sup> *Id.*

<sup>14</sup> *Id.*; see also John R. Thomas, *Collusion and Collective Action in the Patent System: A Proposal for Patent Bounties*, 2001 U. ILL. L. REV. 305, 328-30 (2001)

America Invents Act<sup>15</sup> (AIA) was “designed to establish a more efficient and streamlined patent system that will improve patent quality and limit unnecessary and counterproductive litigation costs”<sup>16</sup> because “patents of dubious probity only invite legal challenges that divert money and other resources from more productive purposes . . . such as raising venture capital, commercializing inventions, and creating jobs.”<sup>17</sup>

The PTO submitted a *21<sup>st</sup> Century Strategic Plan* to Congress in June of 2002.<sup>18</sup> This report included thirty-seven “action initiatives comprising the five-year strategic plan.”<sup>19</sup> In this report is perhaps the first concrete example of the PTO’s desire to progress towards a system of post-grant review.<sup>20</sup> In one of the action papers in the report, entitled “Post-Grant Review of Patent Claims,” it was argued that a system of post-grant review would “enhance the patent system as a whole” by strengthening those patents that survive the review and eliminating those that do not.<sup>21</sup> Soon thereafter, in 2002, the Federal Trade Commission also recommended “an administrative procedure for post-grant review and opposition that allows for meaningful challenges to patent validity short of federal court litigation.”<sup>22</sup> Two years later, in 2004, the National Research Council of the National Academies argued a similar position.<sup>23</sup> Further, the International

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(Professors Janis, Nard, and Amazon CEO have been calling for opposition proceedings since the late 1990s). *But see* Carl E. Gulbrandsen, Stephanie Adamany, Sandra Haberny & Jason Sheasby, *Patent Reform Should Not Leave Innovation Behind*, 8 J. MARSHALL REV. INTELL. PROP. L. 328, 344-47 (2009) (“Reduced patent quality is symptomatic of an overworked USPTO . . . .” Claims that too many “low quality patents issue in the United States” and they “rarely are accompanied by any objective parameters about what constitutes a low quality patent, or metrics demonstrating an increase in the issuance of low quality patents”).

<sup>15</sup> PUB. L. NO. 112-29.

<sup>16</sup> Consilvio & Stroud, 21 J. INTELL. PROP. L. at 43-45. *See generally* Robert A. Armitage, *Understanding the America Invents Act and Its Implications for Patenting*, 40 AIPLA Q.J. 1, 9 (2012) (for a more in-depth examination of the history of patent law reform).

<sup>17</sup> Consilvio & Stroud, *supra* note 4, at 43-44.

<sup>18</sup> Lorang *supra* note 10, at 3-8.

<sup>19</sup> *Id.*

<sup>20</sup> *Id.* (One of the action 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.”).

<sup>21</sup> *Id.*

<sup>22</sup> *Id.*

<sup>23</sup> *Id.*; *see also* William C. Rooklidge & Alyson G. Barker, *Reform of A Fast-Moving Target: The Development of Patent Law Since the 2004 National Academies Report*, 91 J. PAT. & TRADEMARK OFF. SOC’Y 153, 196 (2009) (“The National Academies report introduced the idea of an open review of issued patents to improve the quality of patents in a way more efficient than litigation or existing reexamination



Trade Commission (ITC) also argued for a post-grant review mechanism in the United States as a way to produce better patents and avoid costly litigation.<sup>24</sup>

None of these proposals, nor the 2006 or 2007 Congressional proposals for post-grant review, included language similar to § 324(b),<sup>25</sup> which permits the Director of the PTO to institute PGR to resolve “novel or unsettled legal questions.”<sup>26</sup> This part of the statute, which is the main provision of concern discussed below,<sup>27</sup> was first introduced in the Patent Reform Acts of 2008 and 2009, neither of which became law.<sup>28</sup> The § 324(b) provision was in the original bill as introduced by Senator Leahy in 2011, however the congressional record<sup>29</sup> of both the House and Senate is silent as to this provision; the provision remained untouched between initial introduction with the bill and eventual passage as the America Invents Act in 2011.<sup>30</sup>

### B. Post-grant review

Post-grant review is generally viewed as the PTO’s most powerful tool for invalidating patents.<sup>31</sup> Post-grant review was added by section six of the AIA, which added Chapter 32 to title 35 of the United States Code.<sup>32</sup>

The purpose of the new post-grant review proceedings established by the AIA is to provide a cost-effective alternative to litigation for patent validity challenges.<sup>33</sup> Post-grant review (PGR) is

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proceedings . . . recommend[ing] ‘an Open Review procedure . . .’”.

<sup>24</sup> Katharine M. Zandy, *Too Much, Too Little, or Just Right? A Goldilocks Approach to Patent Reexamination Reform*, 61 N.Y.U. ANN. SURV. AM. L. 865, 883-85 (2006).

<sup>25</sup> 35 U.S.C. § 324(b) (2012).

<sup>26</sup> *Id.*

<sup>27</sup> Lorang *supra* note 10, at 8-9.

<sup>28</sup> *Id.*

<sup>29</sup> See Joe Matal, *A Guide to the Legislative History of the America Invents Act: Part II of II*, 21 FED. CIRCUIT B.J. 539, 599-605 (2012) (For an in-depth review of the legislative history of the America Invents Act, specifically with respect to the history of post-grant review).

<sup>30</sup> Lorang *supra* note 10, at 8-9.

<sup>31</sup> Sarah Tran, *Patent Powers*, 25 HARV. J.L. & TECH. 609, 631-33 (2012).

<sup>32</sup> Hung H. Bui, Esq., *An Overview of Patent Reform Act of 2011: Navigating the Leahy-Smith America Invents Act Including Effective Dates for Patent Reform*, 93 J. PAT. & TRADEMARK OFF. SOC’Y 441, 460-61 (2011).

<sup>33</sup> William Hannah, *Major Change, New Chapter: How Inter Partes Review and Post Grant Review Proceedings Created by the America Invents Act Will Shape Litigation Strategies*, 17 INTELL. PROP. L. BULL. 27, 32 (2012); Robert L. Stoll, *Maintaining Post-Grant Review Estoppel in the America Invents Act Revisited: A Call for Legislative Restraint*, 23 FED. CIRCUIT B.J. 15, 15-19 (2013).

an adversarial and trial-like post-grant opposition procedure available to *any party other than the patentee*.<sup>34</sup> The petition must be filed within nine months of the patent grant or reissue date.<sup>35</sup> The filing fee is \$35,000, and each additional claim costs \$800.<sup>36</sup> The entire proceeding, including discovery, is estimated to cost between \$175,000 and \$338,000.<sup>37</sup> The petition must 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.”<sup>38</sup> The patent owner has a right to file a preliminary response after a petition is filed in which the owner argues why PGR should not be instituted.<sup>39</sup> The decision of whether to authorize PGR then rests with the PTO Director,<sup>40</sup> and her decision is final and non-appealable.<sup>41</sup>

The director may only authorize PGR under either § 324 (a) or (b).<sup>42</sup> The Director may authorize PGR under § 324(a) if the Director is able to determine that the information contained within the petition, if not rebutted, demonstrates that it is more likely than not that at least one of the claims in the challenged patent is patentable.<sup>43</sup> The Director may authorize PGR under § 324(b), “Additional Grounds,” if there is a showing “that the petition raises a *novel or unsettled legal question* that is important to other patents or patent applications.”

The scope of PGR is broader than other challenge proceedings under the AIA.<sup>44</sup> *Ex parte* reexamination, which remains in force from the old patent system in the U.S., allows any third party to challenge a patent, at any time, for prior art consisting of patents or printed publications or statements of the patent owner in federal court

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<sup>34</sup> Lawrence B. Ebert, *Comment on “Patent Grant Rates at the United States Patent and Trademark Office”* 25 INTELL. PROP. & TECH. L.J. 3, 3-4 (2005) (PGR has been available for covered business method patents since September 16, 2012); see also Arjun Rangarajan, *Towards A More Uniform Procedure for Patent Invalidation*, 95 J. PAT. & TRADEMARK OFF. SOC’Y 375, 378 (2013).

<sup>35</sup> Ebert *supra* note 34, at 3-4 (PGR of a CBM may only be filed by a party, party in interest, or privy of the party, that has been sued for or charged with infringement of the patent, but may be filed at any time after the CBM patent grant, for as long as the business method review procedure remains in effect.); see also William Hannah *supra* note 33, at 36-37.

<sup>36</sup> Hannah *supra* note 33, at 33.

<sup>37</sup> *Id.* at 41.

<sup>38</sup> Lorang *supra* note 10, at 3-8.

<sup>39</sup> *Id.*

<sup>40</sup> *Id.*

<sup>41</sup> *Id.*

<sup>42</sup> *Id.*

<sup>43</sup> *Id.*

<sup>44</sup> Hannah *supra* note 33, at 36-37.

regarding claim scope that create substantial new questions of patentability.<sup>45</sup> *Inter partes* review, which phases out parent *inter partes* reexamination, allows any person to challenge the validity of an issued patent based on novelty or obviousness on the basis of prior art consisting of patents or printed publications.<sup>46</sup> Importantly, both of these challenges are limited to either prior art or statements in federal court concerning claim scope.<sup>47</sup>

PGR, on the other hand, can be instituted for *any* ground of invalidity under 35 U.S.C. § 282(b)(2) or (3),<sup>48</sup> including novelty, obviousness, utility, indefiniteness, written description, enablement, and, most importantly for the scope of this note, patentable subject matter.<sup>49</sup> The petitioner must show that it is “more likely than not that at least one of the challenged claims is unpatentable”<sup>50</sup> or that the petition raises a “novel or unsettled legal question that is important to other patents.”<sup>51</sup> The standard of review for PGR is a “preponderance of the evidence.”<sup>52</sup>

Importantly, PGR is only available to those patents filed under the new first-to-file provisions of the AIA.<sup>53</sup> This means that, in general, only those patents with an effective filing date on or after March 16, 2013, will be eligible for post grant review.<sup>54</sup>

The Patent Trial and Appeal Board (PTAB), which replaces the Board of Patent Appeal and Interferences,<sup>55</sup> is comprised of three administrative patent judges appointed by the secretary of commerce,<sup>56</sup> and is required under the AIA<sup>57</sup> to complete its review of a PGR petition and decide on patent validity within one year of the institution of the proceeding.<sup>58</sup> This is intended to be a significant improvement over prior post-grant review procedures, including

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<sup>45</sup> See 35 U.S.C. § 301(a)(1)-(2) (2012); see also 35 USC § 302 (2012).

<sup>46</sup> 35 U.S.C. § 311(b) (2012); see also Bui *supra* note 32, at 459.

<sup>47</sup> *Id.*

<sup>48</sup> 35 U.S.C. § 282(b)(2)-(3) (2012).

<sup>49</sup> Ebert *supra* note 34, at 3-4 (PGR cannot be based on inventorship, unenforceability, inequitable conduct or best mode issues); Hannah *supra* note 33, at 36-37; Stoll *supra* note 33, at 15-19 (2013).

<sup>50</sup> Ebert *supra* note 34, at 3-4; 35 USC § 324 (2012).

<sup>51</sup> Bui *supra* note 32, at 460-61.

<sup>52</sup> *Id.*

<sup>53</sup> Stoll *supra* note 33, at 15-19.

<sup>54</sup> *Id.* (This is especially interesting for biotechnology and pharmaceutical patents, which generally take longer to issue. A large upswing in PGR is likely on the horizon.)

<sup>55</sup> Hannah *supra* note 33, at 38.

<sup>56</sup> 35 U.S.C. § 6(a) (2012).

<sup>57</sup> Pub. L. No. 211-12.

<sup>58</sup> Ebert *supra* note 34, at 4.

reexaminations, which took anywhere from one to five years to complete.<sup>59</sup>

Finally, discovery is significantly broadened in PGR under the AIA. The broadened discovery should give an accused infringer a greater ability to invalidate claims in view of the prior art.<sup>60</sup>

### C. Power of the PTO

The PTO has the power to make rules, including questions of “substantive patent law.”<sup>61</sup> The PTO may issue regulations governing the conduct of the office, screen patent applications, address patentability questions, and interpret statutory and civil law.<sup>62</sup> The PTO’s new responsibilities over PGR leave an institutional structure that permits the PTO considerable discretion to implement and set patent policy.<sup>63</sup>

The AIA’s new post-grant mechanisms give the PTO power to “develop presumptively binding interpretations of substantive patent law” through adjudicatory proceedings.<sup>64</sup> The AIA requires that PGR take place in an adversarial, court-like proceeding before the PTAB, where the parties are each entitled to discovery and oral argument.<sup>65</sup>

Importantly, the AIA is silent as to the deference owed to the PTO’s legal determinations announced during PGR.<sup>66</sup> This raises serious questions about whether Congress intended for the PTO, which already has sole authority to adjudicate the validity of patent applications, to have interpretive authority over the Patent Act.<sup>67</sup> Some scholars argue that Congress did in fact intend for the PTO to have interpretive authority over the Act because Congress intended the PTO to effectuate PGR through formal adjudication,<sup>68</sup> and because this grant of formal adjudicatory power accompanied a

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<sup>59</sup> *Id.* (This long period was cited by district courts and the ITC alike as a reason not to stay proceedings during PTO reexam).

<sup>60</sup> Hannah *supra* note 33, at 41-42 (“If more prior art and testimony are considered when meeting a lower burden, then logically it is more likely to find claims not novel or obvious”).

<sup>61</sup> John M. Golden, *The U.S.P.T.O.’s Soft Power: Who Needs Chevron Deference?*, 66 SMU L. REV. 541, 543-46 (2013).

<sup>62</sup> *Id.*

<sup>63</sup> Tran *supra* note 31, 631-33.

<sup>64</sup> Golden *supra* note 61, at 543-46.

<sup>65</sup> Melissa F. Wasserman, *The Changing Guard of Patent Law: Chevron Deference for the PTO*, 54 WM. & MARY L. REV. 1959, 1976-77 (2013).

<sup>66</sup> *Id.*

<sup>67</sup> *Id.*

<sup>68</sup> *Id.*

delegation of interpretive authority.<sup>69</sup>

Administrative authority is an ongoing and evolving question in 2015.<sup>70</sup> In June, the U.S. Supreme Court issued its landmark decision on healthcare in *King v. Burwell*.<sup>71</sup> Referencing the two-step *Chevron* framework, the Court noted that this approach is “premised on the theory that a statute’s ambiguity constitutes an implicit delegation from Congress to the agency to fill the statutory gaps.”<sup>72</sup> The Court in *King*, however, refined this view to mean that a statute’s ambiguity constitutes an implicit delegation from Congress to the agency to fill the statutory gaps, provided such a “filling” *comports with the overall plan of the legislation*.<sup>73</sup>

Importantly, unlike the pre-AIA reexamination proceedings, PGR permits challenges before the PTAB on any grounds of patentability.<sup>74</sup> This permits challengers under PGR to raise broad legal and policy issues outside of novelty and obviousness.<sup>75</sup> Accordingly, the statutory language of the AIA including the expansion in statutory basis for challenging bad patents supports the argument that Congress viewed PGR as a “law-making vehicle” by which the PTO could announce legal and policy determinations that could affect the rights of many for long periods of time.<sup>76</sup>

## II. PTO POWER TO DETERMINE WHAT CONSTITUTES PATENTABLE SUBJECT MATTER DOES NOT CREATE LONG-TERM SECURITY FOR INVESTMENT

The PTO’s power to determine what constitutes patentable subject matter may not create long-term security for those wishing to

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<sup>69</sup> *Id.*

<sup>70</sup> *King v. Burwell*, 135 S. Ct. 2480, 2488-89 (2015); see also Daniel Fisher, *Did a judge just kick off the great unraveling of the administrative state with SEC ruling?*, available at <http://www.forbes.com/sites/danielfisher/2015/06/09/did-a-judge-just-kick-off-the-great-unraveling-of-the-administrative-state-with-sec-ruling/> [<http://perma.cc/Y55D-TK8Y>]; *Hill v. S.E.C.*, No. 1:15-CV-1801-LMM, 2015 WL 4307088, at \*9 (N.D. Ga. June 8, 2015); *E.P.A. v. EME Homer City Generation, L.P.*, 134 S. Ct. 1584, 1610, 188 L. Ed. 2d 775 (2014) (Scalia, J., concurring).

<sup>71</sup> *King*, 135 S. Ct. at 2488-89.

<sup>72</sup> *Id.* citing *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 159, 120 S.Ct. 1291, 146 L.Ed.2d 121 (2000).

<sup>73</sup> *King*, 135 S. Ct. at 2496 (“In a democracy, the power to make the law rests with those chosen by the people. Our role is more confined— ‘to say what the law is.’ . . . But in every case we must respect the role of the Legislature, and take care not to undo what it has done. A fair reading of legislation demands a fair understanding of the legislative plan.”)

<sup>74</sup> Wasserman *supra* note 65, at 1976-77.

<sup>75</sup> *Id.*

<sup>76</sup> *King*, 135 S. Ct. at 2496.

invest in patent protection because as technology develops at a quicker pace, what is “patentable subject matter” may be subject to rapid changes over time as popular opinions change.

A patent is intended to be a means to the end of innovation.<sup>77</sup> The U.S. Constitution gives Congress the ability to give inventors an exclusive right to their discoveries for a limited time.<sup>78</sup> This monopoly is intended to promote the progress of science and the useful arts.<sup>79</sup> The concept of providing monopolies to create incentive structures to innovate is not a novel one:<sup>80</sup> The Venetians offered exclusive rights to inventors and entrepreneurs that brought new technologies to Venice in 1474 in order to incentivize skilled artisans to come to Venice.<sup>81</sup> This model was copied by other European countries to stimulate innovation and promote economic development.<sup>82</sup> Britain’s Statute of Monopolies, which offered legal property rights in ideas, played a critical role in encouraging Britain’s Industrial Revolution.<sup>83</sup> The United States created the first modern patent system, which was, and remains instrumental in encouraging technological progress and economic growth in the United States.<sup>84</sup>

Stronger patents induce investment in research and development<sup>85</sup> and promote innovation and economic growth<sup>86</sup> by securing to inventors exclusive rights to make, use, offer to sell, or sell what they invent for a period of time.<sup>87</sup> Both positive political theory and simple intuition help to explain why: Individuals are rational, opportunistic, and operate in uncertain economic and strategic environments.<sup>88</sup> Accordingly, economic actors pursue investment

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<sup>77</sup> Robert Reis, *Smoke and Mirrors: America Invents Act 2011: A Chill in the Air?*, 6 AKRON INTELL. PROP. J. 301, 304 (2012).

<sup>78</sup> U.S. CONST., art. 1, § 8 cl. 8.

<sup>79</sup> *Id.*

<sup>80</sup> See Petra Moser, *Patents and Innovation: Evidence from Economic History*, 27 J. ECON. PERSP. 1, 23-44, 25 (2012).

<sup>81</sup> *Id.*

<sup>82</sup> *Id.*

<sup>83</sup> *Id.*

<sup>84</sup> *Id.*

<sup>85</sup> See generally William D. Nordhaus, *Theory of Innovation: An Economic Theory of Technological Change*, 59 AM. ECON. REV. 2 18-28 (1969).

<sup>86</sup> Khan, B. Zorina, & Kenneth L. Sokoloff. “Schemes of practical utility”: entrepreneurship and innovation among “great inventors” in the United States, 1790-1865”, 53 J. ECON. HIS. 2, 289-307 (1993).

<sup>87</sup> 35 U.S.C. § 271(a) (2012).

<sup>88</sup> Terry M. Moe, *The Politics of Structural Choice: Toward a Theory of Public Bureaucracy*, in ORGANIZATION THEORY: FROM CHESTER BARNARD TO THE PRESENT AND BEYOND, 115-150, 122 (1990).

vehicles that separate “politics from administration.”<sup>89</sup> The foundation of economic organization is that actors can focus on putting their property to its most efficient uses because a legal framework that guarantees property rights now can be reasonably assumed to exist in the future.<sup>90</sup> Politics, however, lacks this foundation.<sup>91</sup> Preferred policy choices change as often as popular opinion changes.<sup>92</sup> Accordingly, it is desirable for investors to separate politics and popular opinion from their long-term investment vehicles, such as patents.

Levy and Spiller demonstrate this concept by using transaction cost economics to analyze what makes privatized utilities succeed in different political and social circumstances.<sup>93</sup> The authors examine, specifically, the success of telecommunications utilities in Argentina, Chile, Jamaica, the Philippines and the United Kingdom to determine how political institutions interact with regulatory processes and economic conditions.<sup>94</sup> The authors determined that economic performance, in any geographic region, could be satisfactory as long as arbitrary administrative action could be restrained.<sup>95</sup> Specifically, the ability of an agency framework to facilitate investment is dependent on its credibility and effectiveness.<sup>96</sup> Credibility and effectiveness of a framework can produce satisfactory economic performance when (a) there are substantive restraints on the discretion of the agency; (b) formal or informal constraints are placed on changing the agency’s system; and (c) there are institutions that enforce the above formal substantive and procedural constraints.<sup>97</sup> Without a commitment to these three factors, long-term investment and economic growth do not take place.<sup>98</sup>

Similarly, Eskridge and Ferejohn argue that a fear of rapid changes in popular opinion also motivated the design of the United States Constitution, as the framers sought a separation of powers and a procedure for generating legislation that would change only

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<sup>89</sup> *Id.* at 125.

<sup>90</sup> *See id.*

<sup>91</sup> *Id.*

<sup>92</sup> *See id.*

<sup>93</sup> Brian Levy & Pablo T. Spiller, *Institutional Foundations of Regulatory Commitment: A Comparative Analysis of Telecommunications Regulation*, 10 J. L., ECON. & ORG. 201-246 (1994).

<sup>94</sup> *Id.*

<sup>95</sup> *Id.*

<sup>96</sup> *Id.* at 202.

<sup>97</sup> *Id.*

<sup>98</sup> *Id.*

incrementally over time, avoiding large shifts. First, the framers of the Constitution created a legislative process whereby most social and economic problems would not generate legislation.<sup>99</sup> Second, the framers intended that if a social or economic problem did in fact generate legislation, shifts away from the status quo would be moderate, rather than radical.<sup>100</sup> Third, the framers intended that once legislation was enacted into law, it would progressively be interpreted over the course of time to reflect the original intended policy balance.<sup>101</sup>

Accordingly, the design of lawmaking in Article I, Section 7 of the Constitution of a bicameral presidential lawmaking model was desired by the framers because of their rejection of lawmaking by simple majority votes.<sup>102</sup> Leaving long-reaching policy up to simple majority votes was viewed as dangerous by the framers because temporary alliances, desires, and voter preferences could result in short-sighted policies not in line with the long-term public interest.<sup>103</sup> The model we use today is representative of the framers' desires to balance republican liberty with long-term stability.<sup>104</sup> Popular and perhaps temporary preference should play a role in the legislative process, however it should not play such a large role that it creates short-sighted policies.<sup>105</sup>

Positive political theory shows that institutional security for long-term investment can be created a number of ways. Most importantly, whatever specific mechanisms are used, the target for creating security for investment is to separate the investment vehicle, in this case patent protection, from the changing tide of popular opinion. There is a significant question whether the new PGR process under the AIA, which permits the PTAB to make legal decisions on

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<sup>99</sup> William N. Eskridge, Jr., *The Article I, Section 7 Game*, 80 GEO. L.J. 523, 532 (1992); see also U.S. CONST. art. I, §. 7.

<sup>100</sup> William N. Eskridge, Jr., *The Article I, Section 7 Game*, 80 GEO. L.J. 523, 532 (1992).

<sup>101</sup> *Id.*

<sup>102</sup> *Id.* at 528. Eskridge and Ferejohn have modeled the Constitution's requirements for lawmaking into a sequential game. The start of the game is the status quo. In our bicameral presidential system, under Article I, Section 7, we only get a new law when one of two things happen. First, a law is passed if the median legislator in both chambers and the President all agree that the status quo should be changed to a particular new law. Second, a law will be passed if two-thirds of the members of each chamber agree that the status quo should be changed to a particular new law. Never is there a new law passed with a simple majority vote, which can occur in parliamentary systems of government.

<sup>103</sup> *Id.*

<sup>104</sup> *Id.*

<sup>105</sup> *Id.*



the scope of patentable subject matter, appropriately shields the law from the changing views of the public and patent bar.<sup>106</sup>

### III. 35 U.S.C. § 101 AND PGR

35 U.S.C. § 101<sup>107</sup> requires that the subject matter of a patentable new invention be a new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof.<sup>108</sup> The U.S. Supreme Court has explained that this statutory language “specifies four independent categories of inventions or discoveries that are eligible for protection: processes, machines, manufactures, and compositions of matter.”<sup>109</sup> The Supreme Court has further identified “laws of nature, physical phenomena, and abstract ideas” as patentable subject matter.<sup>110</sup>

35 U.S.C. § 324(b), new under the patent law, maintains that a patent can be challenged as invalid “on any ground . . . as a condition for patentability,” including patent eligible subject matter, non-obviousness, and novelty, among others. Accordingly, a petitioner may “argue that a patent does not cover patent eligible subject grounds on which the challenge to each claim is based, and the evidence that supports the grounds for the challenge to each claim.”<sup>111</sup>

There must be “a showing that the petition raises a novel or unsettled legal question that is important to other patents or patent applications.”<sup>112</sup> The post-grant review, once authorized by the director, is governed by the Patent Trial and Appeal Board (PTAB), which is comprised of the Director, Deputy Director, the Commissioner of Patents, the Commissioner of Trademarks, and administrative patent judges.<sup>113</sup> The administrative patent judges are

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<sup>106</sup> Members of the patent bar recognize that policy-based judicial decisions are bad for business. See *Ariosa is a good example of outcome driven § 101 decisions*, available at <http://www.ipwatchdog.com/2015/08/09/ariosa-is-a-good-example-of-outcome-driven-c2-a7-101-decisions/id=60433/> [<http://perma.cc/8NMJ-UKR4>] (“Courts these days are making policy-based decisions, untethered from any rule of law, aimed at killing patents they don’t like and I am skeptical that any amount of skill could have changed that in *Ariosa* (or in *AMP*, *In re Roslin*, *UURF v. Ambray*, etc.)”).

<sup>107</sup> 35 U.S.C. § 101.

<sup>108</sup> *Id.*

<sup>109</sup> Karen A. Lorang, *The Unintended Consequences of Post-Grant Review of Patents*, 17 *UCLA J.L. & TECH.*, Spring 2013 at 1, 10-11.

<sup>110</sup> *Id.*

<sup>111</sup> *Id.* at 10-11.

<sup>112</sup> *Id.*

<sup>113</sup> *Id.*

appointed by the Secretary of Commerce.<sup>114</sup>

What constitutes patentable subject matter is quite broad, but is limited to processes, machines, manufacture, or compositions of matter.<sup>115</sup> Abstract ideas, natural phenomena, and laws of nature are not eligible for patent protection because these principles represent “the basic tools of scientific and technological work,” and are “part of the storehouse of knowledge of all men . . . free to all men and reserved exclusively to none.”<sup>116</sup>

What constitutes patentable subject matter under § 101 has evolved slowly over time, but always with the courts.<sup>117</sup> The law is perpetually unsettled, and the pace of change is accelerating, especially in biotechnology.<sup>118</sup> The judiciary has recently produced a slew of cases discussing what constitutes patentable subject matter,<sup>119</sup> and the PTO has produced four sets of guidelines focused on subject matter eligibility based on these cases.<sup>120</sup> This has led to additional challenges to subject-matter eligibility of biotechnology inventions since *Mayo*, the first of these biotechnology cases, was decided.<sup>121</sup>

In *In re Bilski*,<sup>122</sup> an *en banc* decision for the Court of Appeals for the Federal Circuit, the Federal Circuit stated that the “machine-or-transformation test” was the appropriate test for what constitutes

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<sup>114</sup> *Id.*

<sup>115</sup> Melissa F. Wasserman, *The Changing Guard of Patent Law: Chevron Deference for the PTO*, 54 WM. & MARY L. REV. 1959, 2008 (2013).

<sup>116</sup> *Id.*

<sup>117</sup> Lorang, UCLA J.L. & TECH., Spring 2013, at 1, 10-11; see also the legal questions in *Bilski* and *Prometheus*.

<sup>118</sup> *Id.*; Kate Gaudry, *Trends In Subject Matter Eligibility For Biotechnology Inventions*, available at <http://www.ipwatchdog.com/2015/07/12/trends-in-subject-matter-eligibility-for-biotechnology-inventions/id=59738/>.

<sup>119</sup> Gaudry, *Trends in Subject Matter Eligibility for Biotechnology Inventions*, available at <http://www.ipwatchdog.com/2015/07/12/trends-in-subject-matter-eligibility-for-biotechnology-inventions/id=59738/> [<http://perma.cc/LM4Z-5BYJ>]; see also *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. \_\_\_, 132 S.Ct. 1289 (2012); *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. \_\_\_, 133 S.Ct. 2107 (2013); *Alice Corp. v. CLS Bank Int'l*, 134 S.Ct. 2347 (2014).

<sup>120</sup> Gaudry, *Trends in Subject Matter Eligibility for Biotechnology Inventions*, available at <http://www.ipwatchdog.com/2015/07/12/trends-in-subject-matter-eligibility-for-biotechnology-inventions/id=59738/> [<http://perma.cc/LM4Z-5BYJ>].

<sup>121</sup> *Id.* (“Across the 1630, 1640 1650 and 1670 biotechnology art units, the average office-action count rose 25 from 2.0 in the January 2012 Pre-Mayo time period to 2.5 in the February 2015 After Interim Guidelines time period. Art unit group 1630, which evaluates claims related to molecular biology and DNA, among other things, shows the highest number of office actions before allowance than any other art unit group shown.”).

<sup>122</sup> *In re Bilski*, 545 F.3d 943, 959 (Fed. Cir. 2008) *aff'd but criticized sub nom. Bilski v. Kappos*, 561 U.S. 593 (2010).

patent-eligible subject matter.<sup>123</sup> “The machine-or-transformation test is a two-branched inquiry; an applicant may show that a process claim satisfies § 101 either by showing that his claim is tied to a particular machine, or by showing that his claim transforms an article.”<sup>124</sup>

In *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*,<sup>125</sup> the Supreme Court decided in 2012 that a personalized medicine dosing process was not eligible for protection because the process was effectively an unpatentable law of nature.<sup>126</sup> Perhaps most importantly, in *Mayo* the Supreme Court “set forth a framework for distinguishing patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts.”<sup>127</sup> The first step is to determine whether the claims at issue are directed to a patent-ineligible concept.<sup>128</sup> If so, the Court will then consider the elements of each claim both individually and “as an ordered combination” to determine whether additional elements “transform the nature of the claim” into a patent-eligible application.<sup>129</sup> The second step of this analysis is to search for an “inventive concept,” an element or combination of elements that is “sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself.”<sup>130</sup>

Finally, in *Association for Molecular Pathology v. Myriad Genetics, Inc.*,<sup>131</sup> the Supreme Court in a 9-0 decision overturning the Federal Circuit, held that isolated natural DNA sequences containing genes are not patentable subject matter.<sup>132</sup> Important in *Myriad* is the history of the case presented to the Supreme Court. The Federal Circuit, in deciding that isolated DNA molecules are patent eligible subject matter afforded considerable deference to the PTO, citing the

<sup>123</sup> *Id.*

<sup>124</sup> *Id.*

<sup>125</sup> *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1294 (2012).

<sup>126</sup> *Id.* (“We find that the process claims at issue here do not satisfy these conditions. In particular, the steps in the claimed processes (apart from the natural laws themselves) involve well-understood, routine, conventional activity previously engaged in by researchers in the field. At the same time, upholding the patents would risk disproportionately tying up the use of the underlying natural laws, inhibiting their use in the making of further discoveries.”).

<sup>127</sup> *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1375-76 (Fed. Cir. 2015).

<sup>128</sup> *Id.*

<sup>129</sup> *Id.* (citing *Mayo*, 132 S. Ct. at 1298).

<sup>130</sup> *Id.*

<sup>131</sup> *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2111 (2013).

<sup>132</sup> *Id.*

“longstanding practice of the PTO and the courts,”<sup>133</sup> and that “the PTO has issued patents relating to DNA molecules for almost thirty years.”<sup>134</sup> The Federal Circuit further deferred to the PTO’s conclusions that genes are patentable in the Journal of the Patent and Trademark Office Society and the PTO’s own Utility Examination Guidelines to reach its own conclusion that genes were in fact patentable.<sup>135</sup> This position was criticized by the Supreme Court, which cited Congress’s purported failure to endorse the views of the PTO in legislation post-*J.E.M. Ag Supply*<sup>136</sup> and the United States’ own *amicus* argument that genes were not patentable and that “the PTO’s practice was not ‘a sufficient reason to hold that isolated DNA is patent-eligible.’”<sup>137</sup>

*Ariosa v. Sequenom*<sup>138</sup> is the most recent case concerning patentable subject matter. In *Ariosa*, a test for determining fetal abnormalities using prenatal DNA screening was determined to not be patentable subject matter because “appending routine, conventional steps to a natural phenomenon, specified at a high level of generality, is not enough to supply an inventive concept.”<sup>139</sup> This has led members of the patent bar to accuse the courts of “expanding their war on innovation in the United States.”<sup>140</sup>

35 U.S.C. § 324(b), which allows the PTAB to review novel

<sup>133</sup> *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 689 F.3d 1303, 1332 (Fed. Cir. 2012) *aff’d in part, rev’d in part sub nom.* *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013).

<sup>134</sup> *Id.* at 1333.

<sup>135</sup> *Id.*

<sup>136</sup> *J.E.M. Ag. Supply v. Pioneer Hi-Bred International*, 534 U.S. 124 (2001).

<sup>137</sup> *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2119 (2013) (citing Brief for United States as *Amicus Curiae* 20-33).

<sup>138</sup> *Ariosa Diagnostics*, 788 F.3d at 1378.

<sup>139</sup> *Id.*

<sup>140</sup> Robert L. Stoll, *Courts are making bad patent law*, available at <http://thehill.com/blogs/pundits-blog/the-judiciary/248054-courts-are-making-bad-patent-law#.VafCSf53ps0.linkedin> [<http://perma.cc/QYX3-2YW5>] (“The courts’ focus on subject matter eligibility as a mechanism to deny patents for these inventions will drive investment into research in these technologies to other areas. We will lose our edge in the world and many further valuable contributions to science will not come to fruition . . . . If the courts are unwilling to listen to the scientists and the patent community as to the effects these positions have on innovation, perhaps it is time to engage the legislators and the White House to clarify the law to ensure that we continue to promote the useful sciences.”); *see also Ariosa is a Good Example of Outcome-Driven § 101 Decisions*, available at <http://www.ipwatchdog.com/2015/08/09/ariosa-is-a-good-example-of-outcome-driven-c2-a7-101-decisions/id=60433/> [<http://perma.cc/X6CY-EYRA>] (“[] I perceive a common thread running through these decisions . . . supporting the growing feeling amongst the innovation community that § 101 decisions have taken on an arbitrary, outcome-driven quality”).

legal questions regarding what constitutes patentable subject matter, is a clear break from pre-AIA practice, and gives considerable power to the patent office to make legal determinations regarding the very heart of patent law. This presents a concern for any person wishing to pursue patent protection, from the perspective of institutional security for long-term investment, especially in the life sciences and biotechnology. The PTO has already tried to push patent policy such that § 101 would encompass human genes as patentable subject matter. Now, we live in a brave new world of synthetic biology,<sup>141</sup> which can reliably combine genetic pieces to produce consumer products, including biofuels and cosmetics.<sup>142</sup> It is becoming more and more difficult to determine what is “synthetic,” and patentable, and what is “natural,” and not patentable,<sup>143</sup> and it is no secret that the patent bar is actively pursuing an expansion of what constitutes patentable subject matter.<sup>144</sup> As research is performed at a quicker pace, and as the world of knowledge grows around us, and as the break between natural and artificial begins to blur, serious questions will be raised regarding what is a “process, machine, manufacture, or composition of matter” and is patentable, and what is a natural process, and is not patentable. The judiciary is the best tool to provide patent-seekers long-term security in investment.

There must be an active judiciary; there must be a threat of being overturned on appeal in order to ensure that the PTO does not stray far from its delegated authority, especially for what constitutes patentable subject matter. How to do this is addressed in the next section.

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<sup>141</sup> Jay Keasling, *Why Synthetic Biology Is the Field of the Future*, PBS NOVA (Feb. 28, 2013), <http://www.pbs.org/wgbh/nova/next/tech/why-synthetic-biology-is-the-field-of-the-future/> [<http://perma.cc/DYU6-3YHW>].

<sup>142</sup> *Id.*

<sup>143</sup> *Id.*; see also Berthold Rutz, *Synthetic Biology and Patents*, European Patent Office (Nov. 11, 2009) [http://www.synbioproject.org/process/assets/files/6384/\\_draft/rutz\\_slides1.pdf](http://www.synbioproject.org/process/assets/files/6384/_draft/rutz_slides1.pdf) [<http://perma.cc/28FB-4B9C>] (raising questions about artificial codons, non-natural amino acids, and protocells); Luigi Palombi, *Beyond Recombinant Technology: Synthetic Biology and Patentable Subject Matter*, 12 J. WORLD INTELLECTUAL PROPERTY 5, 371-401, 381 (2009).

<sup>144</sup> Letter from Lisa Dunner, ABA IPL Section Chair, to Michelle Lee, Director USPTO (“*Alice*, *Myriad*, and *Mayo* were narrow decisions, and the Office should allow the courts to incrementally determine, over time, what should not be patent-eligible subject matter, rather than attempting to affirmatively delineate the scope of patent-eligible subject matter, thereby risking excluding whole classes of inventions, including prospectively excluding deserving but yet-to-be discovered technology. The Section fears that the Office may be improperly excluding from patent-eligibility many important diagnostic, nature-based products, computer-implemented, software, and/or business method inventions, which would otherwise allow many new businesses to flourish.”).

#### IV. CLOSE REVIEW OF PTAB DECISIONS ON WHAT CONSTITUTES PATENTABLE SUBJECT MATTER CREATES SECURITY FOR INVESTMENT IN PATENT PROTECTION

The best way to create security for long-term investment in patent protection may be for the Federal Courts to act as a check on PTAB decisions.

The Federal Circuit, as it is currently constructed, may not be an effective check on the PTO. The Federal Circuit's overt specialization in the patent law has led several commentators to suggest that the Federal Circuit is prone to tunnel vision and bias with respect to review of PTO decisions,<sup>145</sup> the patent bar is especially vocal towards the Federal Circuit,<sup>146</sup> and the Court draws its staff, including clerks, from patent-centric law firms.<sup>147</sup> The policy-driven PTO, rather than the courts, is given primary interpretive authority over *legal* questions of core patentability standards, which is concerning over the long-term if the Federal Circuit does not serve as an effective check on PTO decisions.<sup>148</sup>

The Federal Circuit has been shown to be more likely to uphold the PTO's determination of a patent's validity when compared with the regional circuits that came before it.<sup>149</sup> Henry and Turner find that the Federal Circuit has been pro-patent with respect to the PTO's determinations of validity.<sup>150</sup> Further, the Federal Circuit has been reluctant to apply traditional administrative law principles when

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<sup>145</sup> Melissa F. Wasserman, *The Changing Guard of Patent Law: Chevron Deference for the PTO*, 54 WM. & MARY L. REV. 1959, 2015 (2013).

<sup>146</sup> See generally Lawrence Baum, JUDGES AND THEIR AUDIENCES, 97-99 (2006) (Judges serving on specialized courts are likely to orient themselves toward the lawyers and legal fields in which they concentrate.”).

<sup>147</sup> Wasserman, *supra* note 145 at 2015 (2013) (“[T]he possibility that the Federal Circuit’s decision-making process is unduly influenced by factions, at the very least, gives pause to dismissing the concept of the PTO playing a larger role in patent policy based on agency capture alone”); see also Timonthy Lee, *After a Scandal at America’s Patent Court, It’s Time for Reform*, Vox Topics (May 27, 2014), available at <http://www.vox.com/2014/5/27/5753866/the-real-problem-with-the-federal-circuit> [<http://perma.cc/N4W7-ZTGC>] (discussing Judges of the Federal Circuit seem to have absorbed the pro-patent worldview of the lawyers who spend so much time practicing in their courtroom. Federal Circuit judges and patent attorneys also see a lot of each other outside the courtroom. Federal Circuit judges attend patent lawyers’ conferences, read patent lawyers’ publications, and inevitably form friendly relationships with members of the patent bar.).

<sup>148</sup> Wasserman, *supra* note 145 at 1959.

<sup>149</sup> Paul R. Gugliuzza, *The Federal Circuit As A Federal Court*, 54 WM. & MARY L. REV. 1791, 1854-55 (2013).

<sup>150</sup> Matthew D. Henry & John L. Turner, *The Court of Appeals for the Federal Circuit’s Impact on Patent Litigation*, 35 J. LEGAL STUD. 85, 114-15 (2006).

reviewing PTO decisions.<sup>151</sup>

In contrast to the Federal Circuit's treatment of other agencies, the Federal Circuit views PTO policy decisions as encompassing fact and law, or sometimes fact, law, and discretion.<sup>152</sup> Patentees are estimated to be three times more likely to overcome a district court finding of invalidity since the inception of the Federal Circuit.<sup>153</sup> Perhaps because of this, district courts have found patents to be invalid about half as often as before that inception of the Federal Circuit.<sup>154</sup>

The Supreme Court, under Chief Justice Roberts, has recently granted certiorari to many more cases appealed from the Federal Circuit than it has in the past.<sup>155</sup> The Federal Circuit has seemingly used its monopoly power over patent appeals to shift patent law towards the favors of patent holders, rebuking the Supreme Court.<sup>156</sup>

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<sup>151</sup> Craig Allen Nard & John F. Duffy, *Rethinking Patent Law's Uniformity Principle*, 101 NW. U. L. REV. 1619, 1666-67 (2007).

<sup>152</sup> 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, 305-08 (2007).

<sup>153</sup> *Id.*

<sup>154</sup> *Id.*

<sup>155</sup> Timothy B. Lee, *Obama Wants To Fix The Patent System. Here's a Crucial Reform He Overlooked*, Wash. Post (Jan 29, 2014), available at <http://www.washingtonpost.com/blogs/the-switch/wp/2014/01/29/obama-wants-to-fix-the-patent-system-heres-a-crucial-reform-he-overlooked/> [<http://perma.cc/3UQD-Y8AR>]; see also Anna B. Laakmann, *An Explicit Policy Lever for Patent Scope*, 19 MICH. TELECOMM. & TECH. L. REV. 43, 45-46 (2012) citing *In re Bilski*, 130 S. Ct. 3218 (2010) (patentable subject matter); *Medimmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007) (standing to challenge a patent); *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007) (nonobviousness); *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006) (injunctive relief); *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193 (2005) (statutory research exemption); *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722 (2002) (prosecution history estoppel) (Moreover, the court has allowed the patent doctrine to become unmoored from the law's overarching utilitarian purpose. In the last decade, the Supreme Court has granted certiorari in an unprecedented number of Federal Circuit decisions. The Supreme Court's uncharacteristic level of involvement in patent matters suggests that it too is dissatisfied with the Federal Circuit's performance.).

<sup>156</sup> Timothy B. Lee, *Obama Wants To Fix The Patent System. Here's a Crucial Reform He Overlooked*, Wash. Post (Jan 29, 2014), available at <http://www.washingtonpost.com/blogs/the-switch/wp/2014/01/29/obama-wants-to-fix-the-patent-system-heres-a-crucial-reform-he-overlooked/> [<http://perma.cc/3UQD-Y8AR>]; see also *Chief Justice Roberts' comment on the Federal Circuit* (June 3, 2009), available at [http://thepriorart.typepad.com/the\\_prior\\_art/2009/06/chief-justice-roberts-and-the-federal-circuit.html](http://thepriorart.typepad.com/the_prior_art/2009/06/chief-justice-roberts-and-the-federal-circuit.html) [<http://perma.cc/PYC6-T4NX>] (Chief Justice Roberts: They can't say, I don't like the Supreme Court rule so I'm not going to apply it, other than the Federal Circuit.); Timothy B. Lee, *How a Rogue Appeals Court Wrecked the Patent System: Federal Court of Appeals Court Marks 30 Years of Spreading the "Patent Gospel"*, *Ars Technica* (Sept. 30, 2012), available at <http://arstechnica.com/tech-policy/2012/09/how-a-rogue-appeals-court-wrecked-the->

The Supreme Court has overruled patent-friendly decisions from the Federal Circuit ten times in as many years, while only overruling a Federal Circuit decision going against a patent holder or applicant once.<sup>157</sup> The Federal Circuit's precedent is cited more in pro-patent opinions than in anti-patent opinions.<sup>158</sup>

As of June, 2015, the Federal Circuit has yet to reverse a PTAB decision.<sup>159</sup> Indeed, only one decision has been less than fully affirmed.<sup>160</sup>

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patent-system/ [http://perma.cc/73L7-8UMZ] (The Federal Circuit, he said, also took on “the quieter and subtler effort to re-educate trial judges throughout the judiciary, to make them friendlier to patent-holders (or at least to the system of patents) as well.” (Flanders, it should be noted, is an avowed *supporter* of the Federal Circuit and its efforts to reshape patent law. This dismissive attitude toward Supreme Court precedents apparently survives to this day among patent lawyers. In the wake of this year's decision limiting patents on the practice of medicine, patent attorney Gene Quinn wondered, “How long will it take the Federal Circuit to overrule this inexplicable nonsense?” Obviously, the Federal Circuit can't “overrule” a Supreme Court decision. But with enough persistence, it can, and often does, subvert the principles enunciated by the nation's highest court. And when it does so, it almost always works in the direction of making patents easier to obtain and enforce.).

<sup>157</sup> Timothy B. Lee, *Obama Wants To Fix The Patent System. Here's a Crucial Reform He Overlooked*, Wash. Post (Jan 29, 2014), available at <http://www.washingtonpost.com/blogs/the-switch/wp/2014/01/29/obama-wants-to-fix-the-patent-system-heres-a-crucial-reform-he-overlooked/> [http://perma.cc/3UQD-Y8AR]; see also Jeff J. Roberts, *Supreme Court Rebukes Patent Court Judges (Again)* Gigaom Research (Jan 23, 2014), available at <https://gigaom.com/2014/01/23/supreme-court-rebukes-patent-court-judges-again/> [http://perma.cc/S36T-PCWK].

<sup>158</sup> David R. Pekarek Krohn & Emerson H. Tiller, *Federal Circuit Patent Precedent: An Empirical Study of Institutional Authority and Intellectual Property Ideology*, 2012 WIS. L. REV. 1177, 1212-13 (2012).

<sup>159</sup> See *Softview LLC v. Kyocera Corp.*, 592 Fed.Appx. 949 (Fed. Cir. Feb. 9, 2015) (IPR2013-00004) (joined); *Softview LLC v. Kyocera Corp.*, 592 Fed.Appx. 949 (Fed. Cir. Feb. 9, 2015) (IPR2013-00257) (joined); *Softview LLC v. Kyocera Corp.*, 592 Fed.Appx. 947 (Fed. Cir. Feb. 9, 2015) (IPR2013-00007) (joined); *Softview LLC v. Kyocera Corp.*, 592 Fed.Appx. 947 (Fed. Cir. Feb. 9, 2015) (IPR2013-00256) (joined); *Board Of Trustees Of The University Of Illinois v. Micron Technology, Inc.*, \_\_\_ Fed. Appx. \_\_\_ (Fed. Cir. March 12, 2015) (IPR2013-00005); *Board Of Trustees Of The University Of Illinois v. Micron Technology, Inc.*, \_\_\_ Fed. Appx. \_\_\_ (Fed. Cir. March 12, 2015) (IPR2013-00006); *Board Of Trustees Of The University Of Illinois v. Micron Technology, Inc.*, \_\_\_ Fed. Appx. \_\_\_ (Fed. Cir. March 12, 2015) (IPR2013-00008); *Clearlamp, LLC v. LKQ Corp.*, 594 Fed.Appx. 687 (Fed. Cir. Feb. 18, 2015); *In re Zillow, Inc.*, \_\_\_ Fed. Appx. \_\_\_ (Fed. Cir. March 12, 2015); *Helferich Patent Licensing, LLC v. CBS Interactive, Inc.*, \_\_\_ Fed. Appx. \_\_\_ (Fed. Cir. April 8, 2015); *Bernina Int'l AG v. Handi Quilter, Inc.*, \_\_\_ Fed. Appx. \_\_\_ (Fed. Cir. June 5, 2015) (IPR2013-00364); *Prolitec, Inc. v. ScentAir Technologies, Inc.*, \_\_\_ Fed. Appx. \_\_\_ (Fed. Cir. June 9, 2015) (IPR2013-00180); *In re Cuozzo Speed Technologies, LLC*, 778 F.3d 1271 (Fed. Cir. 2015); *Belden Inc. v. Berk-Tek LLC*, 2015 WL 1781484 (Fed. Cir. Apr. 17, 2015) (IPR2013-00058) (non-precedential); *Belden Inc. v. Berk-Tek LLC*, 2015 WL 1781484 (Fed. Cir. Apr. 17, 2015) (IPR2013-00069) (non-precedential).

<sup>160</sup> See *Microsoft v. Proxyconn, Inc.*, 789 F.3d 1292 (Fed. Cir. 2015).



If long-term investment security is preferred and wide shifts in what constitutes patentable subject matter are to be avoided, a sufficient check on PTO power is required. Nard and Duffy suggest that the Federal Circuit and D.C. Circuit should each have jurisdiction over PTO appeals, stating that “[t]he D.C. Circuit is the foremost appellate authority on administrative law, and would thus bring an experienced voice to administrative and regulatory law issues.”<sup>161</sup> Diversity and competition have been absent from patent law for twenty years.<sup>162</sup> This strips patent law of the benefit of incremental advancements based on innovations in the law.<sup>163</sup>

Judge Posner advocates going further by returning patent appellate responsibility, in whole, to the regional circuits which had jurisdiction prior to the inception of the Federal Circuit in 1982.<sup>164</sup> This would comport with the position of Nard and Duffy, who believe that, given the intricacy of patent law, the complexity of its relationship to the goal of fostering innovation, and its importance for the knowledge-based economy of the twenty-first century, our nation needs a judicial structure that facilitates greater candor, open debate, and thoughtfulness, and that better engages more judges, members of the bar, commentators, and policymakers in evaluating the soundness of legal doctrine in the area [and that] peer dialogue between appellate courts is a traditional vehicle for achieving such goals.<sup>165</sup>

Judge Diane P. Wood, Chief Judge for the Seventh Circuit Court of Appeals, shares this position.<sup>166</sup> The other appellate Courts are comfortable working with other intellectual property regimes, including copyright and trademark, as well as trade secret.<sup>167</sup> There is a great value in obtaining the views of a number of judges.<sup>168</sup>

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<sup>161</sup> *Id.*

<sup>162</sup> Craig Allen Nard & John F. Duffy, *Rethinking Patent Law's Uniformity Principle*, 101 Nw. U. L. Rev. 1619, 1675 (2007).

<sup>163</sup> *Id.* (stating Nard and Duffy explain that peer dialogue would be especially helpful in the development of claim interpretation, nonobviousness, and written description).

<sup>164</sup> Paul R. Gugliuzza, *Saving the Federal Circuit*, 13 CHI.-KENT J. INTELL. PROP. 350, 350-51 (2014).

<sup>165</sup> Craig Allen Nard & John F. Duffy, *Rethinking Patent Law's Uniformity Principle*, 101 Nw. U. L. Rev. 1619, 1655 (2007); see also Paul R. Gugliuzza, *The Federal Circuit As A Federal Court*, 54 WM. & MARY L. REV. 1791, 1854 (2013) (“A regional circuit, which lacks exclusive jurisdiction, would find it more difficult to increase its own importance to a particular area of law.”)

<sup>166</sup> See Hon. Diane P. Wood, *Keynote Address: Is It Time to Abolish the Federal Circuit's Exclusive Jurisdiction in Patent Cases?*, 13 CHI.-KENT J. INTELL. PROP. 1, 6 (2013) (The same basic policies animate all of our Intellectual property regimes.).

<sup>167</sup> *Id.*

<sup>168</sup> *Id.* at 7-8.

Although the technology may be complicated in a given case, the legal issues are relatively straightforward.<sup>169</sup> Judge Wood proposes using a system similar to that used to review decisions of the National Labor Relations Board, where parties have a choice of forum to which they may appeal decisions of the NLRB.<sup>170</sup>

A model of “polycentric decision-making” among the circuits is desirable for ensuring that the PTO stays within its bounds in setting the law for what constitutes patentable subject matter. A polycentric model (1) allows for a more robust and efficient development of the common law;<sup>171</sup> (2) permits increased confidence and legitimacy in a decision of law if multiple circuits decide the same way on an issue;<sup>172</sup> (3) prohibits large national swings in the law over time as the remaining circuits will not be bound by the decision of another circuit concerning the patent law; (4) will introduce competitive pressure on all participating circuit courts to express more complete and thoughtful rationales;<sup>173</sup> and (5) improves judicial candor by avoiding excessive reliance on the precedent of one circuit.<sup>174</sup>

Most importantly, it distances the appeals process away from a seemingly pro-patent Federal Circuit. With this understanding, and not wanting to be overturned, PTAB will presumably not make rapid changes regarding what constitutes patentable subject matter, and will instead make gradual incremental changes. These gradual incremental changes will be to the benefit of all, as patent-seekers will have a realistic expectation that what constitutes patentable subject matter when they apply for patent will be what constitutes patentable subject matter at the end of their patent term. This security will incentive invention, which will serve patent law’s constitutional

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<sup>169</sup> *Id.*

<sup>170</sup> *Id.* at 9-10. (“Such a regime would have a number of advantages. Many of the benefits that accrue from specialization will remain. It is possible—maybe even likely—that the Federal Circuit would still play a leading role in shaping patent law. Its opinions would be closely watched by regional circuits, just as the D.C. Circuit exercises leadership in various aspects of administrative law because it hears so many such cases. The absolute number of patent cases that would return to the regional courts would not be large; there is, thus, no reason to expect that this change would have much of an effect on time to disposition. But, on the positive side, the change would provide those “wide open spaces” for development of patent law, allowing new ideas to percolate and grow. The Supreme Court would also have the benefit of fuller development in the lower courts and, thus, more information about which cases warrant one of the scarce slots in its annual docket.”)

<sup>171</sup> Craig Allen Nard & John F. Duffy, *Rethinking Patent Law’s Uniformity Principle*, 101 NW. U. L. REV. 1619, 1651-52 (2007).

<sup>172</sup> *Id.* at 1653-54.

<sup>173</sup> *Id.* at 1654.

<sup>174</sup> *Id.*

purpose of the promotion of Science and the useful arts.

## V. CONCLUSION

This note argues that (1) the new post-grant review proceeding gives the PTO a considerable amount of power to determine what constitutes patentable subject matter; (2) the PTO's power to determine what constitutes patentable subject matter does not create long-term security in what patentable subject matter is; and (3) the best way to create security for long-term investment in patent protection is for the Court of Appeals to take a more active, policymaking role in their review of PTAB decisions.

The (1) new post-grant review proceeding gives the PTO a considerable amount of power to determine what constitutes patentable subject matter because it permits the PTAB to decide novel legal questions about any question of patentability, including patentable subject matter.

The (2) PTO's power to determine what constitutes patentable subject matter does not create long-term security in what patentable subject matter because it is subject to rapid changes over time as popular opinions change.

The (3) best way to create security for long-term investment in patent protection is for the Courts of Appeals to take a more active and policymaking role in their review of PTAB decisions to keep the PTABs decisions in check. If the PTAB understands that their decision to change what patentable subject matter is in too large of a manner will be overturned, the PTAB will not change it past that point. Because there is concern that the Federal Circuit is overly deferential to the PTO and the decisions of the PTAB, there is also a concern that the PTAB does not consider that check in its decisionmaking process. To recreate the check, this note argues that appeals from PTAB should be available in any Circuit Court in the United States. Understanding that their decision could be reviewed by any Circuit Court, and not necessarily the patent-friendly Federal Circuit, will keep the PTAB from radically shifting what patentable

subject matter is over the course of time. Rather, over time small incremental changes will be made. Small, incremental changes create the type of institutional security that induces investment in innovation, new businesses, and additional research.